C.P.U. No. 298

COMMITTEE ON PUBLIC UNDERTAKINGS

(1975-76)

(FIFTH LOK SABHA)

SEVENTY-SIXTH REPORT

Action taken by Government on the recommendations contained in the Fifty-sixth Report of the Committee on Public Undertakings (Fifth Lok Sabha)

INDIAN DRUGS AND PHARMACEUTICALS LTD.

(Ministry of Petroleum & Chemicals)
(Department of Chemicals and Fertilizer)

LOK SABHA SECRETARIAT
NEW DELHI

September, 1975/Asvina, 1897 (Saka)

Price : Rs. 4.80

CORRIGENDA

Seventy-sixth Report of the Committee on Public Undertakings (1975-76) on Action Taken by Govern on the recommendations contained in the Fifty-si. Report of the Committee on Public Undertakings on Indian Drugs and Pharmaceuticals Ltd.

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(1975-76)

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ACTION TAKEN SUB-COMMITTEE OF THE COMMITTEE ON PUBLIC UNDERTAKINGS

(1975-76)

1. Shri Nawal Kishore Sharma—*Chairman*
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4. Shri Amarnath Vidyalankar
5. Shri G. K. Jaffer Sharief
6. Shri Damodar Pandey
7. Shri Atal Bihari Vajpayee.

INTRODUCTION

I, the Chairman, Committee on Public Undertakings having been authorised by the Committee to submit the Report on their behalf present the Seventy-sixth Report on Action Taken by Government on the recommendations contained in the Fiftieth Report of the Committee on Public Undertakings (Fifth Lok Sabha) on Indian Drugs and Pharmaceuticals Ltd.

2. The Fifty-sixth Report of the Committee on Public Undertakings was presented to Lok Sabha on the 30-4-74. The replies of Government to the recommendations contained in the Report were received in batches and the last batch was received on 10th/12th August, 1975 which also contained further information sought in respect of certain points. The replies of Government were considered by the Action Taken Sub-Committee of the Committee on Public Undertakings and this Report adopted by them at their sitting held on the 20th August 1975. The Report was finally adopted by the Committee on Public Undertakings on the 24-9-75.

3. The Report has been divided into the following four chapters:

(i) Report

(ii) Recommendations that have been accepted by Government.

(iii) Recommendations which the Committee do not desire to pursue in view of Government's replies.

(iv) Recommendations in respect of which replies of Government have not been accepted by the Committee.

4. An analysis of the Action Taken by Government on the recommendations contained in the Report of the Committee is given in Appendix XIII. It would be observed therefrom that out of the total number of recommendations made in the Report 70.1 per cent have been accepted by the Government. The Committee do not desire to pursue 23.0 per cent of the recommendations in view of the Government's replies. Replies of Government in respect of 6.9 per cent of the recommendations have not been accepted by the Committee.

NEW DELHI;
September 29, 1975.
Asvina 7, 1897.

NAWAL KISHORE SHARMA,
Chairman,
Committee on Public Undertakings.

CHAPTER I

REPORT

A. Historical Background

Recommendation S. No. 1 (Paragraph Nos. 1.18—1.20)

The Committee regretted to find that even though the Bureau of Public Enterprises had asked, as far back as in November, 1970, all the Government companies to formulate a statement of their objectives/obligations clearly and communicate the same to Government, the Indian Drugs and Pharmaceuticals Ltd., had not done so till now. The Committee were informed that it was only recently that the statement of objectives/obligations had been prepared and was still awaiting consideration of the Board of Directors. There had thus been a delay of more than three years even in formulating their objectives. The Committee were unhappy that even the Ministry's representative on the Board of Directors failed to impress on the company the need to formulate its objectives early. The Committee trusted that IDPL would finalise the statement of objectives without any further delay in the absence of which critical evaluation of the performance of a Government Company became difficult.

2. The Committee were not sure as to how many more such undertakings were yet to finalise their statements of objectives/obligations as required by the Bureau of Public Enterprises in their circular of 1970. The Committee recommended that the Bureau of Public Enterprises should immediately take stock of the position and finalise the matter without further delay.

3. The Committee also reiterated their recommendations in paragraph 1.44 of their 40th Report (1973-74) on Role and Achievements of Public Undertakings and trusted that Government before long would bring a comprehensive White Paper setting out, *inter alia*, the financial, economic and social objectives of each of the Public Undertakings.

4. *In their Reply the Government stated that the statement of objectives in regard to the IDPL had been prepared and sent to the BPE for their comments and approval.

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*Not vetted by Audit.

5. The question of bringing a comprehensive white paper on the financial, economic and social objectives of Public Undertakings was under the consideration of BPE.

6. The Committee would like that the statement of objectives of IDPL should be finalised expeditiously so that not only the Company has a clear idea of its aims and objects but it is possible for others also to make a critical evaluation of its performance.

7. In this connection, the Committee would also like to draw attention to their recommendation in para 24 of their 72nd Report (1975-76) on the Action Taken by the Government in their 40th Report (1973-74) on Role & Achievements of Public Undertakings and reiterate that the white Paper on the lines recommended by the Committee should be prepared and presented to Parliament without further delay.

B. Performance apppraisal—Antibiotics Plant Rishikesh

Recommendation S. Nos. 5, 8 and 10 (Paragraph Nos. 2.39, 2.40, 2.65 and 2.86)

Recommendation S. No. 5 (Paragraph Nos. 2.39 and 2.40)

8. The Committee noted that the operational experience of Antibiotics Plant, Rishikesh gained during production from May, 1968 onwards had revealed a number of deficiencies in the equipment and system which were subsequently studied by the Soviet Experts who visited the plant from 2nd September, 1969 to 5th October, 1969 with the help of Indian Technologists. As against the original design capacity of the Plant of 290 tonnes or 3,70,250 mlrds. per annum, the maximum attainable capacity was put by the Soviet side at 3,15,800 mlrds. and by the Indian side at 2,55,000 mlrds. which is 19 per cent less than the capacity assessed by the Soviet Team.

9. The Committee were informed that the Russian assessment was based on the efficiency and time cycles which had already been achieved in similar plants in the Soviet Union and which were also capable of achievement in India once the technology was mastered. According to the plant, however, the capacity as assessed by the Soviet Team could not be attained unless certain essential facilities were provided. The outlay for such facilities was estimated at Rs. 108.77 lakhs. The Committee were unhappy at the derating of the plant's capacity. The Committee hoped that with the additional facilities proposed to be provided it would be possible for the plant

to achieve the capacity as assessed by the Russian Team. The Committee recommended that a close watch might be kept by Government to see that expenditure on such additional facilities did result in higher utilisation of capacity and stabilisation of production.

10. In their reply, the Government stated as follows:—

"As recommended by the Committee, close watch will be kept by the Government to see that the additional facilities installed result in achievement of full capacity. It may also be mentioned that with improvements in the yield of new strains of Antibiotics producing Mirco Organism and changes made in the technology at different stages of processes, performance of the first quarter of 1974-75 has improved to 38138 mlrds for the quarter while the average annual production during the 2 years was 121782 mlrds."

11. There is also a marked improvement in the quality of Streptomycin Sulphate where not only the potency of the finished product is improved but the ratio of production conforming to parenteral IP grade to the total production reached 62.3 per cent against 36.3 per cent of the previous year (1973-74) Constraints faced at present in the utilisation of capacities and stabilisation of production as well as action taken are:

(a) Improvement in the recovery efficiency of Potassium Penicillin is yet to be achieved. Superior types of Extractors have been imported from Germany and USA. German machine has been installed and is on trial. The US machine is yet to be installed.

(b) Further production of procaine Penicillin (bulk) has been stopped for the present due to:

(i) limited shelf life;

(ii) inadequate market demand for the bulk drug; and

(ii) non-availability of Glass vials for formulation in ABP itself.

(c) Recovery efficiency of Tetracycline has been successfully improved (improvement from 39.2 per cent in 1973-74 to about 55 per cent in 1974-75) by modifying the initial purification process eliminating the use of non-exchange Resin.

(a) Production of Nystatin is considerably restricted due to inadequate market demand. It is proposed to use unutilised capacity for the production of Griseofulvin.

12. The Committee further enquired:

(a) Have the additional facilities been provided, if so, why has the rated capacity as assessed by the Soviet Team not been reached? Please state in detail indicating as to when this capacity is likely to be achieved.

(b) Has the US machine been installed? If so, with what result?

13. *In reply the Government stated as follows:—

"Most of the additional facilities have been provided. The rated capacity as per Soviet Protocol-1969 (Soviet side) comes to 315000 mlrds. which includes 465000 mlrds of Nystatin. Due to market constraints, production of nystatin has been nearly stopped and production of Potassium and Procaine Penicillin curtailed. The production during 1974-75 was 1,44,562 mlrds. which is equivalent to 54 per cent of the rated capacity excluding Nystatin. Production during the first quarter of 1975-76 is 52017 mlrds. which is equivalent to about 80 per cent of the rated capacity. With this trend, it is expected that the Plant would be able to achieve more than 80 per cent of its rated capacity without Nystatin during the current financial year. Further steps to introduce better strains and modified technology are being taken to increase the capacity of the plant even beyond 100 per cent.

The US machine is under installation. This has been delayed since its installation required shifting of some equipment which could not be done during working as areas involved are explosive and no welding work can be undertaken during working."

Recommendation Serial No. 8, (Paragraph No. 2.65)

14. The Committee noted that in 1972 Antibiotics accounted for 44.5 per cent, 34.4 per cent, 80.8 per cent of the country's licensed capacity for Penicillin, Streptomycin and Tetracycline and its deri-

*Not vetted by Audit.

vatives respectively. The actual production of these drugs in the Antibiotics Plant, however, represented 19.8 per cent and 12.8 per cent and 27.1 per cent respectively of the total production in the country during 1972. The comparative study of the performance of public and private sector for production of these drugs indicated that the share of the Antibiotics Plant in the overall production of these drugs in the country was not commensurate with its share in the overall production capacity. On the other hand the production of producers in the private sector was generally more than their licensed capacity. In this connection the Committee learnt that action to be taken on firms for exceeding the permissible capacity was under consideration keeping in view the country's demand for these drugs. The Committee found that had Antibiotics Plant achieved the production according to its capacity, in respect of Oxytetracycline, imports in 1969-70 and 1970-71 would not have been necessary and even in 1971-72 the imports of this drugs could have been reduced by one third. The Committee found that during 1972-73 import of products in the production range of IDPL amounted to Rs. 54 lakhs. The Committee recommended that Antibiotics Plant should take concerted measures to achieve installed capacities of its various products in order to avoid dependence on imports to that extent.

15. In their reply the Government stated—

"Main constrainsts responsible for non-achieving installed capacity and action taken are as under:

(a) Continuity of services

(b) Labour Management Relations

(c) Improvement in technology

(a) (i) There have been improvements in supply of continuous power by UPSEB during 1974. Steps are being taken to have a minimum size of stand-by generation Unit coupled with Compressor (1.8 MW). Tenders have been called and the matter is under finalisation. A standby Generation Unit will help the plant in keeping the 'Young' Fermentors going even during power break-down in the

supply of UPSEB, thereby reducing losses arising from draining etc.

(ii) It has been our experience that the production gets a set back particularly during high summer and monsoon season. This is mostly due to insufficient refrigeration capacity to condense water vapours in the air which has high humidity during these months. Certain changes have already been made. Use of 8°C chilled water instead of 15°C Chilled water used earlier has also been introduced.

(b) Labour Management Relations:

Labour Management Relations have been indifferent during the recent past. The personnel Manager of the plant has been transferred and a new officer with Engineering background has been posted. Revised pay scales on the pattern of recommendations made by the Third Pay Commission for Central Government Employees have been introduced.

(c) Improvement in technology:

High yielding strains received from Soviet Union have been tried in our laboratory and in our pilot plant. Their introduction in the main plant is in progress. The High Yielding strains received from Soviet Union though superior to the original strains, will have lower activity as compared to strains available in international market. Efforts are therefore being made to get high yielding strains from different sources.

Raw materials viz. Corn Steep Liquor, Hydro, Soyabean were sent for evaluation. Soyabean was found to have peroxide value and also some texic impurities which gave poor results. This is under further investigation.

The set up of Research and Development has been rationalised and Research Departments has been specifically asked to improve the strain and development Department (Pilot Plant) is specifically pursuing the application of such strains in industrial exploitation (Also see reply to recommendation Sl. No. 33).

Basic Chemical Engineering problems like design of the sparger used in fermentation for aeration design of the agitator as well as the rate of agitation will also be studied in the Pilot Plant with a view to improve the biosynthetic activity. This may require 12 to 18 months.

[Ministry of P&C O.M. No. 8(15)|74-Ch.III. dated 30-10-1974].

16. The Committee enquired details of the result of action taken in respect of the constraints mainly responsible for non-achieving the installed capacity, i.e.

(a) Continuity of services;

(b) Labour Management relations;

(c) Improvements in technology.

17. *The Government stated as follows:—

"(a) Continuity of services

(i) As a result of several remedial protective measures taken by UPSEB and the IDPL, the continuity of power to the Antibiotics plant has considerably improved over the last one year.

(ii) Continuous supply of 8°C chilled has been introduced in all the products for maintaining the precise temperature of fermentation vessels. This has eliminated the problem of temperature variation to a large extent.

(iii) One of the major problems of contamination through air has been brought under control by separating the air supply system of all products and installation of additional primary air filters.

(b) Labour Management Relations:

Labour management relations have been considerably improved in the recent past. Revised scale of pay based on 3rd Pay Commission have been introduced and the plant is functioning smoothly at present.

(c) Improvement in technology.

High yielding strains received from USSR have been fully introduced and the productivity in case of streptomycin sulphate, tetracycline and oxytetracycline has shown significant improvement.

(ii) Certain modifications in the technology particularly at the stage of purification have been introduced as a result of the efforts put in by the plant technologists/

*Not vetted by Audit.

scientists and these have resulted in marked improvement in efficiency.

(iii) in order to bring further improvement in the yield of different antibiotics, negotiations are already in hand for introducing better strains from countries other than USSR.

(iv) Proper arrangements for transport and storage of raw materials like CSL and hydrol have been made in order to avoid deterioration in quality.

(v) Soyabean quality has been improved by getting it processed with better technology.

(vi) Pilot Plant facilities have been augmented for evaluation of raw materials & strains.

Production during 1973-74 1974-75 and 1st Quarter 1975-76 is given below:

	Production in mmu. 1973-74	1974-75	1975-76 1st Quarter
Potassium Penicillian (Saleable)	43·56	15·44	..
Sodium Penicillin	6·29	20·37	9·39
Procaino penicillin	13·50	10·40	3·73
Streptomycin sulphate	30·36	43·65	9·98
Tetracycline	14·65	25·91	19·45
Oxytetracycline	12·16	27·81	9·46
Nystatin	0·68	0·96	..
	121·20	144·54	52.01

Recommendation S. No. 10 (Paragraph No. 2.86)

18. The Committee further noted that as far as penicillin was concerned, the ratio of batches harvested to inoculators charged had gone up from 0.43 in 1969-70 to 0.61 in 1972-73 and of seed vessels charged from 0.74 to 0.86. In this connection the Committee have however, found that the Management had not laid down any norms with regard to the numbers of batches harvested to the inoculators/seed vessels charged. The management also do not appear to have assessed the loss on account of the drained inoculators/seed vessels. It was stated that the norms could not be laid down 'on account of

non-stabilisation of technological regime and power feed to the plant'. The Committee noted that the percentage of batches contaminated to batches harvested had come down from 19.29 in 1969-70 to 15.11 in 1972-73. The Committee recommended that a careful watch should be kept to see that batches which became unfit for harvesting due to contamination were not processed, as harvesting of such contaminated batches affected the recovery efficiency. The Committee were informed that Indian Statistical Institute had carried out some studies for controlling the bio-chemical fermentors and had suggested some rules for harvesting the batches on the basis of activity at definite intervals. The Committee recommended that the rules suggested by the Indian Statistical Institute should be considered after weighing the advantages of the adoption of these rules *vis-a-vis* use of standard curves for conducting the bio-synthetic activity in fermentation. The Committee further found that average activity and the yield of filtered broth per batch had varied widely from month to month and year to year. Although the activity per u|ml was much higher than protocol norms on a number of occasions (highest activity achieved in February, 1972 being 11,800 u/ml) the Committee found that the average activity was only 6321 u/ml in 1969-70, 6830 u/ml in 1970-71, 7292 u/ml in 1971-72 and 7687 u|ml in 1972-73 respectively which was less than the protocol norm of 8000. Similarly, as against the protocol norm of 258.4 mlrds of filtered broth per batch, the highest achieved was 245.23 mlrds in February, 1972. The Committee were not able to understand as to why the higher rate of activity attained in February, 1972 could not be sustained continously. The Committee recommended that a careful analysis of the constraints in this regard should be made with a view to taking suitable measures. The Committee also found that the fermentation cycle (except in August, 1969) and the total time cycle were also much above the protocol norm. The Plant did not achieve the protocol level of harvesting 830 batches per annum in any of the years, not with standing, the fact that three additional fermentors had been utilised in 1971-72.

19. In reply the Government stated:

> "ISI recommendations related to harvesting of streptomycin batches and not Penicillin. However, the recommendation has been extended to penicillin also and batches are harvested on the standard curves formulated for the fermentation of penicillin for Biosynthesis.

20. Occasionally, however penicillin batches are required to be harvested before completion of the prescribed fermentation cycle,

due to certain abnormalities such as contamination or deterioration of myceliym due to abnormal temperature and PH or low aeration when the rate of bio-synthesis (increase in activity) declines."

21. The Committee further enquired as to why the higher rate of activity attained in February, 1972 could not be sustained continuously and what was the action taken in this regard.

22. *The Government stated—

In the month of February, 1972, the average activity in case of Penicillin was 8,370 units/ml, yielding filtened 245/ mlrds per batch. Highest activity achieved in one batch reached to 11800 units|ml. No doubt there have been marked variation in the yield of Penicillin but the above levels of average activity, highest activity and filtered mlrds. have been achieved in some months other than February, 1972 also.

Against the protocol norms of 8000 units|ml. activity, the average activity has been varying around 7000 u|ml. Action is being taken to obtain better strains so that this level of activity can be significantly improved upon.

23. To another enquiry, the Government stated—

"The fermentation activity of a strain is not results of interaction of several factors governing complex biochemical processes in the living cells. In such biological processes, variation in yields is a common phenomena in the fermentation industry. However, the average level of activity obtainable generally is the reflection of the potentiality of the strain used and technology followed. The measures of introducing better strains being taken by the IDPL is the best solution of the problem."

24. The Committee note that even though most of the additional facilities which were required to be provided in the plant for achieving the capacity utilisation as assessed by the Soviet team, have been provided, the production during 1974-75 was equivalent to 54 per cent of the rated capacity excluding Nystatin, the production of which has been nearly stopped due to market constraints. They also note that the production during the first quarter of 1975-76 has gone up to about 80 per cent of the rated capacity and the plant authorities expect that the plant would be able to achieve more than 80 per

*Not vetted by Audit.

cent of its rated capacity without Nystatin during the current financial year and further steps to introduce better strains and modify technology are being taken to increase the capacity of the plant even beyond 100 per cent. The Committee hope that a close watch will continue to be kept on the steps already taken to achieve higher utilisation of capacity and stabilization of production and further steps proposed to be taken to increase the capacity utilisation of the plant even beyond 100 per cent will be taken expeditiously.

Recommendation S. No. 6 (Paragraph No. 2.41)

25. The Committee noted that it had not been possible for the company to persuade the medical profession to use Chloro tetracycline Hydro-Chloride for human treatment nor it had been possible to use it as animal feed supplement. Subsequently, the Company had deleted Chloro tetracycline from the plant's product-mix and had diverted equipment of the value of Rs. 36.72 lakhs (out of Rs. 65.55 lakhs) for meeting the deficiencies in other Sections and equipment valuing Rs. 9.11 lakhs was likely to be used for the production of Griseofulvin. The Committee found that even after such decision, plant and equipment of the value of Rs. 19.17 lakhs would still be lying unutilised. The Management claimed that the major portion of the equipment would be utilised in the expansion programme to be finalised. The Committee were sorry to observe that determination of product-mix without adequate demand survey had resulted in equipment value about Rs. 19 lakhs remaining idle. The Committee expected that the expansion programme would be finalised after a detailed market survey of the products and the surplus plant and machinery would be put to best use.

26. In their reply the Government stated that the recommendation of the Committee had been noted. Efforts to utilise|divert the equipments for the manufacture of other products were continuing. Equipments still to be diverted at the end of 1973-74 were valued at Rs. 10.07 lakhs.*

27. The expansion programme of the plant would be finalised by the company and Government after taking into account the demand of each product as assessed by the Task Force on Drugs and Pharmaceuticals, current market demand of drugs, the expected growth potential and international trends in new product development.

*According to the Principal Audit Officer, equipment to be diverted at the end of 1973-74 was of the value of Rs. 17·50 lakhs. Out of these equipments worth Rs. 6·83 lakhs have been earmarked for greseofulvin, leaving a balance of Rs. 10·67 lakhs still to be diverted.

28. The Committee regret to note that equipment worth Rs. 10.07 lakhs remained unutilised at the end of 1973-74 and is still awaiting finalisation of the expansion programme of the Company to be utilised. They would like the IDPL to finalise the expansion programme expeditiously and divert/utilise the idle equipment for production purposes without avoidable delay.

Recommendation Serial Nos. 11 and 14 (Paragraph Nos. 2.87, 2.137)

Recommendation S. No. 11 (Paragraph No. 2.87)

29. The Committee also found that the total time cycle during 1969-70, 1970-71 and 1971-72 was 59,712 hours, 94,162 hours and 1,22,636 hours respectively as against the product norm of 1,09,200 hours thus indicating that the fermentors were not utilised to the full extent in 1969-70 and 1970-71. The Committee noted that in 1971-72, the plant pressed into service three additional fermentors involving a total utilisation of 17.742 hours.

30. The Committee desired that the Management should go into the causes of non-attainment of protocal norms and take suitable measures to remove the constraints.

31. In reply the Government stated—

Causes of non-attainment of protocol norms as well as remedial measures initiated are:

(a) *Low activity of strains*

As already mentioned in reply to S. No. 8 para 2.65 of the Report—efforts are in progress to introduce new strains of higher activity in regular production. They are expected to be fully established in regular production by the end of 1974.

(b) *Contamination*

Contamination of Fermentors is one of the factors responsible for lowering the production below the protocol level. Necessary steps have been taken in this regard and the levels of contamination are now reduced: except in tetracycline as can be seen from the following:—

Product	1971-72	1972-73	1973-74	1974-75
Penicillin	21.95	15.11	14.66	7.34
Streptomycin	51.97	48.40	35.14	32.05
Tetracycline	23.18	11.90	5.41	17.00
Oxytetracycline	28.18	31.76	16.67	5.77

(c) *Quality of raw materials like Corn steep liquor*

One of the factors responsible for variation in the yield is found to be the variation in the quality of the raw materials varying from lot to lot as well as supplier to supplier.

Sources of supply have now been finalised on the basis of past experience and the suppliers advised to control variation in the quality as much as possible. Feasibility of transportation of Corn Steep Liquor by road tanker, to reduce variation of quality from drum to drum is under active consideration.

(d) *Temperature of Fermentation*:

Penicillin, requiring comparatively low temperature fermentation was adversely affected when temperature of chilled water was somewhat high. In order to overcome this problem, temperature of chilled water has recently been reduced to 8°C and the cooling coils of the fermentors have been modified.

(e) *Recovery efficiency*:

Recovery efficiency gets depressed to some extent when contaminated batches are processed. Further, the performance of Rossia Extractors did not come up to expectation. Measures to arrest contamination have already been initiated. New type, i.e. prodblenisk Extractors have recently been imported which are expected to improve the recovery efficiency as also the capacity of the section.

(f) Diaphram valves are being imported to replace globe valves on the sterile product lines.

(g)* Dial Thermometers have been provided as a countercheck on the temperature recording system to avoid possible error due to instruments.

(h) More rigid control has been introduced for checking sterility of the inoculum in the laboratory.

32. The Committee further enquired—

The contamination level in the case of Tetracycline in 1974-75 though less than 1971-72 still continues to be higher than 1972-73 and

*At the time of factual verification Audit had pointed out that the work of providing Dial Thermometers was in progress.

1973-74. What are the reasons therefor and what is the latest position?

33* The Government stated as follows:—

The contamination level in case of Tetracycline during 1974-75 came to 24.1 per cent which is comparatively on the higher side. During this year, there was a severe epidemic of contamination during the months of June and July, 1974 in all the products which ultimately resulted in nearly stoppage of the plant. Several actions including separation of air supply system and installation of additional filters were taken and the position subsequently have shown improvement. The contamination level during the first quarter of 1975-76 in the case of tetracycline fermentation comes only to 6.6 per cent.

Recommendation S. No. 14 (Paragraph No. 2.137)

34. The Committee found that in the case of streptomycin sulphate, the ratio of batches harvested to the inoculators charged ranged between 0.34 to 0.41 during the period 1969-70 to 1973-74 (upto September, 1973) and to seed vessel charged 0.75 to 0.78. The management had not laid down any norm as to the number of batches harvested to the inoculators/seed vessels charged nor have they assessed the losses on account of the draining of inoculators seed vessels. The Committee also found that the percentage of contaminated batches to batches harvested ranged between 35.67 to 51.97 during 1969-70 to 1973-74 (upto September, 1973). According to the Management the probable reasons for contamination of batches were, drawbacks during chargings, defective charging or undetected contamination passed from seed vessels, defective oil system, not holding of valves in the running cycle. It would thus appear that the contamination of batches was due to operational factors and was thus largely controllable. In view of this it was not clear to the Committee as to why concerted and determined measures could not be taken by the Plant Management earlier to set right the deficiencies which continued to affect adversely the operations year after year. The Committee recommended that necessary corrective measures should be taken without further delay so as to minimise, if not eliminate, the percentage of contaminated batches.

35. In reply the Government stated:—

The position of contamination of batches has already been mentioned in Reply to S. No. 11. para 2.87.

(a) The following corrective measures have been taken to minimise contamination in fermentation batches. Air filtered system along

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*Not vetted by Audit.

with primary air filters have been separated for each product to facilitate better control according to the requirements of the product.

(b) Modifications of dehumidification system of air has been done by providing secondary cooler of bigger capacity. One of the entrainment separators has been modified on the principle of cyclone Separator. Results obtained so far indicate that the moisture removal has improved.

The schedules of packing and unpacking of primary air filters, number of sterilisation of primary air filters, check of air sterility, etc. have been made more rigid to avoid failure of filters.

(c) Weekly schedules of hydraulic checking and rectification of transfer line have been introduced to take care of leakages in sterile system.

(d) Air lines in streptomycin have been steam jacketed to avoid condensate in the air supply line.

36. The Committee further enquired:

Have the corrective measures taken to minimise the contamination in fermentation batches, yielded any results so far? If so, please state in detail.

37*. The Government have stated as follows:

The corrective measures taken to reduce the contamination level in the fermentation batches in streptomycin have yielded marginal advantages. The average contamination in the fermentor during the first quarter of 1975-76 has come down to 25 per cent as against 51.97 per cent, 48.4 per cent 35.14 per cent and 34.4 per cent during 1971-72, 1972-73, 1973-74 and 1974-75 and 33.3 per cent during the first quarter of 1974-75.

38. There was a serious epidemic of contamination in all products including streptomycin during June and July, 1974.

39. The Committee note that the contamination level in the course of processing in the case of Tetracycline though less than that in 1971-72 was higher than that in 1972-73 and 1973-74. They further note that several remedial measures are stated to have been taken and the contamination level in the course of processing during the 1st quarter of 1975-76 has come down to 6.6 per cent. Although it is an improvement over the 1974-75 level, it is still more than that

*Not vetted by Audit.

in 1973-74. They also note that as a result of various measures taken, there has been only a marginal improvement in the contamination level in the course of processing in the case of Streptomycin. The Committee reiterate their earlier recommendation and stress that IDPL should continue to keep strict watch over the levels of contamination of all these products and take all possible measures to minimise the contamination levels.

Recommendation Sl. No. 22 (Paragraph No. 2.253 and 2.254)

40. The Committee noted that according to the design, 30 per cent of the steam condensate should return to the boilers. However, the condensate return was found to be not more than 5 to 6 per cent resulting in the increased use of steam for internal consumption to the extent of about 20 per cent of internal load. The Committee find that the excessive consumption of steam cost Rs. 11.91 lakhs during the period of 1968-69 to 1973-74 (upto September, 1973). The Committee understand that the question of low condensate return was studied by the Chief Soviet Expert in October, 1969 but no success was stated to have been achieved.

41. The Committee recommended that best expert advice in the field should be taken so as to improve the condensate return thereby avoiding the extra cost.

42. In reply the Government stated "the studies conducted at the plant indicate that hardly 10 per cent of condensate against the quantity of steam supplied could be considered fit for use in the Boiler House, whereas the rest gets heavily contaminated with media, etc. and processing of this condensate for chemical purification is not considered safe for use in the Boiler House.

43. The problem has also been examined by IDPL in the light of practice followed by Hindustan Antibiotics Limited, Pimpri. They have no integrated system for the return of the condensate to the Boiler House in the manufacture of Penicillin. However such a system exists in the manufacture of Streptomycin, but they have no precise measurement to find out the actual percentage of condensate returned to the control system. The condensate from the fermentation vessels which is likely to be contaminated with the broth is however not returned by HAL to the central system, nor have they evolved any method to purify the condensate for use in the chemical purification plant. The IDPL are being asked to study the problem further in consultation with Indian and foreign experts to examine the feasibility of decontaminating the steam condensate."

44. The Committee further enquired as follows:—

"it is stated that IDPL are being asked to study the problem further in consultation with Indian and Foreign experts to examine the feasibility of decontaminating the steam condensate. Please state:

(a) When was IDPL asked to do so? Please furnish a copy of the letter, etc., issued in this regard.

(b) What has been the outcome of the study? Please give details."

45. *The Government stated in their further reply the IDPL was advised, during the discussions on the action taken on the recommendations of the COPU, to study the problems further with a view to improve the steam condensate return. They had also since initiated action. This had been followed up by a letter to the Managing Director, Indian Drugs and Pharmaceuticals Limited.

46. The Committee note that the IDPL has been advised by Government to study the problem of low return of steam condensate in consultation with Indian and foreign experts and that the IDPL is reported to have initiated action on this advice. The Committee would like the IDPL to conclude this study expeditiously and take steps to control the excessive consumption of steam and to improve the condensate return to the boilers to the level of norm provided in the design.

Recommendation Sl. No. 24 (Paragraph No. 2.269 and 2.270)

47. The Committee found that out of total rated production of 299 tonnes of Antibiotics Plant, Rishikesh, a Quantity of 165 tonnes was to be in the form of ready made drugs and the remaining 125 tonnes in the bulk form. In October-November, 1970 the Committee were informed by the Ministry that as against the rated capacity of 218 tonnes based on the efficiency levels indicatedly the Soviet Team in 1969, existing formulation capacity was only 115 tonnes. (80 tonnes for vialling, 25 tonnes for capsulation and 10 tonnes for tabletting). The Committee found that the Quantity formulated by IDPL had been less than even the reduced capacity of 115 tonnes, the quantity actually formulated being only 19.23 metric tonnes in 1969-70, 40.03 metric tonnes in 1970-71, 71.20 metric tonnes in 1971-72, 55.29 metric tonnes in 1972-73, 22.02 metric tonnes in 1973-74 (upto September, 1973). The main reasons for the set back to the formulation programme of IDPL had been the non-availability of packing material;

*Not vetted by Audit.

like glass vials, stoppers and empty gelatine capsules, non-utilisation of machine capacity because of inadequacy of spare parts. In order to raise the utilisation of formulation capacity the plant is stated to have taken measures to have a glass vials factory as an anciallary industry at Rishikesh. The Plant had also developed some indigenous sources of supply of packing materials and spare parts.

48. The Committee failed to understand why preventive measures were not taken well in advance to develop the manufacture of glass vials and gelatine capsules to match the manufacturing capacity of the Plant. The Committee desired to be informed within six months the concrete action taken by the Government|IDPL to make good this deficiency.

49. *In reply the Government stated:—

"*Supply of vials*: The requirement of vials as per the rated capacity of the Antibiotics Plant is 150 millions p.a. or 5 lakhs per day.

50. M|s. J.G. Glass Industries Private Limited, Poona have set up a unit near the Rishikesh Plant as an ancillary industry and their production capacity is sufficient to meet the full requirements of the plant. Unfortunately, they are having teething difficulties at present and only two of their three machines are working. The third machine is expected to start working when additional power is supplied by the U.P. State Electricity Board shortly as promised by them. M|s. J. G. Glass Industries are also having raw material problems but both the requirements of power as well as raw materials are being attended to.

51. The quality of the glass vials also is not yet of adequate standard and out of 4.201 million supplies in August, 1974, 2.813 millions were rejected on technical grounds thereby making available only 1.388 million vials against the monthly requirement of about 7 million vials from the Rishikesh plant of the J.G. Glass Works in addition 3 million glass vials are to be supplied from their Poona factory but during August, 1974 they despatched only 1.67 million vials and the balance is expected to be supplied during September, 1974. Government have also requested other glass vial manufacturers to supply the requirements of this unit. It is expected that when the production of the J.G. Glass Industries Factory at Rishikesh stabilises there will be no difficulty in the matter. Government are also separately considering setting up of a vials unit by Hindustan Antibiotics Limited.

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*Not vetted by Audit.

52. *Supply of Empty Gelatine Capsules*: The requirement of capsules as per the capacity of the plant is 120 million per annum or 4 lakh capsules per day. Earlier, IDPL proposed to set up a 200 million plant and a letter of intent was also issued but this could not be utilised in the absence of technical knowhow. The Indian Drugs and Pharmaceuticals Limited have, however, again started considering also having a plant of their own and discussions with M|s. Cherry Burrel Corporation are in progress.

53. Government have, however, issued letters of intent and Industrial licence for a total capacity of 1400 m. nos. in the private sector. One of the units licenced is pharmaceutical capsules laboratories, limited who have a total licenced capacity of 450m million Nos. Indian Drugs and Pharmaceuticals Limited is obtaining their requirements regularly for the past six months from this unit and no difficulty in obtaining their requirements is anticipated."

54. The Committee further enquired—

"it has been stated that IDPL have however again, started considering having a plant of their own (for gelatine capsules) and discussions with M|s. Cherry Burrel Corporation are in progress. Please state the latest position in this regard, in detail and when the said Plant likely to be set up and start production?"

55. *In reply the Government stated M|s. Cherry Burrel Corporation had submitted quotations for the machinery for manufacturing Gelatine Capsules to IDPL. IDPL had further negotiations with the representatives of the Company and had been asked for to prepare a Feasibility Report for the manufacture of 400 million Nos. per annum of Gelatine Capsules. Apart from quotations received from the Cherry Burrel Corporation IDPL had obtained quotations from R and J Machine and Engineering Corporation Limited of Canada. They had also invited quotations from other parties.

56. The Committee note that though a private sector unit has been set up as an ancillary industry to meet the requirements of vials of the IDPL unit at Rishikesh, it has not yet come into full production and the quality of the glass vials also is not yet of adequate standard with the result that the full requirements of the Rishikesh unit of the IDPL are not being adequately met. They also note that Government are also separately considering the setting up of a vials unit by Hindustan Antibiotics Unit. They are informed that the IDPL is also pursuing a proposal to have a plant of its own for gelatine

*Not vetted by Audit.

capsules but not much progress has so far been made in this regard. As one of the main reasons for the set back to the formulation programme of IDPL have been the non-availability of packing material like glass vials, gelatine capsules etc. the Committee recommend that concrete action should be taken without further delay to make good the deficiency of packing material and vials and to expedite the production of vials, with strict quality control, by the proposed unit of Hindustan Antibiotics Ltd.

57. The Committee note with satisfaction that IDPL is very vigilant and conscious to the need for maintaining control over the quality of vials being supplied as is evident from the rejection of 2.813 million glass vials out of 4.201 millions supplied in August 1974. They would urge that IDPL should continue to exercise this vigilance always.

Recommendation S. No. 26 (Paragraph No. 2.298)

58. The Committee found that the profitability Report drawn up in March, 1970 had provided for handling losses of packing materials to the extent of 15 percent in glass vials and 5 percent for capsules. While in the case of vials the handling losses were within the norms, in the case of capsules, however, these were quite high in 1970-71 and 1971-72. The excess over norm of 5 percent being 15,48,701 numbers in 1970-71 and 49,94,642 numbers in 1971-72. The Committee recommended that the abnormal high handling losses incurred in the case of capsules may be investigated and concrete measures taken to bring such losses within the norm fixed by the Management themselves.

59. In their reply the Government stated that the consumption norms had been formulated by IDPL based on the types of capsules and type of machine used for filling. Loss during filling with indigenous and imported capsules on automatic GKF machine had been fixed at 6 percent and 3 percent respectively. In addition there was further loss of 2 percent at the stage of strip packing and post strip packing inspection. Figures relating to handling losses were:

Year	Capsuls filled	Capsuls used	Percentage of excess
1971-72	7,75,67,960	8,64,41,000	11·44
1972-73	3,66,95,140	3,94,30,000	7·45
1973-74	9,13,43,200	*	11·48
1974-75 (Ist Quarter)	2,98,72,000	3,34,08,000	11·84

*10,18,33,400

60. The percentage of rejections continued to be high and IDPL had been asked to make a thorough investigation.

61. The Committee regret to note that no satisfactory solution has so far been found of the problem relating to the abnormally high handling losses in the case of capsules and the percentage of losses over and above the norms instead of going down, has gone up from 11.44 of in 1971-72 to 11.84 percent in 1974-75 (1st quarter).

62. They would like the government/company to identify the precise causes for these abnormally high losses and take, serious and effective measures to bring down the losses to the level of the norms fixed in this regard early.

Recommendation Sl. No. 27 (Paragraph No. 2.299)

63. The Committee noted that the rejections in the case of Sodium Penicillin, Procaine penicillin and Streptomycin were much higher than the norms and ranged between 10 per cent to 57 per cent of the total production and the total increase in cost due to rejections pertaining to these three drugs amounted to Rs. 5.18 crores from 1968-69 to 1971-72. The Committee also gone through the reasons put forward by the Management for such high rejections and feel that these reasons are not such as cannot be remedied. The Committee urge that remedial measures must be taken without delay to reduce if not eliminate the rejections and thus avoid waste.

64. The Committee would like to draw pointed attention to the reported poor quality of raw materials. The Committee stress that steps should be taken to see that raw materials of requisite quality become available.

65. In reply the Government quoted figures relating to gross production and incidence of rejects.

66. The rejections in the case of Penicillin were high but modifications had been made to Penicillin Section in order to improve performance. Stabilisation of Penicillin production after modifications was in progress and this was expected to improve the performance of the plant.

67. The following steps have been taken for ensuring availability of quality raw materials. The specifications for all the raw materials used for production have been finalised by Quality Control Deptt. on the basis of information given by Soviet Collaborators and in consultation with the consumer blocks. The raw materials used in production are tested in quality control Department according to the

prescribed specifications and only those lots which conform to the prescribed specifications are released for consumption. In addition to Quality Control testing, biological testing of the agricultural products etc. is carried out in the Process Control Laboratories of the blocks and these tests are given due consideration at the time of release of the lots of raw materials. These steps ensured that only good quality of raw materials are used for production. As a long term measure, prospective suppliers have been given specifications of the requirements of raw materials to enable them to meet the specifications.

68. The Committee note that although certain steps are reported to have been taken to reduce the incidence of rejections in the case of sodium penicillin, procaine penicillin and streptomycin, percentage of rejects in the case of sodium penicillin in 1974-75 though lower than that in 1973-74 was much higher than that in 1971-72 and 1972-73; the percentage of rejects in the case of procaine penicillin jumped from 10.43 per cent in 1973-74 to 35.7 per cent in 1974-75 which is the highest since 1971-72; and the percentage of rejects in the case of streptomycin in 1974-75 again showed an increase over that in 1973-74. The Committee find that the very fact that the percentage of rejections has increased in 1974-75 shows that the quality control measures which have been instituted are not quite effective. They are not sure whether strict quality control measures have been introduced at each stage of processing of the product. The Committee would therefore like the management to review the quality control measures already instituted and intensify them so that at each stage of the process and at the end stage of the process of the product the rejections are kept to the minimum, if not completely eliminated.

Recommendation Sl. No. 28 (Paragraph 2.300)

69. The Committee deprecated that apart from rejections of antibiotics in the course of production detected by the quality Control, bulk antibiotics and formulations worth Rs. 8.82 lakhs and Rs. 1.06 lakhs respectively passed by the Quality Control were returned by the customers. The Committee desired this matter to be investigated thoroughly and all the requisite measures taken to strengthen Quality Control so that such flaws would not recur.

70. In reply the Government stated "the Quality Control Department of the plant is equipped to carryout all tests on the finished products prescribed by Indian Pharmacopoeia. The finished products are released for sale only after satisfying the standards prescribed in the Indian Pharmacopoeia.

71. However, some deterioration in the quality of the product takes place in transit or under improper storage conditions of the purchaser etc."

72. The Committee further enquired:—

"(a) In the case of formulations the value of sales return in 1972-73 is Rs. 3.5 lakhs against Rs. 10,645 in 1971-72. Why? (b) Losses due to re-processing of bulks in 1972-73 has increased from 20 per cent to 25 per cent. In the case of formulations the loss due to reprocessing in 1972-73 is 66 per cent. Does this not indicate poor quality control or greater defects? Please state in detail."

73. In reply the Government stated "(a) the sale return of Rs. 3.5 lakhs during 1972-73 pertains only to one product *i.e.* fortified penicillin where about 7.7 lakhs vials were withdrawn from the market due to problem of instability in one of the components *i.e.* Sodium Penicillin. As a matter of fact, the quality of sodium penicillin that was being produced in ABP as per the original Soviet technology was not upto the mark particularly in respect of its shelf life. Subsequently, in consultation with our Soviet collaborators, the technology of Sodium Penicillin was modified to a process involving azsotropic distillation. This involved major modifications in the Section and ever since this section with modified technology has been commissioned, the problem of shelf life in this product has been overcome."

(b) The losses as a result of re-processing in formulations compared to bulk are bound to be high as the salvages from the vials and separation of different components of the formulated products involve several steps resulting into greater losses. The losses due to reprocessing both in case of bulk and formulation are significantly more due to the improper quality of sodium penicillin.

74. In view of the facts stated above in respect of poor quality of shelf life of sodium penicillin, the sale returns does not reflect on the working of the quality control.

75. The Committee note that about 7.7 lakhs vials of fortified penicillin were withdrawn from the market in 1972-73 due to problem of instability in one of the components i.e. sodium penicillin and that subsequently in consultation with Soviet collaborators the technology of sodium penicillin was modified and since then the problem of shelf life in this product has been overcome. The Committee would like IDPL to continue to keep a close watch on the sales returns of bulks

and formulations and losses due to their reprocessing in order to ensure that these are kept within reasonable limits.

C. Material Management and Inventory Control—Antibiotics Plant, Rishikesh

Recommendation Sl. No. 34 (Paragraph No. 2.348)

76. The Committee found that though the stock of raw materials with the Antibiotics Plant in terms of month's consumption had come down year after year, it was still more than the prescribed limit of the buffer stock, that is two months for indigenous and six months for imported material in certain cases. The management had stated that the build up of the inventory in these cases had been due to frequent changes in the production plans, low off take, transportation in bigger lots, failure of the supplier to strictly adhere to delivery schedule, changes due to technological requirements etc. The Committee also found that according to the review conducted by the Management in 1971-72 stores of the value of 22.10 lakhs were declared surplus. Out of these stores, and spares of the value of Rs. 10.59 lakhs were awaiting disposal for more than one year. The Management had also fixed minimum, maximum and reordering levels for upto 546 items in February, 1973 out of 10,484 store items. The norms of the maximum and minimum limits were reviewed by the Management in 1972-73. The Committee had been assured that this work would be over within a period of next two years in respect of all items except some spare parts which were basically stocked as insurance items. The Committee recommended that the Management should expedite this work and ensure that in no case, the stock of raw materials in terms of months' consumption exceeded the prescribed limit.

77. In their reply the Government stated that the recommendation had been noted and so far a total of 840 items had been included under the automatic procurement system after fixing their maxima, minima and reordering levels. Further work was stated to be in progress.

78. The following raw materials were stated to be held in excess over the norms and action had been taken by the Antibiotics plant to transfer some of these raw materials to the Synthetic Drugs Plant, Hyderabad.

INDIGENOUS

S.No.	Description of raw materials	Unit	Monthly Consumption	Stock position as on 16-10-74
1	2	3	4	5
1	Ammonium Nitrate . . .	MT	11·58	122·75
2	Sodium Bromide . . .	MT	..	All stock transferred to SDP, Hyderabad.
3	Sodium Tripely Phosphate .	MT	9·54	114·30
4	Magnesium Sulphate .	MT	0·53	1·785
	Imported			
1	Lactose	MT	62·86	347·604
2	Ammonium Thie Cyanate .	MT	Nil	All stock transferred to SDP, Hyderabad
3	Ion-exchange resins			
	i. KU-2-20 . .	MT	..	5·892
	ii. KB-4P-2 . . .	MT	..	13·995
	iii. EDE-10P	MT	..	7·269
	iv. SBS-3 . .	MT	..	0·324
	v. KU-2 . . .	MT	..	0·985
	vi. KB-2 . . .	MT	..	12·920

79. Ion-exchange resigns—are not consumed every month and are used either for making up the loss or for complete replacing in the columns. However, it was stated that this stock would last for about 1 to 2 years.

80. The Committee regret to note that, so far, the maxima, minima and re-ordering levels have been fixed in respect of only 840 items out of 10,481 items. They feel that the progress of work in fixing these levels is too slow and if the progress is not stepped up, the work would not be completed by the end of 1975-76 as assured by the Company during evidence. The Committee would like the Company to take all possible measures urgently so as to complete this work within the stipulated period.

Recommendation Sl. No. 35 (Paragraph No. 2.355)

81. The Committee noted that in December, 1962 the private firm of Bombay was appointed as the Company's clearing agent for clearing and forwarding all machinery and equipment imported from USSR and other countries. According to the terms and conditions of the Contract, the Clearing Agents were to pay landing and all other Port Trust charges in the first instance and to claim reimbursement of

the amount so paid in bills, duly supported with relevant receipts. However, the Company opened two personal deposit accounts (December, 1962 and March, 1966) with Port Trust Authorities. Opening of these accounts was a material deviation from the conditions attached to the notice inviting tender. Specific reasons for opening these accounts by the plant were not on record. Out of the amounts deposited by the project Authorities a sum of Rs. 29.13 lakhs was adjusted by the Port Trust Authorities on account of ground rent, wharfage and demurrage. The incidence of demurrage included in that amount worked out to Rs. 27.37 lakhs (Approx.). Out of this, a sum of Rs. 3.95 lakhs only was refunded by the Port Trust Authorities and an amount of Rs. 0.247 lakhs was written off by the Company. According to the Company the payment of demurrage of the order of Rs. 23.16 lakhs was mainly due to the negligence on the Part of the clearing agents in obtaining wagons, and expeditious customs clearance. The Committee felt that IDPL should have recovered the amount of demurrage from the clearing charges. As the matter was stated to be pending in a Court of Law, the Committee refrained from offering any comments at that stage. The Committee however recommended that the whole position may be reviewed by the Management after the case had been decided by the Court. The Committee liked to be informed of the final position.

82. In their reply the Government had stated that the recommendation of the Committee had been noted for guidance. The Court case was stated to be still pending.

83. The Committee reiterate their earlier recommendation and desire that they should be informed of the final position in this regard as soon as the Court case, which is stated to be still pending, is finalised.

D. Project Estimates—Synthetic Drugs Plant, Hyderabad.

Recommendation Sl. No. 38 (Paragraph No. 3.22 to 3.25)

84. The Committee noted that the actual expenditure up to 31st March, 1972 included an amount of Rs. 83.14 lakhs incurred upto September, 1968 and during the period April, 1969 to March, 1972 on carrying out a number of modifications in the course of the erection and also with a view to assessing installed capacity and production practices.

85. The Committee regretted to note that no details were available about the expenditure incurred on the modifications during the period of October, 1968 to March, 1969 with the result that the responsibility of the collaborators, if any, could not be assessed and the expenditure got automatically charged to the Project estimates. Although, a procedure for estimating the effect of modification was

prescribed in October, 1967, the Committee noted that this procedure was not implemented with the result that the effect of this modification could not be evaluated.

86. The Committee also noted that the estimates of 1971 included new works costing Rs. 48.57 lakhs. The Committee regretted that even though these new items constituted material modification of the original estimate of the Project, these were not got approved by the Government nor were these brought to the notice of the Parliament as recommended by the Committee in paragraph 2.20 of their 39th Report (1972-73—5th Lok Sabha). The Committee expected that Management/Government would bring these facts to the notice of the Parliament without delay.

87.* In their Reply the Government stated that modifications carried out during the stabilisation stages were not treated as separate works of capital nature for the collaborators themselves had given in accordance with the supply contract certain quantum of reserve equipments and pipelines (spares) to be used during the commissioning stages (for changes as and when they become necessary).

88. The collaborators could carry out, according to the agreement modifications from time to time in the light of technological developments taking place in their country and the expenditure on such modification during the period of erection and commissioning were to be borne by the Company by charging it to project estimates.

89. However, as the number of such modifications and their value appeared to be on the increase, it was felt that a procedure should be laid down for keeping a separate account for such modifications carried out and this could be achieved only after detailed examination of the various aspects of the problem. After such a procedure was prescribed in April, 1969, a detailed codified account of all modifications carried out had been maintained.

90. The procedure for estimating the effect of modifications prescribed in October, 1967, was in respect of capital replacements and capital modification, which were to be taken up after the commissioning of the plant. Since the modifications were initially carried out during the course of the erection, no separate study of the impact of the modification in the manner laid down by the procedure prescribed in October, 1967 was possible.

91. The inclusion of new items of equipments etc. in the Project had the approval of Government. However, the question of bringing

*Not vetted by Audit.

this to the notice of the Parliament was under consideration in consultation with the Ministry of Finance.

92. The Committee reiterate that the cost estimate of the project which stood materially modified as a result of the inclusion of new items of equipment etc. in the project should be brought to the notice of Parliament without the further delay as recommended by the Committee in paragraph 2.20 of their 39th Report (1972-73). The Committee also desire that a procedure should be evolved by which items of modifications of a capital nature which are to be charged to Project etc. are kept separately in an account distinct from that relating to maintenance and repairs of a recovery nature.

E. Performance Appraisal—Synthetic Drugs Plants Hyderabad Recommendation No. 42 (Paragraph No. 3.50 and 3.51)

93. The Committee noted that there had been shortfall in production in Vitamin B1, Vitamin B2, Folic Acid, Amidopyrine, Piperazine salts and D.C. citrate etc. on account of which the country had to import these drugs to the extent of Rs. 269.83, Rs. 366.81 and Rs. 219.98 lakhs in 1969-70, 1970-71, and 1971-72 respectively. The Committee stressed that any shortfall in production and non-utilisation of the capacity would only increase the import of the drugs with greater out-go of foreign exchange.

94. The Committee recommended that IDPL should ensure the full utilisation of the capacity in all products and thus avoid the necessity of importing them to save valuable foreign exchange.

95. In their reply the Government stated that the items referred to in the above recommendation, their installed capacity and production during 1973-74 and 1974-75 (six months) are indicated below:*—

S. No.	Item	Installed Capacity	Production 1973-74	Production 1974-75 (six months)
1.	Vitamin B1	30	30.31	7.52
2.	Vitamin B2	5	1.81	2.18
3.	Folic Acid	1	2.37	1.40
4.	Amidopyrine	10	2.66	0.61
5.	Piperazine Salts	50	67.41	32.52

*According to the Principal Audit Officer, the installed capacity in respect of Folic Acid is 2·5 tonnes and not 1 tonne and there is no separate installed capacity for Amidopyrin. Moreover, as against the total installed capacity of 200 tonnes for Analgin and Amidopyrine, the production thereof during 1973-74 was 159·6 tonnes.

96. It would be seen therefrom that there was an improvement in the production of Vitamin B2, Folic Acid and Piperazine salts. The main constraints in increasing the production were the non-availability of raw-materials and the steps as indicated in reply to recommendation No. 41 were being taken by Government.

97. The Committee find that the production of vitamin B1, B2 and Amidopyrine during 1973-74 and 1974-75 continued to be below the installed capacity and the steps reported to have been taken to increase production have not brought about the desired improvement in this regard. In fact, instead of improving, the position in respect of Vitamin B1 and Amidopyrine worsened in 1974-75 (six months) as compared to 1973-74. They reiterate their earlier recommendation and urge that IDPL should take effective steps to ensure full utilisation of the capacity in all products so as to avoid the necessity of importing them to save valuable foreign exchange.

F. Loss of mercury—Synthetic Drugs Plant, Hyderabad.

Recommendation Sl. No. 46 (Paragraph No. 3.104 to 3.106)

98. The Committee found that though according to the process of production of Ribose, almost the whole quantity of mercury used should be salvaged with insignificant loss at the end of the process cycle, the loss of mercury in the plant was quite abnormal. The Committee would also recommend that the security arrangements for the mercury in the Ribose Section should be tightened to guard against the possibilities of such pilferages. The Committee would like to be informed of the action taken in the matter within six months.

*99. In reply the Government stated—

> "As recommended a Technical Committee consisting of Dr. B. Shah, DDG, DGTD, Dr. B. L. Sattur, Regional Research Laboratory, Hyderabad and Dr. P. L. Gupta, Drug Adviser, Ministry of Petroleum & Chemicals has been constituted to review the matter and fix responsibility for the loss of mercury. The Committee visited the plant and had examined all aspects. Its report is awaited."

100. Continuous electrolytic process for the production of D-Ribose is under stabilisation. Results achieved so far are encouraging. This process involves less handling of mercury which enables a

*Not vetted by Audit.

stricter control being kept on pilferage or wasteful practice. A close watch is also kept on the consumption of mercury by the plant management.

101. Existing security arrangements provide for maintenance of a complete record, with date and time of entry and departure of every person from the Ribose section, where mercury is handled. All persons leaving the section are thoroughly searched by the Security Guard.

102. On an enquiry whether the Technical Committee had submitted its Report, and if so, please give its finding and recommendations and the follow up action taken thereon by IDPL/Government and also furnish a copy of the report also, the Government stated that a Technical Committee consisting of Dr. B. Shah, DDG, DGTD, Dr. P. B. Sattur, Dy. Director, Regional Research Laboratory, Hyderabad and Dr. P. R. Gupta, Adviser (Drugs), Ministry of Petroleum & Chemical was constituted to examine the entire matter relating to the theft of Mercury, and the Committee observed—"***it is very difficult to pinpoint responsibility on any one individual." The Committee submitted its report and it was now under consideration of Government.

103. The Committee note that a Technical Committee was constituted to examine the entire matter relating to the theft of mercury and fix responsibility for the loss of mercury. They further note that the Technical Committee has submitted its report which is now under the consideration of Government. According to the Technical Committee "it is very difficult to pin point the responsibility on any individual". They would like the Government to finalise remedial action to be taken in the light of the suggestions made by the Technical Committee in the report to plug all loopholes and prevent the loss of mercury in the future.

Recommendation Sl. No. 47 (Paragraph 3.107)

104. The Committee found that the project Report had indicated a loss of 0.0064 tonnes of mercury per tonne of Vitamin B2 but in order to arrive at the extent of loss due to pilferage alone, an exercise was made by the Management by assuming an operational loss of mercury at 0.185 K.g. per K.g. of Ribose produced. Subsequently the Committee which was constituted in January, 1971 recommended that the normal consumption of mercury should be 0.2 k.g. of mercury per 1 k.g. of Ribose.

105. The Committee felt that in order to inspire confidence refixation of norm should have been done by an independent agency after taking into account norms followed in similar plants in the collaborators country, lest upward revision of norm by the Management themselves should be construed as an indirect regularisation of a loss.

106. *In their reply the Government stated that as mentioned in reply to Recommendation No. 46, continuous electrolytic process was under stabilisation at present. Norm would be fixed in consultation with an independent agency after the process stabilised.

107. The Committee recommend that the realistic norm as regards consumption of mercury should be fixed in consultation with an independent agency as early as possible.

G. Performance Appraisal—Surgical Instruments Plants, Madras and Actual Production Performance

Recommendation Sl. Nos. 58, 59 and 64 (Paragraph Nos. 4.22 to 4.25, 4.38, 4.71)

Recommendation S. No. 58 (Paragraph No. 4.22 to 4.24)

108. The Committee regretted to note that SIP was commissioned in September, 1965 to produce 2.5 million instruments for stock without a proper market survey with the result that the instruments did not command a ready indigenous market because of high prices, restricted number of varieties and pattern of instruments not carrying conviction with Indian Surgeons. Consequently the plant was faced with an accumulated stock of Rs. 2.57 lakhs at the end of March, 1968. The Committee found that in April, 1966 a market survey was conducted by the NCAER. Subsequently in 1967-68, the Marketing Division of IDPL conducted a "Quick Demand Survey". According to both these surveys, the original product mix in the DPR needed to be modified. In 1967-68, a Committee of Surgeons recommended that only about 25 per cent of the original product-mix could be acceptable in the Indian market and the remaining are either to be modified or given up and instead of new types of instruments were to be developed. No exercise was done by the Company to determine the rated capacity of the Plant in the light of the changes in product-mix based on this survey till, May, 1972 when the rated

*Not vetted by Audit.

capacity was brought down from 2.5 million instruments to 1 million instruments and Rs. 30 lakhs of job orders.

109. The Committee were informed that the reduction in the rated capacity was not placed before Government for approval.

110. It had been admitted by the Management that "The market demand for surgical instruments in the country is not expected to meet fully the break even requirements of the Plant". The Committee were of the opinion that all the problems of the Plant are due to the absence of a market survey before deciding upon the product-mix for this plant. The Committee felt that even now it was not too late to ascertain the types of surgical instruments which would be suited to the Indian market and re-determine the existing product-mix suitably so as to make the plant economically viable.

111. The Committee desired Government to go carefully into the question of export possibilities from this plant to East European and other countries and have a long term arrangement so that the built in capacity which is surplus to requirements can be put to profitable use. The Committee desired to be informed within six months of the concrete steps taken in pursuance of this recommendation.

112. *In reply the Government stated that a Committee consisting of Adviser (Medical), Chief Marketing Manager and the General Manager of the Surgical Instruments Plant has investigated the demand for surgical Instruments in the indigenous market and a total of 289,000 instruments is expected to be produced during the current year. In addition job works to a value of Rs. 10 lakhs will be executed during the current year.

113. The Company has been asked to place before the Board for its consideration notes in regard to reduction in the rated capacity as well as the demand now estimated by the Committee referred to above.

114. A note on the instruments produced at the plant, their prices etc. has been circulated to the Indian Embassies in Europe and USA to explore the possibilities of their exports to these countries. The Company on their own also are exploring such possibilities.

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*Not vetted by Audit.

115. The Committee further enquired:—

(a) What will be the utilisation and is there any improvement as a result of the investigation made by the Committee consisting of Adviser (Medical) Chief Marketing Manager and the Central Manager of Surgical Instruments Plant into the demand for surgical instruments in the indigenous market?

(b) Has the IDPL placed before the Board and the Government for consideration notes in regard to the reduction in the rated capacity? What is the result of the consideration of the Board and the Government? Please state in detail indicating whether the reduction in the rated capacity was justified.

(c) What specific action has been taken by IDPL/Government for exploring the possibilities of export of Surgical Instruments to East European and other countries?

Please state in detail.

116. *In reply the Government stated:

(a) The production plan for 97 types of instruments was drawn up in July, 1974. However, this could not be fulfilled because of the power cut imposed by the Tamil Nadu Government. This power cut ranging from 2/3rd to complete power cut in that area also affected the export agreement for the instruments numbering 296,000 valued at Rs. 33,71,640. Out of this agreement, only Rs. 123,000 instruments worth Rs. 12,34,780 could be supplied.

(b) There has been no reduction in the rated capacity. However there has been a change in the product-mix. The earlier higher capacity of production pertaining to simpler items whereas the present rated capacity of 1 million instruments is for a specific product-mix.

(c) The Ministry of Petroleum and Chemicals have issued circular letters to the Indian Embassies located in East European and other countries. Accordingly, the IDPL received enquiries from a few Embassies and have also submitted to them their quotations together with samples. Negotiations are afloat and IDPL are awaiting orders. However, the Plant Committee has also pointed out that

*Not vetted by Audit.

the export might not be remunerative as the international prices are low and have stated Pakistan Industry is being subsidised to the extent of 40 per cent for export of surgical instruments.

Recommendation Sl. No. 59 (Paragraph No. 4.38)

117. The Committee note that the Surgical Instruments Plant was commissioned in September, 1965 and was designed to produce 2.5 million surgical instruments of 166 types according to the Detailed Project Reports. As only 46 types were acceptable to the Indian Market, the Plant was faced with the problem of unsold stock of Rs. 25 lakhs. In July, 1967 the Board of Directors decided that no further production should be undertaken unless there were definite orders for the same. The Committee found that since the Plant was essentially designed for bulk production of small number of instruments and the orders received by the Plant were only in small lots, with the result there was diversion of customers to other sources. Since 1970-71 the Plant had been mainly dependent on export orders. The Committee recommended that as the Plant was designed to produce large bulk of a restricted number of varieties of instruments, the Government/IDPL should pool in coordination with the State Governments, the requirements of Surgical Instruments for the Government Hospitals all over India so that the Plant could take up the production of such instruments in economic lots. This may be of some help in finding orders for the utilisation of the existing capacity of the Plant.

118. *In reply the Government stated—

"The question of assessment of surgical instruments required by Hospitals, etc. has been taken up with the Ministry of Health & FP. In the meantime, as already mentioned in reply to recommendation No. 58, demand survey of instruments has been made by a Committee of IDPL and the programme for 1974-75 envisages the manufacture of 97 types of instruments including 68 newly developed and 29 types of instruments from the original product-mix of 166 types."

119. The Committee further enquired—

"(a) Has the IDPL/Government taken up with State Governments the question of assessment of surgical instruments

*Not vetted by Audit.

required by Hospitals etc. all over India? If so, what is the outcome thereof? Please state in detail.

(b) It is stated that a demand survey of instruments has been made by a Committee of IDPL and the programme for 1974-75 envisages the manufacture of 97 types of instruments including 68 newly developed and 29 types of instruments from the original product-mix of 166 types.

What about the remaining types of instruments?"

120. *In reply the Government stated:—

"(a) It is extremely difficult to earmark specific requirements on yearly basis as the same are changing. However, the State Governments have been asked to issue directives to their respective departments to buy their requirements only after obtaining a non-availability certificate from IDPL. A few State Governments have already issued such instruments.

(b) The Company had already constituted a Committee which gave its findings that certain diversification has to be done. For further scrutiny, these reports have been submitted to the Director General, BPE. In the meantime, Government has also appointed a Committee to study the working of surgical instruments plant, in pursuance of the recommendations made by the Committee on Public Undertakings."

Recommendation Sl. No. 64 (Paragraph No. 4.71)

121. The Committee found that as a part of diversification programme the Surgical Instruments Plant had taken up the manufacture of family planning instruments. An analysis of production performance indicated that the production of Family Planning Instruments had declined from 1.60 lakhs in 1968-69 to 30,000 in 1972-73. The percentages of these Instruments with reference to total instruments produced come down sharply from 88 per cent in 1968-69 to 4.4 per cent in 1972-73. The Committee were informed that based on past experience, Management assessed the requirement for Family Planning instruments not exceeding Rs. 15.20 lakhs per annum, out of which share of surgical instruments plant would be around

*Not vetted by Audit.

Rs. 10.12 lakhs per annum. This would work out to 10—12 per cent of the total production of instruments (1 million capacity). The Committee recommended that Government should pool their requirements for Family Planning Instruments in advance so that there was steady flow of orders and the plant was able to utilise its spare capacity to the maximum extent possible. The Committee desired that Government should take up the matter with the State Governments "in the interest of securing firm orders for Family Planning Instruments."

122. *In reply the Government stated—

"The production of Family Planning Instruments declined from 1.6 lakhs in 1968-69 to 30,000 in 1972-73 because of diversion of capacity to meet the export orders from Russia. The production of family planning instruments during 1973-74 was 24,223 valued at Rs. 2,92,217/-. It may be mentioned that the emphasis, in the family planning programme has since shifted to other methods like Nirodh and pills etc. and this has affected sale of instruments. Also earlier, supplies of family planning kits were being made while now only individual instruments are required. During 1974-75, the programme of the plant is to manufacture 36,300 instruments valued at Rs. 5,95,900.

123. The Company has already approached the Central Government Departments in regard to the orders for family planning instruments being placed on Indian Drugs and Pharmaceuticals Limited. They have also approached State Governments, for the issue of necessary directives to their departments for purchase of instruments from IDPL without calling of quotations.

124. The assessment of requirements of family planning instruments has also been taken up in consultation with the Ministry of Health and Family Planning.

125. The Committee further enquired "what is the result of approaching the State Governments for the issue of necessary directives to their Departments for purchase of instruments from IDPL without calling quotations? Please state in detail indicating the latest position."

In reply Government invited attention to reply to Recommendation at Sl. No. 59.

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*Not vetted by Audit.

126. The Committee note that the IDPL had constituted a Committee which went into the question of diversification of production in the Surgical Instrument Plant and their findings are under scrutiny of the Director General BPE. The Committee would like the question of diversification to be finalised early and action initiated without avoidable delay.

127. The Committee also note that the Government have also appointed a Committee to study the working of Surgical Instrument Plant. They hope that the Government Committee will go into the various aspects of the working of this plant and recommend concrete measures to enable it to utilise its capacity fully.

Recommendation Sl. No. 61 (Paragraph No. 4.46)

128. The Committee note that the percentage of rejections in SIP to the total production ranged from 18.95 per cent in 1971-72 to 27.37 per cent in 1970-71. The Committee also found that the percentage of rejections was the highest in the Grinding and Assembly Shops where the rejections showed an increase from 27,538 number of instruments in 1968-69 to 1,06,160 in 1972-73. The Committee were informed that the Management had taken a number of steps to reduce the rejections by more rigid check on the raw materials, stricter inspection of forging tools, improvement in tooling and machinery, promoting facilities for cleaning of stainless steel instruments etc. The Committee were also informed that the rejections in the Grinding and Assembly Shops were high due to inexperienced workmen being frequently put on more and more skilled operations. The Committee were surprised that in spite of the plant having been in operation for more than eight years the necessary skill for operating the plant could not be developed. The Committee desired that in the interest of attaining high standards in production and minimising the rejections, the Undertaking should consider feasibility of introducing a time bound programme for training the workers in specified skills and deploy them suitably with a view to achieving quality production. The Committee recommended that norms for rejections may be finalised without any further delay.

129*. In reply the Government stated—

"The rejections that occur in the manufacture of surgical instruments are mainly due to (i) material defect (ii) non-flow of material during forging (iii) breakage or damage to instruments during fitting and (iv) undersize in grinding. The material defects are now

*Not vetted by Audit.

analysed with more specified processes and defects are removed at an early stage. However such rejections at an early stage are also included for computation of percentage of rejections. It may be mentioned that the defects in the raw materials are not assessable in visible inspection before taking up production. The defect of undersize is also due partly to defects in the raw material. The training of workmen was not possible due to the change in the product mix year to year from the inception. This has resulted in lack of high adequate skill amongst the workmen though the general technical know how and skill is not lacking. While trying to achieve an increase in productivity at the initial stage of processing in instruments, higher percentage of rejection occur. Even if there had been a gap of month or two when the workmen are put again on the same time for a few days, the rejections will be more and the productivity will also be less.

130. Taking into account the high standard of production required for meeting surgical instruments, the minimum rejection during the process has been worked out by the plant authorities on the basis of their experience and is under consideration of the Board of Directors. A statement showing the rejections for the year 1972-73 and 1973-74 is attached. The average of rejection of these two years is of the order of 20 per cent. It is hoped to improve the performance and reduce rejections to the minimum and this will be feasible with a permanent pattern of production which is now being evolved through market survey and sales projection. The training to the extent a corrective action is required to reduce the rejections will be imparted."

131. The Committee further enquired—

"(a) What steps have been taken to reduce rejections which have not come down substantially?

(b) Has the feasibility of introducing a time bound programme for training the workers in specified skills and deploy them suitably with a view to achieving quality production as recommended by the Committee, been considered and if so, with what results?

(c) Have the norms for rejections been finalised? If so, the details thereof may be given."

132. In reply the Government stated:—

'(a) and (b) After the new product mix has been evolved, the production has been very limited due to power shortage and all efforts are being made to minimise the rejections.

(c) The norms for rejections have been finalised."

133. The Committee note that though norms of rejections in the manufacture of Surgical Instruments have been finalised, the IDPL has not indicated the steps taken to reduce the rejections and to impart training to the workers with a view to achieving quality production. The Committee would like to reiterate that in the interest of attaining high standards in production and minimising the rejections the undertaking should consider the feasibility of introducing a time bound programme for training the workers and deploy them suitably.

Recommendation Sl. No. 62 (Paragraph No. 4.69)

134. The Committee noted that the SIP had not been able to use all the machines in the Plant. The Committee regretted to note that no machine utilisation statements were prepared by the plant till 1970-71. It had been reported that, at the end of August, 1972, the Plant had 15 surplus machines valued at Rs. 9.35 lakhs awaiting disposal. The Committee learnt that the management had already circulated the list of surplus machines to all the public sector undertakings and also given necessary publicity in Lok Udyog. The Committee hope that the plant would be able to dispose off the surplus machinery soon in the best interest of the unit.

135. *In reply the Government stated—

"Efforts for the disposal of surplus machines are continuing. All representatives of public undertakings visiting the plant are also given the lists of the surplus machines with complete specifications to enable them to procure them if need be. So far however there has been no disposal."

136. On an enquiry of the Committee as to what specific efforts were being made by IDPL|Government for the disposal of 15 surplus machines valued at Rs. 9.35 lakhs and what was the result thereof—the Government stated that list of 15 equipments which had been declared surplus for disposal was circulated to various public sector undertakings and an advertisement was also given in the leading dailies. The response received against the advertisement was however not encouraging. Efforts were still being made for disposal.

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*Not vetted by Audit.

137. The Committee note that although the IDPL has circulated the list of surplus machines to various public sector undertakings and has also published an advertisement for their disposal in the leading dailies, it has not been able to dispose of the surplus machines so far. The Committee stress that the Committee already appointed to go into the various aspects of the working of the surgical Instruments Plant should also go into the question of utilisation of this machinery, if necessary, by diversification of production for the full utilisation of the plants capacity.

H. Cost Control—Surgical Instruments Plants Madras

Recommendation Sl. Nos. 67 & 68 (Paragraphs Nos. 4.101 and 4.102)

Recommendation S. No. 67 (Paragraph No. 4.101)

138. The Committee noted that so far no standard cost had been worked out in respect of the products of Surgical Instruments Plant and only a system of job costing was in vogue by which the cost of production of each type of instrument was worked out. The Committee found that even under the system of job costing, the cost of production of all instruments in 1970-71 was higher than the selling prices both in respect of local sales and also for external market. The Committee were informed that during 1971-72 the sale value covered the direct cost although in 1972-73 there were as many as 20 items whose selling prices did not cover even the prime cost of production. The main reasons for such a situation were stated to be that fixed overheads of the Plant were of the orders of 42 per cent of the break-even expenditure of Rs. 160 lakhs; the selling prices had been following a uniform pattern for the indigenous as well as for exports inspite of abnormal increase in the cost of material and wages. Lower productivity in grinding and Assembly shop was also stated to be one of the reasons for high cost.

139. The Committee found that there was a wide variation as between the total cost of production and the selling prices of various instruments. The Committee recommended that the plant should take concerted measures to bring down the cost of production and raise the level of productivity, particularly in the Grinding and Assembly shop.

140. *In reply the Government stated—

> "The prices of instruments were revised with effect from the 1st May, 1974 and in this full costs including depreciation and interest are covered for 11 types of instruments, and overhead charges partially covered in respect of 76 other items.

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*Not vetted by Audit.

141. As regards raising the level of productivity and also reducing the cost of production, the Government proposes to appoint a Committee/consultant to examine all aspects of the Plant."

142. The Committee further enquired has the Committee/Consultant been appointed? If so, when and what are the terms of reference? Has the Committee/Consultant submitted its report, if so, the salient features there of and the action taken by Government/IDPL thereon and if not when is it expected to submit its report.

143. In reply the Government stated:—

"After detailed consideration and in consultation with the Planning Commission, a Committee consisting of the following was set up in this Ministry's Memorandum No. 8(86)/74-Ch. III dated the 27th June, 1975:—

1. Sh. H. R. Verma, Director (Engg) Planning Commission.
2. Sh. Bazle Karim, Adviser (Production) BPE.
3. Sh. K. N. Ramaswamy, IA, DGTD.
4. Sh. M.S.B.K. Rao, Tech. Manager, Hindustan Tele-Printers Limited, Madras.
5. Dr. P. P. Goel, Consultant in Surgery, Safdarjung Hospital, New Delhi.
6. Dr. B. N. Sinha, 9-A. P. Sen Road, Lucknow (U.P.).
7. Sh. Inderjit Singh, N-246, Greater Kailash, New Delhi.
8. Sh. S. K. Sachdeva, FA&CAO, IDPL, N-12, NDSE, Part-I, New Delhi-110049.
9. Dr. Kameswaran, Director, ENT, General Hospital, Madras.
10. Representative of Min. of Finance (Cost Accts. Br.).
11. Representative of Association of Surgenons, Madras.
12. Shri R. Grover, Director, Min. of P&C—Convenor.

144. The terms of reference are as follows:—

(i) To examine the working of the Surgical Instruments Plant to identify the areas where the cost of production can be reduced and to suggest viable selling prices for each type of instrument;

(ii) To examine the adequacy of technical build up and organisation of the plant to achieve the capacity envisaged by the Management;

(iii) To examine the economics of the plant, scrutinise its product mix de-novo to increase the prospects of increasing sale of instruments in the domestic markets so as to make the plant economically viable;

(iv) To explore the scope for diversification and for exports to other countries at remunerative prices;

(v) To examine the adequacy of the present Management both administrative and technical, productivity level of workers adequacy of the present systems of management and to suggest scope for improvement, administrative reorganisation, and etc.;

(vi) To suggest future set up for the plant.

The Committee is required to submit its report within three months."

Recommendation Sl. No. 68 (Paragraph 4.102)

145. The Committee found that the prices of Surgical Instruments were fixed in 1966 on the basis of estimated cost of 1966-67 when only a fraction of the capacity of the Plant could be utilised. The prices were consequently very high compared to the corresponding instruments manufactured in the private sector. It had been claimed by the company that Instruments of this plant were superior in quality. The Committee regretted to note that in spite of the revision of the prices of instruments substantially in July, 1967, taking into account changes in product mix, current cost and market prices, the selling price continued to be lower than the cost of production in all items except one and the extent of difference in the case of individual instruments varied from Rs. 2.24 to Rs. 206.20.

146. The Committee were not however convinced that the cost of production was high due to lack of orders. The Committee had already pointed out elsewhere in this Report that the plant had pending orders worth lakhs of rupees which could not be executed. The Committee failed to understand as to why in spite of existence of such orders, there had been shortfall in production leading to underutilisation of capacities with consequential higher cost of production.

147. The Committee also found that during 1972-73 the plant produced 2892 instruments (code No. 05-01) at a total cost of 55.60 rupees per instrument and sold the same at only Rs. 11 per instrument. The prime cost of this instrument was stated to be Rs. 12.93. There were a number of other instruments where the selling price was not only

far below the overall cost of instruments but did not cover even the prime cost of the instrument. The Committee felt that if selling prices continue at the present level without any reduction in cost of production the working of the plant could not be expected to become economically viable in the near future. The Committee, therefore, recommended that a high power Committee should be appointed to go into the entire working of the Surgical Instruments Plant to identify the areas where the cost of production could be reduced and to suggest viable selling prices for each type of instruments, including scope for diversification.

148. *In reply the Government stated:—

"A Committee of the type suggested by COPU is proposed to be appointed shortly. That Committee would also go into the cost aspects of the products of Surgical Instruments Plant with a view to formulating norms for fixation of realistic sale prices.

149. To a further query whether the said Committee had since been appointed, if so, when and what are its terms of reference, and when was the Committee likely to submit its report, the Government invited attention to a reply to Recommendation at Sl. No. 67.

Recommendation S. Nos. 67 & 68

150. The Committee note that a Government Committee have been appointed in June 1975 to examine the entire working of the surgical instruments plant, its economics, product-mix, scope for diversification and exports, future set-up, and also the cost of production and selling prices for each type of instrument. The Committee hope that the report of the Government Committee would become available soon and Government will not lose any further time thereafter to finalise action on the report and take steps in the light thereof to bring about overall improvement in the working of the plant. They would like the Government to inform Parliament of the action taken and results achieved in this regard in due course.

I. Material Management and Investory Control-Surgical Instruments Plant, Madras.

Recommendation Sl. No. 70 (Paragraph Nos. 4.113 and 4.114)

151. The Committee found that the plant was holding huge stocks of raw materials, stores and spares, compared to the average annual

*Not vetted by Audit.

rate of consumption. The stock of indigenous raw materials as on 31st March, 1973 represented 150 months consumption while the indigenous stores and spares 144 months consumption. The stock of imported raw materials represented 5 months consumption while the stock of imported stores and spares represented 100 months consumption. An analysis of some of the individual items indicated that stainless steel and alloy steel valued at Rs. 40 lakhs imported from USSR during 1965-66 to 1967-68 had been lying unused. It was stated that this had been ordered even before the plant went into production taking into account the product mix and capacity envisaged in the project report.

152. The Committee regretted to note that even though the unit came into existence in September, 1965 no maximum and minimum limits have been fixed for the items. It had been indicated that the original stocking of spares was based on the advice of the collaborators and because of less utilisation of the equipment there had not been much out-go or replacement of the spares.

153. The Committee were informed that a Technical Committee had been appointed early in 1973 to go into the requirements of the spares and assess the inventory holdings under three categories (a) insurance items (b) stores which may be possibly required during the next five years; and (c) spares which could be straightway declared as surplus and disposed of.

154. The Committee were also informed that this Technical Committee have now recommended declaration of stores worth Rs. 50,000/- as surplus and the management was now taking action for their disposal and also maximum and minimum limits have been fixed in respect of certain items. The Committee recommended that the Technical Committee should complete its work soon and identify stores which are really surplus to the requirements so that the undertaking can take immediate action to divert the surplus to more profitable use to other undertakings or dispose them of to the best interest of the undertaking. The Committee desired that Management should take action to fix maximum and minimum limits for all the stores without further delay so that the risk of high inventory holding is avoided.

155. The Committee found that stainless steel and alloy steel valued at Rs. 40 lakhs imported from USSR during 1965-66 to 1967-68 had been lying unused. The Committee are not sure whether the stainless steel and alloy steel has been used or disposed of. The Committee would like to be informed of the latest position.

156. *In reply the Government stated:—

The Technical Committee has not yet finalised the requirement of spares and assessed the inventory under the three categories indicated. The necessary action on the basis of their recommendations will be taken by the plant management, and the maximum and minimum limits will be fixed.

157. Out of the stock of Rs. 34.44 lakhs, materials to the extent of Rs. 10.72 lakhs have been declared as surplus as they were not required by the plant. The list of surplus stores materials has been circulated to all the public sector undertakings and Defence organisations. The disposal of these stores would also require the buyer to obtain the permission of the Import Control authorities. Deducting the value of surplus stores, the value of stock items will be Rs. 23.72 lakhs which represents 24 to 60 months consumption depending on the product mix.

158. On a further enquiry of the Committee—

Whether the Technical Committee which was appointed in early 1973 to go into the requirements of the spares and to assess the inventory holdings under the said three categories, submitted its report? If so, what are its salient features and what follow up action has been taken thereon. if not, when is the Committee likely to submit its report and what are their reasons for such a long delay?

(b) The statement showing the inventory of imported stainless steel and alloy steels lying unutilised, stated to have been attached with the reply to this recommendation has not been received. Please furnish requisite number of copies thereof.

(c) What is the latest position of the disposal of stainless steel and alloy steel? Why such a huge quantity thereof was imported at all?

(d) Even now the 24 to 60 months consumption is examined. Please comment.

159. The Government stated:—

(a) The Technical Committee went into the study of non-moving stores and have listed out items worth Rs, 53,314 to be disposed of. All the spares available other than one item (Piston rods for drop forge hammers) are considered as insurance items.

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*Not vetted by Audit.

(b) The statement showing the inventory of imported stainless steel and alloy steels lying unutilised is attached.

(c) The stainless steel and alloy steel was imported originally based on the product mix and the capacity envisaged in the project report. However every effort is being made to dispose of these surplus items. Recently, we have advertised for sale and tenders are yet to be opened.

(d) Since the product mix has not yet been established, the inventory figures appear to be excessive. IDPL have taken suitable steps to dispose of these items. In this connection, a separate cell has already been formed for the disposal of surplus items.

160. The Committee note that the inventory of imported stainless and alloy steel has come down from Rs. 40.92 lakhs as on 31-3-1972 to Rs. 34.44 lakhs as on 31-8-1974, out of which materials to the extent of Rs. 10.72 lakhs have been declared as surplus and the list thereof circulated to all the public sector undertakings and Defence Organisations and also advertised for sale. The Committee would like that the surplus materials should be disposed of early in the best interest of the unit. The Committee would like to be informed of the manner of disposal and the names of the parties/authorities to whom the stainless and alloy steel has been disposed of.

Even after excluding the surplus stores the Committee feel that the inventory of stocks (Rs. 23.72 lakhs) which represents 24 to 60 months consumption is excessive. The Committee would like to reiterate that management should take early action to fix the maximum and minimum limits for all the stores so that the risk of high inventory holding is avoided.

J. Pricing Policy

Recommendation No. 71 (Paragraph Nos. 5.22 to 5.25)

161. The Committee noted that the prices of products of the Antibiotics Plant and the Synthetic Drugs Plant were fixed for drugs likely to be on sale in 1968 on the basis of the then ruling maximum prices in the market, even though the cost of production at that time warranted higher prices. The Undertaking had, however, to reduce the prices to lower levels and to sell the products at reduced prices to secure fair span of the market. With the taparing of imports, the Company was able to progressively increase its prices of Sulphas and penicillin when the Drugs (Prices Control) Order came into effect

from the 16th May, 1970 and certain drugs were defined as "essential bulk drugs". The prices of bulk drugs were, however, frozen at the rates ruling on 15th May, 1970. The Committee were informed that the prices fixed did not take into account the actual cost of production in the Antibiotics Plant with the result that the recommendations of the Drugs (Price Control) Order proved uneconomical to IDPL. A similar difficulty was also felt in the case of Synthetic Drugs Plant since the process of rationalisation of the prices had not been completed. There had also been a number of escalations in the prices of raw materials, wages, services etc. As bulk drugs are sold mostly to the private sector for formulation purposes the Committee felt that as a result of transfer of bulk drugs to formulators in the private sector, they were allowed to earn a greater margin of profit.

162. The Committee also noted that the company approached Government for fixing the selling Prices after taking into account its ultimate cost of production including return on capital. The Committee understand that on the 11th September, 1970, Government constituted a Working Group of Bureau of Industrial Costs and Prices for settling the cost structure of 25 bulk drugs and to recommend fair selling prices therefor. The Committee regretted to note that though the recommendations of the Bureau were received by Government as far back as October, 1972, Government took an unduly long time in taking a decision on these recommendations.

163. *In their reply the Government stated that the Government had since taken a decision on the Report of the Working Group constituted under the Chairmanship of the Chairman, BICP in so far as the revision of prices of bulk drugs and revision of norms for conversion costs and packaging were concerned. These covered the specific terms of reference to the Working Group. A statement on this was laid on the Table of the Lok/Rajya Sabha on the 19th/24th April, 74. Other recommendations which the Working Group had made under the residuary terms of reference were under examination of Government.

164. Government had also allowed increases in prices further on the basis of the recommendations of the BICP to the extent of increases in the cost of raw materials. A statement indicating the previous prices and the present selling prices of drugs in the range of the IDPL was attached. The revised prices were expected to improve the economics of the plants.

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*Not vetted by Audit.

165. Efforts were being made to secure improved technologies and strains. With this aim in view, a team consisting of Deputy, DGTD, Adviser (Drugs) Ministry of Petroleum and Chemicals and the Managing Directors of IDPL and HAL visited various countries from the last week of February to the first week of April, 1974. The matter was being further pursued with the parties who showed positive response.

166. The Committee note that a statement containing the decision of the government on the report of the working group of the Bureau of Industrial Costs and prices regarding the revision of prices of bulk drugs and norms for conversion costs and packaging was laid on the Table of the Houses in April, 1974. They would like the government to expedite decision on the recommendations which the working group of the Bureau had made under the residuary terms of reference and lay it also on the Table of the Houses of Parliament.

K. Organisation—Labour Management Relations

Recommendation No. 86 (Paragraph No. 8.30)

167. The Committee noted that the Managing Director was the chief executive of the Company. At the Unit level the General Manager functions as chief executive of the individual Unit and is responsible for the efficient performance of the Unit in accordance with the policies and Plans approved by the Board. The IDPL has three Plants, one at Rishikesh, the second at Hyderabad and the third at Madras. Though these were distinct units each specialising in a special field of production they were under one Management. The General Managers are not invited to participate in the meetings of the Board although according to general directions issued by the Bureau of Public Enterprises such an arrangement might be considered in the interest of the working of the units and the Undertaking as a whole. The Committee were informed that the Ministry was already examining the future set up of the IDPL and HAL with a view to coordinate their activities and rationalise the management of the units in the context of the targets envisaged in the Fifth Plan and ensure that the plants manufacturing similar products are under the same Management. The Committee desired that the Ministry should complete its examination soon and rationalise the Management so as to have a more broad based Board.

168. *In their reply the Government stated that the recommendation had been noted and the question of having a common marketing organisation for both the public sector units is under consideration.

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*Not vetted by Audit.

169. The Committee on Drugs and Pharmaceuticals Industry constituted under the Chairmanship of Shri Jaisukhlal Hathi had made certain recommendations on the various antibiotics to be manufactured by the IDPL and HAL and also the organisational structure. These were also under consideration and an early decision was expected to be taken.

170. The Committee note that the Committee on Drugs and Pharmaceuticals has since made certain recommendations on the various antibiotics to be manufactured by IDPL and HAL and also the organisational structure. They hope that the Government will take an early decision on these recommendations and rationalise the production pattern and the management of the Company.

CHAPTER II

RECOMMENDATION THAT HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation (Sl. No. 1)

The Committee regret to find that even though the Bureau of Public Enterprises had asked, as far back as in November, 1970, all the Government Companies to formulate a statement of their objectives/obligations clearly and communicate the same to Government, the Indian Drugs and Pharmaceuticals Ltd., has not done so till now. The Committee were informed that it is only recently that the statement of objectives/obligations has been prepared and is still awaiting consideration of the Board of Directors. There has thus been a delay of more than three years even in formulating their objectives. The Committee are unhappy that even the Ministry's representative on the Board of Directors failed to impress on the Company the need to formulate its objectives early. The Committee trust that IDPL would finalise the statement of objectives without any further delay in the absence of which critical evaluation of the performance of a Government Company becomes difficult.

The Committee are not sure as to how many more such undertakings are yet to finalise their statements of objectives/obligations as required by the Bureau of Public Enterprises in their circular of 1970. The Commitee recommended that the Bureau of Public Enterprises should immediately take stock of the position and finalise the matter without further delay.

The Committee also reiterated their recommendation in paragraph 1.44 of their 40th Report (1973-74) on Role and Achievements of Public Undertakings and trust that Government before long would bring a comprehensive White Paper setting out, *inter alia*, the financial, economics and social objectives of each of the Public Undertakings. (Paras 1.18 to 1.20)

Reply of Government*

The statement of objectives in regard to the IDPL has been prepared and sent to the BPE for their comments and approval.

The question of bringing a comprehensive White Paper on the financial, economic and social objectives of the Public Undertakings is under the consideration of the BPE.

[Min. of P & C. O.M. No. 8(25)/ 74-Ch. III dated 30-10-1974].

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*Not vetted by Audit.

Comments of the Committee

Please *see* paras 6 and 7 of Chapter I of the Report.

Recommendation (Sl. No. 2)

In para 5.3 of their 46th Report (1968-69) the Committee had pointed out that the project estimates of the Antibiotics Plant, Rishikesh were revised five times during the period 1961—68. As against the original estimate of Rs. 15.75 crores the estimate prepared in 1968 was for Rs. 26.32 crores. Thereafter revised estimates were prepared in December, 1970 and approved by Government in August, 1971. As against the revised estimates of Rs. 27.43 crores approved by Government in August, 1971 the actual expenditure upto 30th November, 1973 was stated to be Rs. 26.77 crores. The Committee find that though the average actual expenditure has not exceeded the estimate of Rs. 27.43 crores approved by Government, there has been an excess of more than 20 per cent in the case of Commissioning Expenses. The increase in the estimates revised in December, 1970 and approved by Government in August, 1971 over the estimate of August, 1968 was stated to be mainly because of increase (18.14 lakhs in estimated outlay on new works, and provision made for outlay on protocol works (Rs. 50.99 lakhs) which was jointly agreed upon between the Russians and the Indian Technological Team in 1969 to set right certain imbalances and deficiencies in the plant, provision for 360 residential quarters (Rs. 42 lakhs). The Committee find that while October, 1966 estimates did not take into account the commissioning expenses and interest on Government loans, the estimates of August, 1971 did not include an amount of Rs. 108.77 lakhs representing the capital outlay on a number of works. It was admitted by the Undertaking as well as by Government that non-inclusion in the project estimates approved in 1968 of the expenditure on commissioning and interest on Government loan was an omission The Committee were assured that Government do not expect any further rise in the estimates beyond what was sanctioned in August, 1971. The Committee are concerned to note that the project estimates in the case of Antibiotics Plant had to be revised a number of times and each time one or the other provision was found to be lacking. The Committee recommend that project estimates should be drawn up realistically and provision made for all essential items so that these estimates have not to be revised so frequently. The Committee also recommend that Government should view with concern any cases wherever the actual expenditure on sub-heads of estimates exceeds the approved estimates by more than 10 per cent so that remedial and other action could be taken in time. **(Para 2.24)**

Reply of Government

This recommendation has been noted for guidance and has also been communicated to the Ministry of Finance.

As far as IDPL is concerned, experience gained so far in the preparation of the project estimates and subsequent amendments etc., arising during the execution will be utilised in drawing up realistic and comprehensive project estimates for schemes proposed to be taken up in future.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dated 22-11-1974].

Further information asked for by the Committee

(a) What action has been taken by the Ministry of Finance in this regard? Please state in detail.

(b) Is there any circular issued by BPE in this regard? If so, please furnish a copy thereof.

(LSS O.M. No. 26-PU/74, dated 21-5-1975)

Further reply of Government*

(a) and (b):

The Ministry of Finance (BPE) have informed that Government views all capital outlay over run exceeding 10 per cent of the sanctioned amount very seriously and that Government fully shares the anxiety expressed by the Committee. No specific instructions in addition to what they have issued already has been considered necessary by them.

[Min. of P & C. O.M. No. 8(25)|74-Ch. III dated 10-8-1975].

Recommendation (Sl. No. 3)

The Committee also find that owing to delay in the completion of the Project the stay of Soviet Experts had to be prolonged. As against the Provision of Rs. 30.20 lakhs in August, 1968 towards the cost of Soviet Experts the actual expenditure upto 31st March, 1972 had been Rs. 62.66 lakhs. The Committee find that the contract did not envisaged sharing of the expenditure by the collaborators in cases where the extension was owing to limitations in the plant and equipment. The contract was also silent as to the Collaborators responsibility for loss of production due to malfunctioning of plant and

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*Not vetted by Audit.

equipment. Government have agreed that "contracts with collaborators should make clear provisions for sharing an expenditure on experts in such circumstances." The Committee recommend that suitable guidelines may be issued in the matter so that such lapses do not occur. In any of the public undertakings. The Committee need hardly stress that agreements with collaborators should be drawn up most carefully so as to safeguard public interest.

(Para 2.25)

Reply of Government*

The Committee on Public Undertakings in its 1st Report (5th Lok Sabha) on Hindustan Steel Limited desired that Government/BPE should undertake a review of all important agreements entered into with consultants/collaborators by public sector enterprises and evolve further guidelines taking into account difficulties experienced in the Past. On the basis of a detailed study made by BPE and the relevant recommendations received from the Public Sector enterprises, a standard check list on foreign consultancy|foreign collaboration agreements has been prepared and issued to the enterprises. A copy of the check list is attached. It is expected that these check lists would adequately met all the shortcomings of such agreements in future.

[Min. of P & C O.M No. 8(25)|74-Ch. III dated 22-11-1974].

Further information asked for by the Committee

The copy of the check list stated to have been attached has not been received with the reply. Please furnish a copy thereof and state whether the points therein are in the best interest of Government.

(LSS O.M. No. 26-PU|74, dated 21-5-1975).

Further Reply of Government*

A copy of the check list is enclosed at Appendix I. The check list was prescribed in November, 1974 and the BPE have indicated that the public enterprises ought to ensure that the various points referred to are properly covered in the contracts and the interest of the Government/Public enterprises is suitably safeguarded. It is expected that the points covered in the check lists are in the best interest of Government.

[Min. of P & C. O.M. No. 8(25)|74-Ch. III dated 10-8-1975].

*Not vetted by Audit.

Recommendation (Sl. No. 5)

The Committee note that the operational experience of Antibiotics Plant, Rishikesh gained during production from May, 1968 onwards had revealed a number of deficiencies in the equipment and system which were subsequently studied by the Soviet Experts who visited the plant from 2nd September, 1969 to 5th October, 1969 with the help of Indian Technologists. As against the original design capacity of the Plant of 290 tonnes or 3,70, 250 mlrds. per annum, the maximum attainable capacity was put by the Soviet side at 3,15,800 mlrds. and by the Indian side at 2,55,000 mlrds, which is 19 per cent less than the capacity assessed by the Soviet Team.

The Committee were informed that the Russian assessment was based on the efficiency and time cycles which had already been achieved in similar plants in the Soviet Union and which were also capable of achievement in India once the technology was mastered. According to the plant however, the capacity as assessed by the Soviet Team could not be attained unless certain essential facilities were provided. The outlay for such facilities was estimated at Rs. 108.77 lakhs. The Committee are unhappy at the derating of the plant's capacity. The Committee hope that with the additional facilities proposed to be provided it would be possible for the plant to achieve the capacity as assessed by the Russian Team. The Committee recommend that a close watch may be kept by Government to see that expenditure on such additional facilities does result in higher utilisation of capacity and stabilisation of production.

(Paragraphs 2.39 and 2.40).

Reply of Government

As recommended by the Committee, close watch will be kept by the Government to see that the additional facilities installed result in achievement of full capacity. It may also be mentioned that with improvements in the yield of new strains of Antibiotics producing Micro Organism and changes made in the technology at different stages of processes, performance of the first quarter of 1974-75 has improved to 38138 mlrds for the quarter while the average annual production during the 2 years was 121782 mlrds.

There is also a marked improvement in the quality of Streptomycin Sulphate where not only the potency of the finished product is improved but the ratio of production conforming to parenteral IP grade to the total production reached 62.3 per cent against 36.3 per

cent of the previous year (1973-74). Constraints faced at present in the utilisation of capacities and stabilisation of production as well as action taken are:

(a) Improvement in the recovery efficiency of Potassium Penicillin is yet to be achieved. Superior types of Extractors have been imported from Germany and USA, German machine has been installed and is on trial. The US machine is yet to be installed.

(b) Further production of Procaine Penicillin (bulk) has been stopped for the present due to—

(i) limited shelf life,

(ii) inadequate market demand for the bulk drug, and

(iii) non-availability of Glass vials for formulation in ABP itself.

(c) Recovery efficiency of Tetracycline has been successfully improved (improvement from 39.2 per cent in 1973-74 to about 55 per cent in 1974-75) by modifying the initial purification process eliminating the use of ion-exchange Resin.

(d) Production of Nystatin is considerably restricted due to inadequate market demand.

It is proposed to use unutilised capacity for the production of Griseofulvin.

[Min. of P&C OM No. 8(25)/74-Ch. III dt. 30-10-74]

Further Information asked for by the Committee

(a) Have the additional facilities been provided, if so, why has the rated capacity as assessed by the Soviet Team not been reached? Please state in detail indicating as to when this capacity is likely to be achieved.

[LSS O.M. No. 26-PU/74 dt. 21-5-75]

Further Reply of Government

Ans.* Most of the additional facilities have been provided. The rated capacity as per Soviet Protocol-1969 (Soviet side) comes to 315000 mlrds. which includes 46500 mlrds of Nystatin. Due to market constrains, production of Nystatin has been nearly stopped and production of Potassium

*Not vetted by Audit.

and proceine penicilline curtailed. The production during 1974-75 was 1,44,562 mlrds which is equivalent to 54 per cent of the rated capacity excluding nystatin. Production during the first quarter of 1975-76 is 52017 mlrds. which is equivalent to about 80 per cent of the rated capacity. With this trend, it is expected that the Plant would be able to achieve more than 80 per cent of its rated capacity without Nystatin during the current financial year. Further steps to introduce better strains and modified technology are being taken to increase the capacity of the plant even beyond 100 per cent.

(b) Has the U.S. machine been installed? If so, with what result?

[LSS O.M. No. 26-PU/74 dated 21-5-1975]

Further Reply of Government

Ans.* The U.S. machine is under installation. This has been delayed since its installation required shifting of some equipment which could not be done during working as areas involved are explosive and no welding work can be undertaken during working.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dated 10-8-1975]

Comments of the Committee

Please see para 24 of Chapter I of the Report.

Recommendation (Sl. No. 7)

2.50. Analysis of production performance of Antibiotics Plant, Rishikesh indicates that except for Streptomycin Sulphate and Oxytetracycline in 1969-70 where the original targets (were revised upwards by 20.1 per cent and 73 per cent respectively) the production targets of rest of the antibiotics during all the years were curtailed drastically in the revised estimates. The Committee find that even those revised targets could not be achieved in all the cases except for Sodium Penicillin, Streptomycin Surphate and Nystatin in 1971-72 and Tetracycline Hcl. in 1968-69 and 1971-72.

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*Not vetted by Audit.

2.51. The main factors responsible for non-attainment of the planned production were stated to be non-attainment of efficiencies compared to reglament norms, technological problems, lack of sterility, clarity and colour; lower potency of streptomycin resulting in heavy rejections; failure of the water supply system in 1970-71 on account of Alaknanda floods and power fluctuations and non-availability of materials of requisite specifications in desired quantities.

2.52. The Borker Committee constituted by Government to study the working of the Antibiotics Plant, Rishikesh has concluded that the major problems of the plant are two fold *viz.* serious shortfalls in all the products and uncommon degree of process and product failure in all stages of production. That Committee also pointed out that the main causes which have operated to the deteriment of the plant in varying degrees have been inadequacy of the equipment of plant design process, assimilation of process technology, lack of proper rapport between management and the workers. Government has assured that once corrective action is taken by the Plant in the light of the recommendations made by the Borker Committee it would be possible to attain the envisaged capacities. The Committee also recommend that as the production in the plant has continued to be far below the installed capacity, thereby affecting not only the economics of the plant but also reducing the indigenous availability of essential antibiotics, Government Management should bend all their energies and see that the plant reaches the installed capacity soon and all impediment in the way of production are removed.

The Committee were informed that the Ministry had accepted all the recommendations made by the Borker Committee except recommendations at Sl. No. 9, 12 and 17 which have been modified. The Committee urge that the recommendations made by the Borker Committee may be implemented and corrective action taken without any further delay in the light of those recommendations. (Paras 2.50 to 2.52).

Reply of Government*

The Project authorities are taking steps to implement the recommendations made by the Technical Committee. A statement showing the recommendations of the Technical Committee and the progress of implementation is attached at Appendix II Government are watching the progress of implementation.

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*Not vetted by Audit.

Recommendation (Sl. No. 8):

The Committee note that in 1972 Antibiotics accounted for 44.5 per cent, 34.4 per cent, 80.8 per cent of the country's licensed capacity for Penicillin Streptomycin and Tetracycline and its derivatives respectively. The actual production of these drugs in the Antibiotics Plant, however, represented 19.8 per cent and 12.8 per cent and 27.1 per cent respectively of the total production in the country during 1972. The comparative study of the peformance of public and private sector for production of these drugs indicates that the share of the Antibiotics Plant in the overall production of these drugs in the country was not commensurate with its share in the overall production capacity. On the other hand the production of producers in the private sector was generally more than their licensed capacity. In this connection the Committee understand that action to be taken firms for exceeding the permissible capacity was under consideration keeping in view the country's demand for these drugs. The Committee find that had Antibiotics Plant achieved the production according to its capacity, in respect of Oxytetracycline, imports in 1969-70 and 1970-71 would not have been necessary and even in 1971-72 the imports of this drugs could have been reduced by one third. The Committee find that during 1972-73 import of products in the production range of IDPL amounted to Rs. 54 lakhs. The Committee recommend that Antibiotics Plant should take concerted measures to achieve installed capacities of its various products in order to avoid dependence on imports to that extent. (Para 2.65).

Reply of Government

Main constraints responsible for non-achieving installed capacity and action taken are as under:

(a) Continuity of services

(b) Labour Management Relations

(c) Improvement in technology

(a) (i) There have been improvements in supply of continuous power by UPSEB during 1974. Steps are being taken to have a minimum size of stand-by generation Unit coupled with Compressor (1.8 MW). Tenders have been called and the matter is under finalisation. A stand by Generation Unit will help the plant in keeping the 'Young' Fermentors going even during power break-down in the supply from UP SEB, thereby reducing losses arising from draining etc.

(ii) It has been our experience that the production gets a set back particularly during high summer and monsoon season. This is mostly due to insufficient refrigeration capacity to condense water vapours in the air which has high humidity during these months. Certain changes have already been made. Use of 8°C chilled water instead of 15°C chilled water used earlier has also been introduced.

(b) *Labour Management Relations* ..

Labour Management Relations have been indifferent during the the recent past. The Personnel Manager of the plant has been transferred and a new officer with Engineering background has been posted. Revised pay scales on the pattern of recommendations made by the Third Pay Commission for Central Government Employees have been introduced.

(c) *Improvement in technology*:

High yielding strains received from Soviet Union have been tried in our laboratory and in our pilot plant. Their introduction in the main plant is in progress.

The High Yielding strains received from Soviet Union though superior to the original strains, will have lower activity as compared to strains available in international market. Efforts are therefore being made to get high yielding strains from different sources.

Raw materials viz. Corn Steep Liquor, Hydro, Soyabean were sent for evaluation. Soyabean was found to have peroxide value and also some toxic impurities which gave poor results. This is under further investigation.

The set up of Research and Development has been rationalised and Research Departments has been specifically asked to improve the strain and Development Department (Pilot Plant) is specifically puruing the application of such strains in industrial exploitation (Also see reply to Recommendation Sl. No. 33).

Basic Chemical Engineering problems like design of the sparger used in fermentation for aeration design of the agitator as well as the rate of agitation will also be studied in the Pilot Plant with a view to improve the biosynthetic activity. This may require 12 to 18 months.

[Min. of P. & C. O.M. No. 8(15)/74-Ch. III dated 30-10-1974].

Further information asked for by the Committee

Please give details of the result of action taken in respect of the constraints mainly responsible for non-achieving the installed capacity, *i.e.*

(a) Continuity of services;
(b) Labour Management relations;
(c) Improvements in technology.

Please give details of improvement, if any, in production of 1973-74 and 1974-75.

[LSS O.M. No. 26-PU/74 dated 21-5-1975]

Reply of Government*

(a) *continuity of services*

Ans.

(i) As a result of several remedial protective measures taken by UPSEB and the IDPL, the continuity of power to the Antibiotics plant has considerably improved over the last one year.

(ii) Continuous supply of 8° chilled has been introduced in all the products for maintaining the precise temperature of fermentation vessels. This has eliminated the problem of temperature variation to a large extent.

(iii) One of the major problems of contamination through air has been brought under control by separatiing the air supply system of all products and installation of additional primary air filters.

(b) *Labour Management Relations*

Labour management relations have been considerably improved in the recent past. Revised scale of pay based on 3rd Pay Commission have been introduced and the plant is functioning smoothly at present.

Q.8 (c) *Improvement in technology*

(i) High yielding strains received from USSR have been fully introduced and the productivity in case of streptomycin sulphate, tetracycline and oxytetracycline has shown significant improvement.

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*Not vetted by Audit.

(ii) Certain modifications in the technology particularly at the stage of purification have been introduced as a result of the efforts put in by the plant technologists/scientists and these have resulted in marked improvement in efficiency.

(iii) in order to bring further improvement in the yield of different antibiotics, negotiations are already in hand for introducing better strains from countries other than USSR.

(iv) Proper arrangements for transport and storage of raw materials like CSL and hydrol have been made in order to avoid deterioration in quality.

(v) Soyabean quality has been improved by getting it processed with better technology.

(vi) Pilot Plant facilities have been augmented for evaluation of raw materials and strains.

Production during 1973-74, 1974-75 and 1st Quarter 1975-76 is given below:—

Production in mmu.

Products	1973-74	1974-75	1975-76 1st qr.
Pottasium Penicillin (Saleable) . .	43·56	15·44	..
Sodium Penicillin	6·29	20·37	9·39
Procaino penicillin	13·50	10·40	3·73
Streptomycin sulphate	30·36	43·65	9·98
Tetracycline	14.65	25·91	19·45
Oxytetracycline	12·16	27·81	9·46
Nystatin .	0·68	0·96	..
	121·20	144·54	52·01

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 10-8-75].

Comments of the Committee

Please see para 24 of Chapter I of the Report

Recommendation (Sl. No. 9)

The Committee find that according to 5th Plan proposals the capacity of the Plant is proposed to be increased by the end of 1978-79, in the case of Penicillin from 105 MMU to 137.2 MMU in the

case of Streptomycin from 85 tonnes to 120 tonnes and in the case of Tetracycline from 22.8 to 95 tonnes. An outlay of Rs. 40 crores has been proposed for inclusion in the 5th Plan. The Committee also find that Government are actually having discussions with the drug manufacturers to examine the possibilities as well as the means as to how the projected requirements of the various antibiotics for the Fifth Plan period could be achieved by the industry. The Committee desire that early decision should be taken by Government in this regard and the target to be achieved by IDPL and other units in the public sector clearly laid down so that concerted measures could be taken to achieve it. The Committee need hardly stress that the progress achieved should be closely monitered to resolves in time difficulties which may be experienced in achieving the targets and to take other timely remedial measures.

The Committee recommend that the target fixed for the 5th Plan for raising the availability of Antibiotics in the country during the plan period should be achieved in full and no efforts should be spared in that direction.

(Para 2.72).

Reply of Government

The recommendation has been noted. Government have published Guidelines for Industries for the year 1973-74 and 1974-75 for the guidance of entrepreneurs which include 'drugs and pharmaceuticals' also. The capacity available for licensing during the Fifth Plan in respect of all industries including antibiotics has been mentioned therein. The applications for Industrial licences as and when received are being considered on merits.

A statement showing the various antibiotics, their approved capacities (licences and letters of intent), Fifth Plan target, gap at present, proposals of the public sector, production and imports during the last two years is attached at Appendix III. It is expected that with the measures taken by Government, the availability of antibiotics apart from other drugs will improve by the end of the Fifth Plan.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dated 30-10-1974].

Recommendation (Sl. No. 10)

The Committee note that as far as Penicillin is concerned, the ratio of batches harvested to inoculators charged has gone up from 0.43 in 1969-70 to 0.61 in 1972-73 and to seed vessels charged from 0.74 to 0.86. In this connection the Committee have, however, found that the Management have not laid down any norms with regard to the numbers of batches harvested to the inoculators/seed vessels charged. The management also do not appear to have

assessed the loss on account of the drained inoculators|seed vessels. It has been stated that the norms could not be laid down "on account of non-stabilisation of technological regime and power feed to the plant." The Committe note that the percentage of batches contaminated to batches harvested has come down from 19.29 in 1969-70 to 15.11 in 1972-73. The Committee recommed that a careful watch should be kept to see that batches which become unfit for harvesting due to contamination are not processed, as harvesting of such contaminated batches affects the recovery efficiency. The Committee were informed that Indian Statistical Institute has carried out some studies for controlling the bio-chemical fermentors and has suggested some rules for harvesting the batches on the basis of activity at definite intervals. The Committee recommend that the rules suggested by the Indian Statistical Institute should be considered after weighing the advantages of the adoption of these rules vis-a-vis use of standard curves for conducting the bio-synthetic activity in fermentation. The Committee further find that average activity and the yield of filtered broth per batch has varied widely from month to month and year to year. Although the activity per u/ml was much higher than protocol norms on a number of occasions (highest activity achieved in February, 1972 being 11,800 u/ml) the Committee find that the average activity was only 6321 u/ml in 1969-70, 6830 u/ml in 1970-71, 7292 u/ml in 1971-72 and 7687 u/ml in 1972-73 respectively which was less than the protocol norm of 8000. Similarly, as against the protocol norm of 258.4 mlrds of filtered broth per batch, the highest achieved was 245.23 mlrds in February, 1972. The Committee fail to understand as to why the higher rate of activity attained in February, 1972 could not be sustained continuously. The Committee recommend that a careful analysis of the constraints in this regard should be made with a view to taking suitable measures. The Committee also find that the fermentation cycle (except in August, 1969) and the total time cycle were also much above the protocol norm. The Plant did not achieve the protocol level of harvesting 830 batches per annum in any of the years, notwithstanding the fact that three additional fermentors had been utilised in 1971-72.

(Para 2.86).

Reply of Government

ISI recommendations related to harvesting of streptomycin batches and not Penicillin. However, the recommendation has been extended to penicillin also and batches are harvested on the standard curves formulated for the fermentation of penicillin for Biosynthesis.

Occasionally, however penicillin batches are required to be harvested before completion of the prescribed fermentation cycle, due to certain abnormalities such as contamination or deterioration of

mycelium due to abnormal temperature and PH or low aeration when the rate of bio-synthesis (increase in activity) declines.

[Min. of P.&C. O.M. No. 8(24)/74-Ch. III dt. 30-10-1974].

Further information asked for by the Committee

Item No. 10(a): Why the higher rate of activity attained in February, 1972 could not be sustained continuously? What is the action taken in this regard?

[LSS O.M. No. 26-PU|74, dt. 21-5-75]

Further reply of Government*

In the month of February, 1972, the average activity in case of Penicillin was 8,370 units|ml, yielding filtered 245|mlrds per batch. Highest activity achieved in one batch reached to 11800 units|ml. No doubt there have been marked variation in the yield of penicillin but the above levels of average activity, highest activity and filtered mlrds. have been achieved in some months other than February, 1972 also as shown below:

Months	Activity u/ml.		Av. filtered mld. per batch
	Highest	Average	
October '71	11,100	7952	231
November '71	11,150	8416	222
Feb. '72	11,800	8370	245
March '72	11,260	7774	220
Sept. '72	11,000	7554	215
March '73	11,600	8085	216
Dec. '73	12,000	8153	244
Nov. '74	13,500	8653	288

Against the protocol norms of 8000 units|ml. activity, the average activity has been varying around 7000 u|ml. Action is being taken to obtain better strains so that this level of activity can be significantly improved upon.

(b) Has any analysis of the constraints in this regard been made and what measures have been taken?

[LSS O.M. No. 26-PU|74, dt. 21-5-75]

*Not vetted by Audit.

Further reply of Government*

The fermentation activity of a strain is net results of interaction of several factors governing complex biochemical processes in the living cells. In such biological processes, variation in yields is a common phenomena in the fermentation industry. However, the average level of activity obtainable generally is the reflection of the potentiality of the strain used and technology followed. The measures of introducing better strains being taken by the IDPL is the best solution of the problem.

[Min. of P.&C. O.M. No. 8(24)/74-Ch. III dt. 10-8-75].

Comments of the Committee

Please see para 24 of Chapter I of the Report.

Recommendation (Sl. No. 11)

The Committee also find that the total time cycle during 1969-70, 1970-71 and 1971-72 was 59712 hours, 94162 hours, and 122636 hours respectively as against the product norm of 109200 hours thus indicating that the fermentators were not utilised to the full extent in 1969-70 and 1970-71. The Committee note that in 1971-72, the plant pressed into service these additional fermentors involving a total utilisation of 17742 hours.

The Committee would like that the Management should go into the causes of non-attainment of protocol norms and take suitable measures to remove the constraints.

(Para 2.87)

Reply of Government

Causes of non-attainment of protocol norms as well as remedial measures initiated are:—

(a) *Low activity of strains*

As already mentioned in reply to Sl. No. 8—para 2.65 of the Report—efforts are in progress to introduce new strains of higher activity in regular production. They are expected to be fully established in regular production by the end of 1974. Progress made in

*Not vetted by Audit.

improving the activity can be seen from the followings:—

Product	Protocol Activity (u/ml)	Average activity U/ml during			
		1971-72	1972-73	1973-74	1974-75 First qtr.
Penicillin	8000	7292	7687	7512	7458
Streptomycin .	5300	4438	4438	4094	4940
Tetracycline	3500	3308	3400	3224	5600
Oxytetracycline .	7800	7436	7071	6996	9519

(b) *Contamination*

Contamination of Fermentors is one of the factors responsible for lowering the production below the protocol level. Necessary steps have been taken in this regard and the levels of contamination are now reduced except in tetracycline as can be seen from the following:—

Product	1971-72	1972-73	1973-74	1974-75
Penicillin .	21·95	15·11	14·66	7·34
Streptomycin .	51·97	48·40	35·14	32·05
Tetracycline	23·18	11·90	5·41	17·00
Oxytetracycline	28.18	31·76	16·67	5·77

(c) *Quality of raw materials like Corn steep liquor.*

One of the factors responsible for variation in the yield is found to be the variation in the quality of the raw materials varying from lot to lot as well as supplier to supplier.

Sources of supply have now been finalised on the basis of past experience and the suppliers advised to control variation in the quality as much as possible. Feasibility of transportation of Corn Steep Liquor by road tanker, to reduce variation of quality from drum to drum is under active consideration.

(d) *Temperature of Fermentation:*

Penicillin, requiring comparatively low temperature fermentation was adversely affected when temperature of chilled water was somewhat high. In order to overcome this problem, temperature of chilled

water has recently been reduced to 8°C and the cooling coils of the fermentors have been modified.

(e) *Recovery efficiency*:

Recovery efficiency gets depressed to some extent when contaminated batches are processed. Further, the performance of Rossia Extractors did not come up to expectation. Measures to arrest contamination have already been initiated. New type, *i.e.* problenisk Extractors have recently been imported which are expected to improve the recovery efficiency as also the capacity of the section. Table below gives the recovery efficiency of different products in the recent past:—

Product	Protocol	1971-72	1972-73	1973-74	1974-75 (1st Qtr.)
Pot. Penicillin	72·40	72·77	58·30	58·30	61·07
Sod. Do.	83·00	65·54	66·38	60·00	58·10
Proc. Do.	86·60	81·21	67·38	81·10	71·60
Strepto Sulphate .	64·50	68·69	64·10	65·80	75·90
Tetracycline Hcl . .	48·00	34·00	35·00	37·40	55·00
Oxytetracycline Hcl.	146·5	31·40	38·00	41·40	45·92

(f) Diagphram valves are being imported to replace globe valves on the sterile product lines.

(g) *Dial Thermometers have been provided as a counter-check on the temperature recording system to avoid possible error due to instruments.

(h) More rigid control has been introduced for checking sterility of the inoculum in the Laboratory.

[Min. of P&C O.M. No. 8(25)/74-Ch.III dated 30-10-74].

Further information asked for by the Committee

The contamination level in the case of Tetracycline in 1974-75 though less than 1971-72 still continues to be higher than 1972-73 and 1973-74. What are the reasons therefor and what is the latest position.

(LSS O.M. No. 26-PU/74, dated 21-5-1975).

*At the time of factual verification Audit pointed out that upto December 1974, the work of providing Dial Thermometers was in progress.

Reply of Government*

The contamination level in case of Tetracycline during 1974-75 came to 24.1 per cent which is comparatively on the higher side. During this year, there was a severe epidemic of contamination during the months of June and July, 1974 in all the products which ultimately resulted in nearly stoppage of the plant. Several actions including separation of air supply system and installation of additional filters were taken and the position subsequently have shown improvement. The contamination level in the case of Tetracycline during the first quarter of 1975-76 in the case of tetracycline fermentation comes only to 6.6 per cent.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dated 10-8-1975].

Comments of the Committee

Please see para 39 of Chapter I of the Report.

Recommendation (Sl. No. 12)

The Committee find that the recovery efficiency from native solution to potassium penicillin as indicated in the protocol is 72.4 per cent. But during 1969-70 to 1973-74 (September, 1973) the recovery efficiency achieved by the plant has ranged between 56.82 per cent to 62.77 per cent. The result of this low yield has been that shortfall in production in terms of value with reference to selling price was Rs. 32.86 lakhs in 1969-70, Rs. 45.44 lakhs in 1970-71, Rs. 54.90 lakhs in 1971-72, Rs. 76.59 lakhs in 1972-73 and Rs. 31.49 lakhs in 1973-74 (upto September, 1973). The Committee have been informed that in order to rectify this situation, the Management have taken certain steps which include rectification of the design defects, installation of two more centrifuges and one vacuum shelf dryer, installation of stainless steel column for the distillation of spend butanol, replacement of Rossia Extractors by Luvesta Extractors. The installation of Luvesta Extractor is likely to improve the efficiency by about 10 per cent. The Committee recommend that efficiency of these measures may be kept under constant review so that the requisite protocol efficiency can be achieved. The Committee would also like to be informed about the utilisation of Rossia Extractors.

(Para 2.93).

Reply of Government

There were nine Rossia Extractors installed in all for extraction of potassium Penicillin in three stages, five for the first butyal acetate extract two at buffer and two for 2nd Butyal acetate extract. Out of

*Not vetted by Audit.

the five extractors at first stage where two Luvesa Extractors have been now installed, one of the Rossia Extractor has been transferred to pilot plant for development work. With the installation of Luvesta Extractors there will be more flexibility in operation and when their performance is stabilised, one or two Rossia Extractors of first stage can be utilised as stand-by equipment for subsequent stages. The surplus Rossia Extractors will also be considered for use in expansion/new products where extraction technology is employed.

The Committee's recommendation about keeping a constant review of the measures taken for the improvement of efficiency has been noted and will be kept in view.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dated 22-11-1974].

Recommendation (Sl. No. 13)

The Committee find that the conversion efficiency from potassium penicillin to sodium and Procaine penicillin as indicated in the protocol was 83 per cent and 86.5 per cent respectively. But during the year 1969-70 to 1973-74 (upto September, 1973) it was possible for the plant to achieve conversion efficiency between 53.36 per cent to 66.38 per cent only. For production of procaine penicillin, efficiency ranged between 67.38 per cent to 81.21 per cent. The value of shortfall with reference to selling price in the case of Sodium Penicillin has been estimated at Rs. 34.67 lakhs in 1969-70, Rs. 45.64 lakhs in 1970-71, Rs. 52.68 lakhs in 1971-72, Rs. 49.48 lakhs in 1972-73 and Rs. 1.72 lakhs in 1973-74 (upto September, 1973). In the case of Procaine Penicillin lower conversion efficiency as compared with protocols norm has resulted in shortfall in production to the extent of Rs. 22.03 lakhs in 1969-70, Rs. 22.36 lakhs in 1970-71, Rs. 9.26 lakhs in 1971-72, Rs. 13.44 lakhs in 1972-73 and Rs. 0.40 lakhs in 1973-74 (upto September, 1973). The Committee find that shortfall in production was more pronounced in the case of Sodium Penicillin. In this connection, the Borker Committee observed that "sterility areas where both Sodium Penicillin and Potassium Penicillin were made earlier were too vast and equipment used was rather cumbersome for sterile operations. The new areas and the new processes were commissioned in August-September, 1973.

The Committee note that although substantial loss of production was taking place right from the beginning on account of low conversion efficiency, the Management did not take prompt action to locate the reasons and remedy them. The Committee recommend that Government should find out the reasons for not taking prompt

action. The Committee would like to be informed about the effect of new areas and new processes on the recovery efficiency of Potassium, Sodium and Procaine Penicillin.

(Paras 2.110—2.111).

Reply of Government

The Sodium Penicillin section was commissioned in May, 1968, but there was serious problem of clarity due to the equipment getting rusted and shedding particles during process. As this was imported equipment, the Soviet party was informed. They sent their expert free of charge in June|July, 1969. These experts carried out grinding and polishing of stainless steel equipment in both Sodium and Procaine Penicillin sections. After this was over, the section was restarted in December, 1969. Then the quality of Sodium Penicillin in respect of clarity improved. However, during accelerated testing carried out in Quality Control it was observed that the product is not having the specified shelf life. It was considered that this powder if properly packed in glass vials and butyl rubber stoppers are used instead of natural rubber stoppers, the keeping quality will be better. This practice was, therefore, adopted. Though there was improvement in life still the shelf life was just marginal. It was, therefore, necessary to improve upon the technology, so that product of still better quality could be made. As the proposed method of Azeotropic distillation was known to give lower recovery efficiency (though of better quality), it was necessary to wait till it was finally established that precipitation process had to be changed by looking to the results from the depots and market. This will normally take 2 to 2½ years, as the shelf life of the product is 2 years, and the results of the material sent in the market would be known only at the end of the period. Therefore, after restarting the Sodium Penicillin Section in December, 1969, it was concluded by middle of 1972 that the quality is not very satisfactory and should be improved further. It was then decided to modify the Section to improve the quality. After modifications the plant is getting conversion efficiency of about 60 to 65 per cent against the expected efficiency of 66 per cent of the one lines.

Procaine Penicillin : The section was commissioned in May, 1968 but there were problems of the product not passing due to (a) Non-sterility, (b) Clarify and colour and (c) consistancy and Syringeability tests. As mentioned earlier, the clarify problem was tackled by the Soviet Experts who came to polish the equipment. The consistency problem was also solved by modification of the equipment by changing the design and speed of agitator of the

reaction vessel in April-August, 1970. Sterility has been further improved by installing gas sterilisation unit in September, 1971. The non-sterility problem was also tackled by reducing the large sterile areas by shifting some of equipments to other rooms so that the area was made more compact in July-August, 1973. Thereafter the production was started and is under stabilisation to achieve the protocol production. Process of stabilisation is likely to take long due to inadequate demand for procaine penicillin.

In view of reasons given above, no further action by Government is considered necessary.

Effective steps taken for improving recovery efficiency of Penicillin are as follows:

Potassium Penicillin: (i) Higher efficiency machine like Westphalia extractors and Podblenik-extractors have been procured and the former have been installed and are under stabilisation. Latter will be installed shortly.

(ii) Arrangements for cooling of butyl acetate sulphuric acid and native solution to the required parameter as stipulated in the reglament have been made and now temperatures of these are being maintained close to the reglament limits.

(iii) Regeneration of butanol has been stream-lined and 100 per cent pure butanol is being obtained for use in washing of potassium penicillin cake.

(iv) For maintaining proper pH during extraction the pH meters, and controllers have been installed but their commission is held up due to non-availability of a special type of cable which is being imported. In addition to the above, the maintenance of Rossia extractors has been made more effective.

Sodium Penicillin: As stated above in reply to para 2.110, the recovery efficiency with the modified process is not expected to exceed 66 per cent. This is also confirmed by the experiment which is carried out in the laboratory. IDPL are already getting recovery efficiency of 60-65 per cent and with stabilisation of the process, the required efficiency as mentioned will be achieved.

Procaine Penicillin: The reglament provides 86.5 per cent efficiency but in the technology given by the Soviet Union the process of micronization is not provided. However, to have procaine penicillin of the required micron size which should pass syringeability

tests, it is found found necessary to install micronization unit which gives 3-4 per cent losses. IDPL are already getting about 80-81 per cent efficiency with micronization and may be considering as having achieved efficiency level stated in the protocol taking account of the losses in micronization.

[Min. of P. & C. O.M. No. 8(25)/74-CHIII, dated 22-11-1974]

Recommendation (Sl. No. 14)

The Committee find that in the case of streptomycin sulphate, the ratio of batches harvested to the inoculators charged ranged between 0.34 to 0.41 during the period 1969-70 to 1973-74 (upto September, 1973) and to seed vessel charged 0.75 to 0.78. The management have not laid down any norm as to the number of batches harvested to the inoculators|seed vessels charged nor have they assessed the losses on account of the draining of inoculators| seed vessels. The Committee also find that the percentage of contaminated batches to batches harvested ranged between 35.67 to 51.97 during 1969-70 to 1973-74 (upto September. 1973). According to the Management the probable reasons for contamination of batches were, draw-backs during defective charging or undetected contamination passed from seed vessels, defective oil system, not holding of valves in the running cycle. It would thus appear that the contamination of batches was due to operational factors and was thus largely controllable. In view of this it is not clear to the Committee as to why concerted and determined measures could not be taken by the Plant Management earlier to set right the deficiencies which continued to affect adversely the operations year after year. The Committee recommend that necessary corrective measures should be taken without further delay so as to minimise, if not eliminate, the percentage of contaminated batches.

(Para 2.137)

Reply of Government

The position of contamination of batches has already been mentioned in Reply to Sl. No. 11—Para 2.87.

(a) The following corrective measures have been taken to minimise contamination in fermentation batches. Air filtered system along with primary air filters have been separated for each product to facilitate better control according to the requirements of the product.

(b) Modifications of dehumidification system of air has been done by providing secondary cooler of bigger capacity. One of the entrainment separators has been modified on the principle of cyc-

lone separator. Results obtained so far indicate that the moisture removal has improved.

The schedules of packing and unpacking of primary air filters, number of sterilisation of primary air filters, check on air sterility, etc. have been made more rigid to avoid failure of filters.

(c) Weekly schedules of hydraulic checking and rectification of transfer line have been introduced to take care of leakages in sterile system.

(d) Air lines in streptomycin have been steam jecketed to avoid condensate in the air supply line.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dated 30-10-1974].

Further information asked for by the Committee

Have the corrective measures taken to minimise the contamination in fermentation batches, yielded any results so far? If so, please state in detail.

[LSS O.M. No. 26-PU/74 dated 21-5-1975]

Further reply of Government*

The corrective measures taken to reduce the contamination level in the fermentation batches in sctreptomycin have yielded marginal advantages. The average contamination in the fermentor during the first quarter of 1975-76 has come down to 25 per cent as against 51.97 per cent, 48.4 per cent, 35.14 per cent, and 34.4 per cent during 1971-72, 1972-73, 1973-74 and 1974-75 and 33.3 per cent during the first quarter of 1974-75.

There was a serious epidemic of contamination in all products including streptomycin during June and July, 1974.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III, dated 10-8-1975].

Comments of the Committee

Please see para 39 of Chapter I of the Report.

Recommendation (Sl. No. 15)

The overall yield of filtration per batch was, 115.70 mlrds in 1969-70, 140.13 mlrds in 1970-71 and 118.53 mlrds in 1971-72 and 116 mlrds in 1972-73. The Committee also find that as against the protocol norms of 162 mlrds of filtered broth per batch, the highest achieved

*Not vetted by Audit.

was 191.42 mlrds in June, 1970. The Committee have been informed that "low yield is mainly due to unstable power feed to the plant and wide variation in the quality of raw material."

The Committee also note that the total time cycle was much higher than the protocol norm. In this connection, the Committee were informed by the Government that "low utilisation of production fermentator has been due to charging of less number of batches to avoid the problems of bunching which cause conjunction in filtration. Judged from the available data the Committee find that as against the protocol norm of 85 per cent, the filtration efficiency achieved was only 78.19 per cent in 1969-70, 80.91 per cent in 1970-71 and 77.49 per cent in 1971-72.

The Committee note that a new strain No. 773 introduced in February, 1970 to improve the yield in fermentation was discontinued from August|September, 1970 as it was suspected to be leading to low potency. It was again introduced in January-February, 1972 as no correlation could be established between the fall of potency and use of this strain. The Committee are not sure whether the huge rejections were not as a result of the use of the new strain. The Committee would like Government|IDPL to go into this aspect in consultation with HAL., Pimpri, so as to take suitable measures to ensure that the biological potency of the finished product is maintained and the rejections are reduced to the minimum.

(Paras 2.138—2.140).

Reply of Government

(i) Figures relating to rejection of Streptomycin Sulphate due to low potency batches are given below:—

Year	No. of batches	No. of batches rejected due to low potency	Percentage of rejection
1971-72	485	25	5·15
1972-73	367	21	5·72
1973-74	453	4	0·88
1974-75 (Ist Qr.)	85		0·0

The problem of rejection due to low potency has now been controlled.

(ii) Average biological potency of Streptomycin Sulphate improved to 718 u|mg. and 725 u|mg during 1972-73 and 1973-74 respectively.

Average potency during the first quarter of 1974-75 is 731 u|mg. registering a further improvement.

It will be noticed that there is improvement in potency as well as reduction of rejections. It is thus clear that the earlier rejections due to low potency were not due to the new strain (No. 773).

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dated 30-10-1974].

Recommendation (S. No. 18)

The problem of rejection due to low potency has now been consumption of raw material during 1972-73 over the reglament norms there have been loss of Rs. 54.67 lakhs, the Committee would like that the Recommendations made by the Technical Committee in this regard may be taken into account and suitable remedial measure introduced to ensure strict adherence to the prescribed norms as any excess consumption would only affect the profitability.

(Para 2.226)

Reply of Government

The Government have looked into the remedial measure adopted by IDPL to ensure adherence to the prescribed norms regarding excess consumption of raw materials *vis-a-vis* the reglament norms. The management of IDPL reports that the quality and consumption efficiency of raw materials is reviewed in weekly and monthly meetings taken by the General Manager of the Plant with the concerned heads of departments. The remedial measures are decided upon during the course of the meeting itself and a report submitted to the headquarters of the Company at New Delhi. The recommendations made by the Technical Committee have also been taken into account by the Plant. The consumption for major raw materials for various antibiotics is given in the Appendix IV. It will be observed that there is substantial reduction in consumption of almost all major raw materials during April—October, 1974 compared to 1973-1974. The improvement has been the result of higher strain activity and better overall recovery yields.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III, dated 10-2-1975].

Recommendation (S. No. 19)

The Committee note that for meeting the requirements of compressed air, the collaborators had supplied three Turbo Compressors (including one as stand-by) each having a compressing capacity of 970 M3 per minute in April, 1972, the Management, however, assessed

that the total demand of compressed air would be 1200 M3 per minute only. As the second Compressor was required to be operated to meet the requirement of compressed air as and when needed, it resulted in venting of surplus quantity of compressed air which was about 75 per cent of the production of the second compressor. The plant therefore contemplated the procurement of a compressor of smaller capacity. Meanwhile venting of compressed air has continued. The Committee find that percentage of air vented to compressed air produced was to the tune of 40.97 per cent in 1972-73. The venting of air in 1972-73 cost the plant Rs. 27.84 lakhs (excluding depreciation and interest). The Committee have been informed that the original proposal of installing a compressor of smaller capacity is being studied by the Management afresh because it is now expected that the expansion plans of the plant specially for tetracycline and streptomycin would enable utilisation of substantial percentage of air vented. The Committee recommend that a decision to instal a compressor of smaller capacity should be taken soon considering the requirements of the expansion plans so that venting of compressed air at a considerable cost may be avoided. (Para 2.233).

Recommendation (Sl. No. 20)

The Committee find that there was excessive consumption of electricity in the production of compressed air over and above the norm fixed by the Management. In all the years from 1970-71 onwards as against the norm of 62.3 KWH fixed by the Management per 10^3M^3 (of compressed air has been of the order of 64.98, KWH, 70.63 KWH, 63.1 KWH and 68.6 KWH during the years 1970-71, 1971-72, 1972-73 and 1973-74 (upto September, 1973) respectively. The cost of excessive consumption of electricity ranged between Rs. 0.68 lakhs in 1972-73 to Rs. 6.50 lakhs in 1971-72. The Committee were informed that the main reasons for excessive consumption of electricity have been variation of the power factor of the load, different load conditions, variation in supply voltage which varies the current and power losses; running of the motor at the maximum excitation. It has been stated that losses due to the running of the compressor below its full load rating according to the requirement of the production department cannot be avoided. In order to meet this situation the plant, it was stated, was considering installation of smaller compressor run on diesel generators with the twin objective of maintaining positive pressure during power failures and avoiding venting of excess air during the normal operation. As recommended earlier, the Committee desire the Management to take an early decision in the matter for installation of Compressor of smaller capacity in the best interest of the smooth and economic running of the plant. (Para 2.238).

Reply of Government

Two big Air Compressors, originally provided, generate compressed air in excess of requirements which is therefore vented at present.

It has now been decided to instal small oil free reciprocating compressors which with the existing one big compressor will meet the total requirement of all the 44 Fermentors. This will lead to economy in power consumption and stop venting of compressed air. Installation of smaller compressors would also help in minimising air starvation to the running fermentors when they will be switched on immediately after resumption of power, after a breakdown, without waiting for clearance from the UPSEB. The other existing big air Compressors will still be required as stand-by and to take care of capital maintenance (six weeks maintenance period of each compressor in a year) and when the small compressors are under capital maintenance.

[Min. of P.&C. O.M. No. 8(25)/74-Ch. III dated 30-10-1974].

Recommendation (Sl. No. 22)

The Committee note that according to the design, 30 per cent of the steam condensate should return to the boilers. However, the condensate return was found to be not more than 5 to 6 per cent resulting in the increased use of steam for internal consumption to the extent of about 20 per cent of internal load. The Committee find that the excessive consumption of steam cost Rs. 11.91 lakhs during the period of 1968-69 to 1973-74 (upto September, 1973). The Committee understand that the question of low condensate return was studied by the Chief Soviet Expert in October, 1969 but no success was stated to have been achieved.

The Committee recommend that best expert advice in the field should be taken so as to improve the condensate return thereby avoiding the extra cost.

(Paras 2.253 and 2.254)

Reply of Government

The studies conducted at the plant indicate that hardly 10 per cent of condensate against the quantity of steam supplied could be considered fit for use in the Boiler House, whereas the rest gets heavily contaminated with media, etc. and processing of this condensate for chemical purification is not considered safe for use in the Boiler House.

The problem has also been examined by IDPL in the light of practice followed by Hindustan Antibiotics Limited, Pimpri. They have no integrated system for the return of the condensate to the Boiler house in the manufacture of Penicillin. However, such a system exists in the manufacture of Streptomycin, but they have no precise measurement to find out the actual percentage of condensate returned to the control system. The condensate from the fermentation vessels which is likely to be contaminated with the broth is, however, not returned by HAL to the central system, nor have they evolved any method to purify the condensate for use in the chemical purification plant. The IDPL are being asked to study the problem further in consultation with Indian and foreign experts to examine the feasibility of decontaminating the steam condensate.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III, dated 8-11-1974].

Further information asked for by the Committee

It is stated that IDPL are being asked to study the problem further in consultation with Indian and Foreign experts to examine the feasibility of decontaminating the steam condensate. Please state:

(a) When was IDPL asked to do so? Please furnish a copy of the letter, etc., issued in this regard.

(b) What has been the outcome of the study? Please give details.

[LSS O.M. No. 26-PU|74 dt. 21-5-75]

Further Reply of Government*

The IDPL was advised, during the discussions on the action taken on the recommendations of the COPU, to study the problems further with a view to improve the steam condensate return. They have also since initiated action. This has been followed up by a letter to the Managing Director, Indian Drugs and Pharmaceuticals Limited, a copy of which is attached at Appendix V.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III, dated 10-8-1975].

Comments of the Committee

Please see para 46 of Chapter I of the Report.

Recommendation (Sl. No. 24)

The Committee find that out of total rated production of 290 tonnes of Antibiotics Plant, Rishikesh, a quantity of 165 tonnes was

*Not vetted by Audit.

to be in the form of ready made drugs and the remaining 125 tonnes in the bulk form. In October-November, 1970 the Committee were informed by the Ministry that as against the rated capacity of 218 tonnes based on the efficiency levels indicated by the Soviet Team in 1969, existing formulation capacity was only 115 tonnes. (80 tonnes for vialling, 25 tonnes for capsulation and 10 tonnes for tabletting). The Committee find that the quantity formulated by IDPL has been less than even the reduced capacity of 115 tonnes, the quantity actually formulated being only 19.23 metric tonnes in 1969-70, 40.03 metric tonnes in 1970-71, 71.20 metric tonnes in 1971-72, 55.29 metric tonnes in 1972-73, 22.02 metric tonnes in 1973-74 (upto September, 1973). The main reasons for the set back to the formulation programme of IDPL have been the non-availability of packing material like glass vials, stoppers and empty gelatine capsules, non-utilisation of machine capacity because of inadequacy of spare parts. In order to raise the utilisation of formulation capacity the plant is stated to have taken measures to have a glass vials factory as an ancillary industry at Rishikesh. The Plant has also developed some indigenous sources of supply of packing materials and spare parts.

The Committee fail to understand why preventive measures were not taken well in advance to develop the manufacture of glass vials and gelatine capsules to match the manufacturing capacity of the Plant. The Committee would like to be informed within six months the concrete action taken by the Government/IDPL to make good this deficiency.

(Paras 2.269 & 2.270)

Reply of Government*

Supply of vials: The requirement of vials as per the rated capacity of the Antibiotics Plant is 150 millions p.a. or 5 lakhs per day.

M/s. JG Glass Industries Private Limited, Poona have set up a unit near the Rishikesh plant as an ancillary industry and their production capacity is sufficient to meet the full requirements of the plant. Unfortunately, they having teething difficulties at present and only two of their three machines are working. The third machine is expected to start working when additional power is supplied by the U.P. State Electricity Board shortly as promised by them. M/s. JG Glass Industries are also having raw material problems but both the requirements of power as well as raw materials are being attended to.

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*Not vetted by Audit.

The quality of the glass vials also is not yet of adequate standard and out of 4.201 million supplies in August, 1974, 2.813 millions were rejected on technical grounds thereby making available only 1388 million vials against the monthly requirement of about 7 million vials from the Rishikesh plant of the JG Glass Works. In addition 3 million glass vials are to be supplied from their Poona factory but during August, 1974 they despatched only 1.67 million vials and the balance is expected to be supplied during September, 1974. Government have also requested other glass vial manufacturers to supply the requirements of this unit. It is expected that when the production of the JG Glass Industries Factory at Rishikesh stabilises there will be no difficulty in the matter. Government are also separately considering setting up of a vials unit by Hindustan Antibiotics Limited.

Supply of Empty Gelatine Capsules: The requirement of capsules as per the capacity of the plant is 120 million per annum or 4 lakh capsules per day. Earlier, IDPL proposed to set up a 200 million plant and a letter of intent was also issued but this could not be utilised in the absence of technical knowhow. The Indian Drugs and Pharmaceuticals Limited have however again started considering also having a plant of their own and discussions with M/s. Cherry Burral Corporation are in progress.

Government have however issued letters of intent and Industrial licence for a total capacity of 1400 m. nos. in the private sector. One of the units licenced is pharmaceutical capsules laboratories limited who have a total licenced capacity of 450m million Nos. Indian Drugs and Pharmaceuticals limited is obtaining their requirements regularly for the past six months from this unit and no difficulty in obtaining their requirements is anticipated.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dated 30-10-1974].

Further information asked for by the Committee

It has been stated that IDPL have however again, started considering having a plant of their own (for gelatine capsules) and discussions with M/s. Cherry Burrel Corporation are in progress. Please state the latest position in this regard, in detail and when the said plant is likely to be set up and start for production?

[LSS O.M. No. 26-PU/74 dated 21-5-1975]

Further Reply of Government*

M|s. Cherry Burrel Corporation have submitted quotations for the machinery for manufacturing Gelatine Capsules to IDPL. IDPL

*Not vetted by Audit.

had further negotiations with the representatives of the company and have been asked for to prepare a Feasibility Report for the manufacture of 400 million Nos. per annum of Gelatine Capsules. Apart from quotations received from the Cherry Burrel Corporation IDPL have obtained quotations from R and J machine and Engineering Corporation Limited of Canada. They have also invited quotations from other parties.

Comments of the Committee

Please see paras 56 and 57 of Chapter I of the Report.

Recommendation (Sl. No. 25)

The Committee find that the demand for various formulations which was of the order of Rs. 300 crores by the end of 1973-74 is likely to go up to Rs. 500 crores by the end of Fifth Five Year Plan *i.e.* 1978-79. The present formulation share of public sector is stated to be about 5.6 per cent (IDPL accounting for a production of Rs. 11.5 crores and Hindustan Antibiotics Ltd. approximately Rs. 5 crores). By the end of 1978-79 the formulation capacity of the public sector is likely to be raised to Rs. 31.5 crores (Rs. 22 crores for IDPL and Rs. 9.5 crores for Hindustan Antibiotics Ltd.) As a result the share of Public Sector would increase to 6.4 per cent by 1978-79. Government have denied that the capacity in public sector was being deliberately kept low to enable the private sector formulators to utilise their formulated capacity. They have however, admitted that idle formulation capacity in Antibiotics Plant is largely due to the market constraint except in the case of Penicillin and Streptomycin where capacity to a large extent could have been utilised had more bulk drug been available. It has been stated by Government that "IDPL has also to play its role in developing the drug industry as a whole in the country and particularly in the small scale sectors". This, it has been stated, "is a social objective, for which the price has to be paid by way of lesser formulations by IDPL". The Committee have been assured by Government that since formulations is a profitable activity the idea is that the IDPL should increase the quantity of its formulation so as to utilise 50 per cent or more of the bulk drugs produced by it. As a matter of fact, since the last few years, Government are stated to be insisting on all drug companies in the organised sector to make available portion of the bulk drug produced to non-associated formulators. It has also been stated that IDPL is now being permitted not only to import the concerned bulk drug for its formulations but is also being allowed to take up formula-

tions not based on bulk drugs produced by it, for example, Chloramphenicol. The Government have claimed that these measures would gradually lead to full utilisation of formulation capacity by IDPL.

The Committee would like Government|Undertaking to remove the various constraints and draw up a time bound programme to put to full use its formulation capacity in the interest of meeting the demand of public for drugs in common use and to improving its financial position. The Committee would like to be informed of the action taken by Government in pursuance of this recommendation.

(Para No. 2.271)

Reply of Government*

The recommendations of the Committee have been noted for guidance and compliance. It is always the endeavour of the Company and the Government to maximise the production with a view to improve the profitability of the plant. This, however, is subject to the availability of bulk drug production in the plants and its obligation to supply certain portion to other formulators. The Antibiotics Plant has planned expansion of encapsulation capacity by another 144 million numbers. Necessary modifications and procurement of filling equipment is in progress.

It may also be added that during the Fifth Plan IDPL propose to expand drug production as follows:—

Expansion of the Synthetic Drugs Plant	.	38 Drugs-Expansion from 1989 tonnes to 3507 tonnes
New plant for the manufacture of Niacinamide	. . . . .	300 tonnes
Expansion of Antibiotics Plant, Rishikesh	.	Streptemycin from 85 to 120 tonnes
		Tetracycline from 25 to 95 tonnes
		Ampicillin 10 T
		Doxycyline 5 T
New Formulation unit	. . .	Tablets 1500 million Vials and Capsules 50 million Syrup 1 lakh litres Ointment 1 KL

It will be seen from the above that production of formulations is proposed in a big way during the Fifth Plan.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III, dated 4-12-74].

*Not vetted by Audit.

Recommendation (S. No. 27)

The Committee note that the rejections in the case of Sodium Penicillin, Procaine Penicillin and Streptomycin were much higher than the norms and ranged between 10 per cent to 57 per cent of the total production and the total increase in cost due to rejections pertaining to these three drugs amounted to Rs. 5.18 crores from 1968-69 to 1971-72. The Committee have also gone through the reasons put forward by the Management for such high rejections and feel that these reasons are not such as cannot be remedied. The Committee urge that remedial measures must be taken without delay to reduce if not eliminate the rejections and thus avoid waste.

The Committee would like to draw pointed attention to the reported poor quality of raw materials. The Committee stress that steps should be taken to see that raw materials requisite quality become available.

(Para 2.299)

Reply of Government*

Figures relating to gross production and incidence of rejects are:

Year	Approved Prodn. Mlrds.	Rejects Mlrds.	Rejects as percentage of Prodn.	Total increase in cost	Incidence of rejects on cost per Mlrds.
		SODIUM PENICILLIN			
71-72	35276·550	4286·610	10·83	14,45,633	40·98
72-73	18315·268	5237·386	22·24	24,99,113	136·45
73-74	5835·35	2899·25	33·19	13,24,145	456·72
		PROCAINE PENICILLIN			
71-72	19751·450	8672·250	30·51	25,61,565	129·69
72-73	6817·426	2657·87	28·05	14,34,446	225.08
73-74	13206·76	1537·42	10·43	521,,967	39·50
		STREPTOMYCIN SULPHATE			
71-72	21704·920	12164·550	35·92	65,16,568	300·23
72-73	†26497·388	3367·80	11·28	16,21,110	16·18
73-74	*30362·92	589·72	1·90	5,885	9·98

*Not vetted by Audit.

†Streptomycin Sulphate—Non-parenteral IP production is included the approval of production as the same is being marketed.

The rejections in the case of Penicillin are high but modifications have been made to Penicillin Section in order to improve performance. Stabilisation of Penicillin productin after modifications is in progress and this is expected to improve the performance of the plant.

The following steps have been taken for ensuring availability of quality raw materials. The specifications for all the raw materials used for production have been finalised by Quality Control Deptt. on the basis of information given by Soviet Collaborators and in consultation with the consumer blocks. The raw materials used in production are tested in quality Control Department according to the Prescribed specification and only those lots which conform to the prescribed specifications are released for consumption. In addition to Quality Control testing, biologial testing of the agricultural products etc. is carried out in the Process Control Laboratories of the blocks and these tests are given due consideration at the time of release of the lots of raw materials. These steps ensure that only good quality of raw materials are used for production. As a long term measure, prospective suppliers have been given specifications of the requirements of raw materials to enable them to meet th specifications.

Figures relating to gross production and incidence of rejects are:

Year	Approved prodn. Mlrds.	Rejects Mlrds.	Rejects as percentage of Prodn.	Total increase in cost	Incidence of rejects on cost per Mlrds.
		SODIUM PENICILLIN			
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72-73	6817·426	2657·87	28·05	14,34,466	225·08
73-74	13286·76	1537·42	10·43	5,21,667	39·50
		STREPTOMYCIN SULPHATE			
71-72	21704·920	12164·550	35·92	[65,16,568	300·23
72-73	*26497·388	3367·80	11·28	[16,21,110	61·18
73-74	*30362·92	589·72	1·90	[5,885	9·98

*Streptomycin Sulphate—Non-Parenteral IP production is included in the approved production as the same is being marketed.

The rejections in the case of Penicillin are high but modifications have been made to Penicillin Section in order to improve performance. Stabilisation of Penicillin production after modifications is in progress and this expected to improve the performance of the Plant.

[Min. of P & C.O.M. No. 8(25)/74-Ch. III dt. 27-1-75]

Further information called for by the Committee

Please furnish similar information for 1974-75.

[LSS O. M. No. 26-PU/74, dt. 21-5-75]

Answer

The information pertaining to the year 1974-75 is given below:—

Product	Approved production (Mlrds.)	Rejects (Mlrds.)	Rejects as %of prodn.	Total increase in cost	Incidence of reject on cost per (Mlrd.)
Sod. Penicillin	20379	8750	30·0		To profitability of 1974-75 is under preparation
Proc. Penicillin	10402	5777	35·7		
Streptomycin	43644	1770	3·9		

[Min. of P & C O.M. No. 8(25)/74-Ch.III, dt. 10-8-75]

Comments of the Committee

Please see para 68 of Chapter I of the Report.

Recommendation (Sl. No. 28)

The Committee deprecate that apart from rejections of antibiotics in the course of production detected by the Quality Control, bulk antibiotics and formulations worth Rs. 8.82 lakhs and Rs. 1.06 lakhs respectively passed by the Quality Control were returned by the customers. The Committee would like this matter to be investigated thoroughly and all the requisite measures taken to strengthen Quality Control so that such flaws do not recur.

(Para 2.300)

Reply of Government

The Quality Control Department of the plant is equipped to carry out all tests on the finished products prescribed by Indian Pharmacopoeia. The finished products are released for sale only after satisfying the standards prescribed in the Indian Pharmacopoeia.

However, some deterioration in the quality of the product takes place in transit or under improper storage conditions of the purchaser etc.

A statement is enclosed at Appendix VI indicating value of sales returns of bulk and formulations for 3 years. It will be seen that the value of sales return is on the decline.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 30-10-1974]

Further information asked for by the Committee

(a) In the case of formulations the value of sales return in 1972-73 is Rs. 3.5 lakhs against 10,645 in 1971-72. Why?

(b) Losses due to re-processing of bulks in 1972-73 is increasing from 20 per cent to 25 per cent. In the case of formulations the loss due to reprocessing in 1972-73 is 66 per cent. Does this not indicate poor quality control or greater defects Please state in detail.

[LSS O.M. No. 26-PU/74, dt. 21-5-75]

Further reply of Government

(a) The sale return of 3.5 lakhs during 1972-73 pertains only to one product *i.e.* fortified penicillin where about 7.7 lakhs vials were withdrawn from the market due to problem of instability in one of the components *i.e.* Sodium Penicillin. As a matter of fact, the quality of sodium penicillin that was being produced in ABP as per the original Soviet technology was not upto the mark particularly in respect of its shelf life. Subsequently, in consultation with our Soviet collaborators, the technology of Sodium Penicillin was modified to a process involving azsotropic distillation. This involved major modifications in the Section and ever since this section with modified technology has been commissioned the problem of shelf life in this product has been overcome.

(b) The losses as a result of re-processing in formulations compared to bulk are bound to be high as the salvages from the vials and separation of different components of the formulated products involve several steps resulting into greater losses. The losses due to reprocessing both in case of bulk and formulations are significantly more due to the improper quality of sodium pencillin.

In view of the facts stated above in respect of poor quality of shelf life of sodium penicillin, the sale returns does not reflect on the working of the quality control.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 10-8-1975]

*Not vetted by Audit.

Comments of the Committee

Please see para 75 of Chapter I of the Report.

Recommendation (Sl. No. 29)

The Committee note that rejections not only arise in bulk production stage but also occur in the course of formulating and filling into vials. The Committee find that total increase in the cost of rejections during 1969-70 to 1971-72 after taking into account salvaged value of rejections viz. Rs. 4.52 lakhs in 1969-70, Rs. 5.59 lakhs in 1970-71 and Rs. 12.59 lakhs in 1971-72 amounted to Rs. 87.27 lakhs, Rs. 69.43 lakhs and Rs. 60.85 lakhs respectively. The Management have attributed these rejections to high bacterial count in sterile area, improper sterilisation temperature in the tunnel, non-availbility of suitable spare parts for the automatic filling machines, shredding of rubber particles by rubber stoppers. It has been claimed that the steps taken by the Management like modification of air-conditioned system and strict check at the intermediate stages of the precessing Streptomycin has significantly, reduced the rejection of filled vials.

The Committee would like the progress to be maintained in this regard and the position intimated to the Committee in due course, based on the results of operation for the full year *i.e.* 1973-74.

(Para 2.301)

Reply of Government*

Increase in cost on account of rejection in 34F Block for the year 1973-74 amounts to Rs. 21.79 lakhs as against Rs. 87.27 lakhs in 1969-70, Rs. 69.43 lakhs in 1970-71 and Rs. 60.85 lakhs in 1971-72 after taking into account the salvaged value of rejection *i.e.* Rs. 4.52 lakhs in 1969-70, Rs. 5.59 lakhs in 1970-71, Rs. 12.59 lakhs in 1971-72 and Rs. 3.61 lakhs in 1972-73 respectively which shows improvements over the previous years.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 10-2-75]

Recommendation (Sl. No. 30)

The Committee note that the Management had fixed parametres for filling up the capsules in April, 1969 and January, 1971 at 5 per cent for "over age and moisture" in the case of tetracycline and 7.8 per cent in the case of Oxytetracycline. The Committee find that the excess consumption of bulk over the norms ranged from 4 per

*Not vetted by Audit.

cent to 15 per cent in the case of Tetracycline and between 14 per cent and 19 per cent in 1972-73, in the case of Oxytetracycline. In 1972-73 the excess consumption over the norms however came down to 2.01 per cent in the case of Tetracycline and 3.96 per cent in the case of Oxytetracycline. Although the excess consumption has come down in 1972-73 as compared to the previous years, it is still more than the norms and that of the private firm to whom the contract was given by the Company for capsulation. The Committee, therefore, recommend that vigilance should continue to be exercised to see that consumption of bulk in filling of capsules does not go beyond the norm. The Committee further recommend that the norm itself should be reviewed in the light of experience gained so as to bring the level of rejection even lower.

(Para 2.302)

Reply of Government*

Figures relating to the standard consumption co-efficient *vis-a-vis* actual consumption of the bulk drug are given below:—

Drug	Standard consumption co-efficient	Actual consumption	%age of excess
Tetracycline	250	256·50	2·6%
Oxytetracycline	260	279·90	7·96%
Chlorophenicol	250	257·50	7%
Chlorostrep	330	366·60	11·1%

The percentage of excess consumption of the bulk during the first quarter of 1974-75 is given below :—

	April	May	June
(a) Tetracycline	1·26	1·20	1·00
(b) Oxytetracycline bulk	1·35	1·34	1·24
(c) Chloramphenicol bulk	1·46	1·40	1·30
(d) Chlorostrep bulk	1·40	1·36	1·20

These figures show that the excess consumption bulk is decreasing. Some modifications have also been incorporated in the system of capsules filling machines. These are expected to lead to further improvement. The norms were reviewed by a Committee of the Plant in April, 1974. The revised norms are generally lower than the previous norms.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 22-11-74]

*Not vetted by Audit.

Further information asked for by the Committee

It has been stated that the norms were reviewed by a Committee of the Plant in 1974. Please give details of the revised norms indicating the extent by which the revised norms are lower than the previous norms. Please also state as to how the excess consumption compares with the revised norms.

[L.S.S. O.M. No. 26-PU/74 dt. 21-5-75]

Further reply of Government*

Information regarding the extent by which the revised norms have been reduced over the previous norms is given below:—

Product	Original norms kg/mlrds.	Revised norms kg./mlrds.	increase/ decrease.
1	2	3	4
Penicillin			
Sugar	8·39	8·388	Nil.
Cornsteep liquor	7·29	7·248	—0·55%
Ammonium Nitrate	0·534	0·501	—5·62%
Groundnut oil	1·40	1·788	27·86%
Butyl acetate	6·30	6·30	Nil.
Butanol	2·55	2·55	Nil.
Streptomycin			
Soyabean	6·52	7·413	+13·65%
Cornsteep liquor	1·70	0·022	—98·82%
Glucose	7·00	5·995	—14·29%
Hydrol	8·15	8·839	+8·47%
Ammonium Sulphate	2·166	2·105	—2·77%
Groundnut oil	2·86	2·683	—6·29%
Oxalic acid	2·47	2·344	—5·26%
Tetracycline			
Starch	15·64	13·03	—16·69%
Cornsteep liquor	5·10	2·884	—43·45%
Soyabean flour	1·52	2·083	+37·04%
Groundnut oil	3·27	2·777	—15·08%
Oxalic acid	3·03	3·935	+29·87%

*Not vetted by Audit.

1	2	3	4
Oxytetracycline			
Starch	9·70	9·759	0·61%
Cornsteep liquor	2·50	2·968	18·72%
Soyabean flour	2·91		+100%
Groundnut oil	3·90	2·945	−24·49%
Oxalic acid HCl	2·11	2·318	9·86%

The increase in consumption norms in some cases is due to change in technology on new strains.

[Min. of P&C O.M. No. 8(25)/74-Ch III, dated 10-81975].

Recommendation (Sl. No. 31)

The Committee find that the economics/profitability of the Antibiotics Plant, Rishikesh was not indicated in the Detailed Project Report. In the Report prepared by the Soviet Experts, however, in October, 1958 it was indicated that the gain on chlorotetracycline, Pencillin and Streptomycin would be Rs. 154.3 million (Per annum) on the total production of Rs. 218.6 million per annum of these three products. It was also indicated in the Report that based on the then existing prices of imported drugs and allowing the profit of 10 per cent thereon, the Antibiotics Project would have a payback period of 4 years. The estimates and cost of profitability were prepared in November, 1961. These estimates were revised on a number of occasions. The Committee find that the main reasons for the reduction in the project profits from 16.59 crores in January 1968 to Rs. 8.38 crores in March, 1970 was the reduction in the capacity of the plant on the basis of protocol discussion. The reduction in the anticipated profit from Rs. 8.38 crores in March, 1970 to Rs. 2.10 crores in October, 1970 was mainly the result of drastic reduction in the selling prices due to the introduction of the Drug Prices Control Order, 1970. These projections of profits did not materialise. On the contrary the plant incurred losses to the extent of Rs. 0.56 crores in 1967-68, Rs. 5.10 crores in 1968-69, Rs. 4.91 crores in 1969-70, Rs. 4.65 crores in 1970-71 and Rs. 2.51 crores in 1971-72. The Committee note that the plant achieved the break-even level in respect of Sodium Penicillin and Tetracycline HCl, in 1971-72. In respect of other items the production in 1971-72 was much below the break-even level. It has

been stated by Government that even the projections of profitability drawn up in October-November, 1970 are not likely to be materialised because of continued problem of regular and steady power supply, and the rise in the cost of raw materials and services. The Committee have been informed by Government that "it does not appear possible to indicate any date by which the plant can be predicted to break even". Now that decision on recommendations of Borker Committee Report have since been taken by Government and the revised selling prices of bulk drugs announced by Government on 19th April, 1974, fresh estimates of profitability may be drawn up as the last estimates were prepared more than 3 years ago.

(Para 2.320)

Reply of Government*

The recommendation made has been noted. Accordingly, the company has undertaken the preparation of revised cost estimates on the basis of the revised selling prices approved by Government and cost escalation on other factors. This however has not been completed so far and the company has been asked to expedite its submission.

[Min. of P&C No. 8(25)/74-Ch. III dt. 27-1-75].

Recommendation (Sl. No. 32)

The Committee find that it has been possible for the Management to reduce the cost of production considerably in 1971-72 as compared with the cost of production in 1969-70, 1970-71 except in respect of one item (Oxytetracycline HC1 capsules) where the decline was marginal. The actual cost was, however, still much higher than the standard costs (except for Tetracycline HC1 Capsules in 1971-72 and Oxytetracycline HC1 capsules in 1969-70). It has been stated that production was less than the projections assumed for the calculation of standard cost and the variable cost was higher on account of consumption co-efficient being higher than the reglament norms and higher percentage of rejection. The Committee have been informed that a critical review of the cost of each item vis-a-vis its standard cost is conducted every month at the top management level. The Committee recommend that the system of preparation of cost of each product on the basis of actual monthly cost of production may be introduced early and cost of production of each of the items which are affected by the higher percentage of rejections may be worked

*Not vetted by Audit.

out, critical analysis of cost on the basis of actual cost sheets may also be prepared.

The Committee would like to be informed of the result.

(Para 2.326)

Reply of Government*

System of preparation of actual cost of production of each product every month is in vogue. Verification in actual cost is analysed with a view to initiating corrective nation. The increased cost of production which can be directly attributed to higher percentage of rejections will, however, be given special emphasis mainly with a view to bring the rejection rates within the prescribed norms.

A note furnished by the Project Antibiotics on this subject is attached at Appendix VII.

[Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 10-2-75]

Recommendation (Sl. No. 33)

The Committee have been informed that as a result of various studies undertaken in the Research and Development section of the Plant, manufacturing process have been improved and new antibiotics found. The antibiotics are however, still under investigation and further work is needed for their identification. The plant has been able to substitute fully 11 out of 30 items of raw materials. Expenditure on Research and Development ranged between one per cent to 1.97 per cent of the total expenditure during the period of 1968-69 to 1973-74 (Upto September, 1973). It has been stated that the present scope of activity of Research and Development is mainly for solution of various technological problems faced by the plant in addition to suggesting improvements in the processes and import substitution. The plant is equipped with a library to keep its technologists and scientists abreast with the latest developments in the fields of specialisation. The Borker Committee which had the occasion to study the working of the plant has however observed "even key technical personnel on the plant are hopelessly out of touch with developing trends in technological and concepts in the management of technology". The Committee recommend that Government should undertake a critical evaluation of the research and development activities of the plant so that emphasis is laid towards development research aimed at identifying new and more effective antibiotics. Government should also ensure that the technical personnel in the

*Not vetted by Audit.

plant keep themselves fully abreast of the latest technological developments in the field of manufacture of antibiotics, so that in course of time they are in a better position to attain higher operational efficiencies in the interest of optimum production. The Committee were also informed that though the Ministry of Petroleum and Chemicals has constituted a coordination Committee comprising representatives of HAL and IDPL to pool their experience in production marketing and research activities, there has not been any appreciable liaison between IDPL & HAL in the matter of R&D of antibiotics. The Committee desire that there should be greater coordination in the R&D activities not only between the two public Undertakings but the Private Sector as well. (Para 2.340)

Reply of Government

The discovery of new antibiotics, as is well-known is a very slow process. During the last several years, no radically new antibiotic of importance has been added and almost all the therapeutically effective antibiotics of present days had their origin prior to this period. However, a significant development that has taken place in the field of antibiotics is modification of the structures of the known antibiotics with a view to improve their therapeutic effectiveness of range. IDPL has also preferred to follow this well-accepted pattern and efforts have been initiated in their R&D Division to develop modifications of Oxytetracycline to produce Doxycycline and semi-synthetic penicillins from penicillin.

The Antibiotics Plant, Rishikesh is still be set with production problems and producing far below the rated capacity. The management therefore, had been giving priority to resolution of production problems so that the available capacity of the Plant is more effectively utilised. The R & D activity has however been streamlined so that specific projects are assigned to individual scientists with their own supporting staff and the progress reviewed from time to time.

The company is also taking steps to bridge the gap between the existing technology at Rishikesh and the technology available at International level by going in for expert advice and collaboration in selected areas.

The Technical Committee set up under the Chairmanship of Shri S. K. Borker has made several recommendations for improving the working of the plant and the company is taking action to implement the recommendations of the Committee. One of the recommendations of the Committee is about the technical personnel of the

plant and the company organising suitable training to the technical officers and personnel of the plant to improve their knowledge and productivity. It may however be mentioned that the plant is staffed with highly qualified personnel which include 19 Ph. Ds.

As regards coordination of R & D activity, the Ministry of P and C has set up a joint Committee on Research and Development with representatives of Department of Science and Technology, CDRI, Lucknow, NCL Poona, PRL Hyderabad, DGTD, DGHS; IDPL; HAL; OPPI, AIMO, and IDMA, the last three being associations of drug manufacturers in India. This Committee has been set up on the basis of the recommendations of the Task Force on Drugs and Pharmaceuticals and to coordinate the activity on research and development in various Public and Private sector Institutions. The Committee has also set up five panels for going into the technology and development of research work on the following categories of Drugs:—

1. Antibiotics and Enzymes
2. Synthetic antibiotics
3. Steroids and Mormenes.
4. Chloroquin and others
5. Sulphas, Vitamins and Analgesics.

These panels consist not only of the representatives of Government Department and Public Sector Units but also Private Sector Research Units. This Committee, it is expected will ensure the necessary coordination in the R&D activity in both Private and Public Sector in the field of drug manufacture.

[Min. of P & C OM No. 8(25)/74-Ch. III dt. 8|11|74]

Further information asked for by the Committee

It is stated that the Ministry of Petroleum and Chemicals has set up a Joint Committee on Research and Development with representatives of the Deptt. of Science and Technology, CDRI, Lucknow, NCL Poona, RRL Hyderabad, DGTD, DGHS, IDPL, HAL; OPPI; AIMO and IDMA. Please state:

(a) When was this Joint Committee set up and what are its terms of reference? Please give details.

(b) When is this Committee expected to submit its report?

[LSS O.M. No. 26-PU/74 dt. 21-5-75]

Further Reply of Government*

The Joint Committee on R&D was set up in this Ministry on the 19th January 1974 comprising of the representatives of DGTD, Ministry of Health/DGHS, Deptt. of Science and Technology, CDRI, NCL, Poona, RRL, Hyderabal, IDPL, HAL; OPPI; AIMO and IDMA with a representative of the Ministry of P&C as convenor. The objectives of the Joint Committee are (i) to identify the areas where further research is immediately called for and allocate the same amongst the various research laboratories depending upon the facilities and technical resources available with them; and (ii) after successful culmination of the research projects, commercial exploitation of the technology developed would be allowed to the entrepreneur who had participated in the programme and in case the entrepreneur is not interested or willing to exploit the results of the research, the know-how may be allocated to other suitable units for exploitation.

In the first meeting of the Joint Group, five panels were set up as mentioned in the reply above. One of the panels, Steroids and Hormones held its meeting on the 13th May 1975 and decided to collect further data and the status of manufacture of steroids in the private sector. The meetings of the other panels are also likely to be held shortly.

Based on the reports of the various panels, suitable action will be taken to advice the industry to modify their manufacturing operations suitably to obtain better results in the manufacture of bulk drugs. It will thus be noted that no time can be fixed for the submission of the report. The work of the Committee is of a continuing nature.

(Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 10-8-1975)

Recommendation (Sl. No. 35)

The Committee note that in December, 1962 the private firm of Bombay was appointed as the Company's clearing agent for clearing and forwarding all machinery and equipment imported from USSR and other countries. According to the terms and conditions of the Contract, the Clearing Agents were to pay landing and all other Port Trust charges in the first instance and to claim reimbursement of the amount so paid in bills, duly supported with relevant receipts. However, the Company opened two personal deposit accounts (December, 1962 and March, 1966) with Port Trust Authorities.

*Not vetted by Audit.

Opening of these accounts was a material deviation from the conditions attached to the notice inviting tender. Specific reasons for opening these accounts by the plant are not on record. Out of the amounts deposited by the Project Authorities a sum of Rs. 29.13 lakhs was adjusted by the Port Trust Authorities on account of ground rent wharfage and demurrage. The incident of demurrage included in that amount demurrage worked out to Rs. 27.37 lakhs (Approx.) Out of this, a sum of Rs. 3.95 lakhs only was refunded by the Port Trust Authorities and an amount of Rs. 0.24 lakhs was written off by the Company. According to the Company the payment of demurrage of the order of Rs. 23.16 lakhs was mainly due to the negligence on the part of the clearing agents in obtaining wagons, expeditious customs clearance. The Committee feel that IDPL should have recovered the amount of demurrage from the clearing charges. As the matter is now stated to be pending in a Court of Law, the Committee would refrain from offering any comments at this stage. The Committee however recommend that the whole position may be reviewed by the Management after the case has been decided by the Court. The Committee would like to be informed of the final position. (Para 2.355)

Reply of Government

Recommendation of the Committee has been noted for guidance. The Court case is still pending.

(Min. of P&C O.M. No. 8(25)/74 Ch. III dt. 30-10-74)

Comments of the Committee

Please see para 86 of Chapter I of the Report.

Recommendation (Sl. No. 37)

The Committee note that Antibiotics Plant, Rishikesh is having a small training cell which essentially caters to the needs of operatives supervisory staff. Apart from imparting industrial training, the Department is engaged in arranging refresher courses designed to upgrade the skill of the existing workers. In organising the training programmes help is also taken of the specialised agencies like the National Productivity Council. The Committee find the expenditure incurred by the Plant on training programme has increased from Rs. 46,000 in 1970-71 to Rs. 55,000 in 1972-73.

The Committee find that as between 21st December, 1968 and 10th May, 1971 as many as 78 trainees had left the Company either be-

fore or after the completion of their training. Out of these 50 trainees, however, did not draw any stipend during the period of their training. The amount recoverable from the 63 trainees was assessed at Rs. 71,814. Out of these 13 trainees resigned mainly due to family circumstances. Amount recoverable from the remaining 15 trainees who discontinued attending duties without any information or notices works out to Rs. 42,190. It has not been possible for the plant to recover the amount so far despite repeated reminders. To avoid such situations the plant introduced in June, 1969 a clause in the draft bond where, besides personal undertaking, such trainees were required to give a surety for the fulfilment of the conditions of the bond. The Committee are surprised that such a surety was not insisted upon by the Management prior to June, 1969.

(Paras 2.373 & 2.374)

Reply of Government

Observation of the Committee has been noted for guidance.

As mentioned in the recommendation, the Company has already introduced a clause in the Draft Bond requiring trainees to give a surety for the fulfilment of the condition of the Bond.

[Min. of P&C O.M. No. 8(25)/74-Ch.III dt. 30-10-74].

Recommendation (Sl. No. 40)

The Committee note that according to DPR the plant was designed to produce 851 tonnes of bulk drugs on the basis of 300 working days. Since it was found that the plant was capable of working for 330 days, the capacity on the basis of actual production pattern was increased to 1,399 tonnes as on 31st March, 1972. The Committee note that out of 16 items of bulk drugs originally provided for in DPR one item Acetazolamide was dropped on account of obsolescence and marketing difficulties, second (INH) was deferred due to high cost of manufacture, third (D.C. Citrate) had to be stopped as the production of plant could not compete with other manufacturers, fourth (Sodium Sulphacetamide) was restricted because of its limited demand in the market and the capacity of fifth (Piperazine adipate) became idle because the imported variety was easily available. Excluding these and including some new items the overall capacity on the basis of actual product-mix was of the order of 1399 tonnes as on 31st March, 1972.

The Committee also note that though the rated capacity has been increased the target of production has been less than the rated capacity. Even the revised target has shown downward trend. Considering the overall performance the actual production has been less than the revised target from 1968-69 to 1971-72 the shortfall ranging from 4 per cent to 32 per cent. However, in the

cases of Piperazine Adipate in 1968-69, Analgin in 1970-71, Sulphanilamide Sodium Sulphacyl, Piperazine Phosphate, Piperazine Hydrate, Phenobarbitone and Sodium PASS in 1971-72 and Phenacetin paracetamol and Phenebarbitone 1972-73, the actual production was in excess of the revised targets. The major reasons for shortfal in production were stated to be non-stabilisation of technology, frequent failure in power and water supply and non-availability of raw materials. The Committee find that the actual time taken by the Plant for stabilisation in the production of certain items was much higher than the reglement of the foreign collaborators or even those fixed by the Management. The Committee were informed that the delay in these cases were mostly due to market constraints and the technology of the collaborators not being acceptable to Indian Market with the result that certain modifications had to be carried out in the plant. The Committee have given recommendations about market constraint a separate Chapter. The Committee also hope that it should be possible for IDPL to develop drugs, acceptable to Indian market with the assistance of the Research and Development facilities available with it so that the existing capacity could be utilised to the fullest extent.

(Para 3.47-3.48)

Reply of Government

The recommendation of the Committee has been noted for guidance and compliance. It may, however, be mentioned that the period for which the plants were kept idle were not sufficient to try any new items of production. However, within the time available and with the help of the Research and Development Section of the Plant, items like Thiacetazone, Sulphamethizole, Phthalyl Sulphacyl, Phenobarbitone Sodium, Sodium Ascorbate, Thiamine Mononitrate etc. are produced in the plant. Further efforts to produce more items continue. Many drugs have been developed in the R&D of the plant. These include Metronidazole which has been developed on the laboratory scale and pilot plant studies have also been taken up.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 4-12-74]

Recommendation (Sl. No. 41)

The Committee also note that Synthetic Drugs Plant Hyderabad was based on assured supply of water to the Plant by the State Government. As it was felt that due to frequent break-downs on account of operational reasons production would be affected, a decision was taken to augment the storage capacity. The Committee hope the work in this regard has been completed and continuous water supply assured.

The Committee recommend that in the interest of continuous production and making available essential drugs to the consumers, Government should render all possible assistance to the undertaking in the procurement of raw materials.

(Para 3.49)

Reply of Government

Additional underground water storage tanks have been completed and now it is possible to run the plant without any interruption in the water supply. The State Government has also been apprised of the requirements of water for the second phase expansion. There has been some delay in the completion and commissioning of the additional water supply facilities being set up by the State Government, but this is expected to be completed by the time additional supply is required by the plant.

As regards raw materials, the items which have been recently in short supply are rectified spirit, Soda ash, Acetanilide, Caustic Soda, Dicyandamide & Meta Amino Pheno. In regard to the rectified spirit, the Government of Andhra Pradesh, Maharashtra, Tamil Nadu and Karnataka were addressed by the Ministry of Petroleum and Chemicals to supply the requirements of Synthetic Drugs Plant. Except Maharashtra, the other States agreed to supply some quantities of alcohol. As regards Soda Ash, the three major producers, namely, Tata Chemicals, Saurashtra Chemicals and Dharangadhara Chemicals were requested to supply and they agreed. Acetanilide and Meta Amino Phenol are produced by Hindustan Organic Chemicals Ltd., whose production was affected due to the reduction in supply of Nitric Acid by FCI, Trombay. The plant of FCI has since been repaired and normal supply is expected to be resumed shortly. In the meantime, in order to avoid shortfall in the production of Sulpha drugs, *ad hoc* imports of 500 tonnes of Acetanilide is being arranged. Hindustan Organic Chemicals have also been requested to give priority to the manufacture of Drug-intermediates which are required by the drug industry for the production of life saving drugs. Regarding Dicyanadmide which is wholly imported, the matter was taken up by the Ministry of Petroleum and Chemicals with foreign suppliers through the Indian missions abroad. Due to shortage of this chemical supplies were not adequate and IDPL have worked out an alternate process using instead of Dicyandamide. Whenever the manufacturing units seek assistance in obtaining raw materials, the Ministry of Petroleum and Chemicals, where necessary, in consultation with the DGTD take up the matter with the concerned suppliers so that the requirements of the plants are met to the extent possible.

[Min. of P&C O.M. No. 8(25)/74-Ch-III dt. 8-11-74].

Recommendation (Sl. No. 43)

The Committee find that overall loss incurred by Indian Drugs and Pharmaceuticals Limited on account of process losses and loss due to drainage have been of the order of Rs. 19 lakhs in 1969-70, Rs. 8 lakhs in 1970-71 and about Rs. 5 lakhs in 1971-72. The Committee also find that the process loss has shown a declining trend from 1969-70 to 1971-72, although the value of such process losses in individual products like Vitamin B-1, Amidopyrine, Folic Acid exceeded Rs. 1 lakh during 1970-71. In regard to loss due to drainage the Committee note that the loss has come down from Rs. 1.95 lakhs in 1969-70 to nil in 1970-71. The Committee recommend that since the production in a number of items has been stablised it should be possible for the Management to fix norms for process losses/rejections and thus have no effective control over such losses.

(Para 3.55)

Reply of Government*

Most of the rejections are due to odour, presence of foreign particles and colour. These are not "final" rejection. The drugs are further processed suitably by drying, picking up of foreign particles, etc., involving reprocessing. Indian Drugs and Pharmaceuticals Limited proposed to watch the position for some more time before fixing the unavoidable process losses so that the norms fixed are minimum.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dt. 30-10-74].

Further information asked for by the Committee

What is the outcome of watching the position so far?

[LSS OM. No. 26-PU/74, dt. 21-5-75].

Further Reply of Government

Some data has already been collected. However, before finally fixing the norms for process|rejection, some further data are being collected. It is expected that for those products where process has been stabilised, the norms will be defined within the next six months.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dt. 10-8-75].

Recommendation (Sl. No. 45)

The Committee are surprised to find that when the Hyderabad Plant is licensed for production of DC Citrate and a stock of 9.734

*Not vetted by Audit.

tonnes of DC-Citrate is lying with the Plant for disposal as on 31st March, 1973 other manufacturers were being allowed to import a later intermediate for manufacture of DC Citrate. It is only after the IDPL has taken up the matter with Government that this item was placed on banned list in the import policy for 1972-73. The capacity thus rendered idle is being utilised for producing other drugs.

The Committee would like to be informed about the disposal of the stock of DC-Citrate. The Committee recommend that Government should look into the capacity available with IDPL and the range of products manufactured by it, before private manufacturers are allowed imports of the same products.

(Para 3.77 & 3.78)

Reply of Government

The stock position of DC-Citrate as at the end of September, 1974 is as follows*:—

Synthetic Drugs Plant	1938·8 Kgs.
Bombay	725·0 Kgs.
Delhi Office	490·0 Kgs.
TOTAL . . .	3153·8 Kgs.

It is hoped to liquidate the available stocks by the end of this financial year.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dt. 30-10-74].

Further information required by the Committee

What action has been taken in regard to the last part of this recommendation, *viz.*, "The Committee recommend that Government should look into the capacity available with IDPL and the range of products manufactured by it, before private manufacturers are allowed imports of the same products". Please state in detail giving the position as at present.

[LSS OM. No. 26-PU/74, dt. 21-5-75].

Further Reply of Government†

The indigenous availability of bulk drugs|intermediates is always kept in view before private manufacturers are allowed imports of the same products. A statement showing the drugs and inter-

*The Principal Audit officer has reported that a quantity of 615.35 Kgs. of D. C. citrate was also lying in the Production Block as at the end of 1974.

†Not vetted by Audit.

mediates produced by IDPL and the present import policy in respect of each item is attached at Appendix VIII. It will be seen therefrom that except for three intermediates, all other items in IDPL's product range are either in the banned list, restricted list or the list of canalised items. In the case of canalised items, import plan for each financial year decided after discussion in an inter-ministerial meeting well before the beginning of the year keeping in view the estimates of the industry's demand and of the indigenous production including that by IDPL.

[Min. of P&C O.M. No. 8(25)/74-Ch.III dt. 10-8-75].

Recommendation (Sl. No. 46)

The Committee find that though according to the process for production of Ribose, almost the whole quantity of mercury used should be salvaged with insignificant loss at the end of the process cycle, the loss of mercury in the plant was quite abnormal. The Committee note that during test trials of the plant in July, 1968, mercury was splashing through the inculation of the pipes. After the damaged pipe was repaired the loss was assessed in July, 1968. An investigation into the matter revealed that location of the mercury trap was discovered only after the loss of mercury was known the trap was not fully completed and was found covered with much and certain shortcomings in design and procedures were not discovered at the time of construction and measurement of work and during test trials. Certain remedial measures proposed by the Deputy Superintendent of the Block were implemented in August, 1968 to avoid similar losses. The Manager after taking into account the relevant facts and circumstances under which the loss took place, decided in July, 1970 to write off the loss of Rs. 1.19 lakhs. They did not also find it possible to pin point the responsibility for the loss.

In February, 1970 the Management, however, felt doubt about the possibility of mercury being pilfered from the process stream in the block. The situation was reviewed by the Management and measures taken to transfer persons of doubtful integrity and also to tighten the security measures. An operator who was caught in the process was placed under suspension pending investigation. On the basis of certain norms decided by the Management the loss of mercury was estimated at Rs. 2.2 lakhs during the period April, 1968 to March, 1970. In view of the frequent complaints of loss and theft of mercury a departmental committee was constituted in January, 1971 to examine the procedure for receipt of storage, security and issue of mercury and also to make a proper scientific

assessment of consumption of mercury in the process of production of Ribose. The Departmental Committee found that (a) the weighment of mercury was not done as soon as the material was received through the transport agencies, (b) the transport agencies did not take any responsibility whenever shortages were detected on open delivery, (c) there were always some delays between the time of receipt of mercury and the accounting of the same, (d) in some cases consignments were not accompanied by documents, (e) mercury was for a long time kept along with the general items, (f) security arrangements for mercury in the Ribose Section were found defective and the workers were allowed to go in and come out of the Ribose Section Freely.

The Committee find it hard to accept the plea of the Management that it was not possible to pin-point the responsibility for the loss of mercury. The Committee would like Government to review the matter and take action to fix responsibility in this regard. The Committee were assured that since adequate precautions have been taken to trap the mercury and the electrolytic process implemented the possibility of pilferage of mercury would not longer be there. The Committee cannot but observe that because of certain shortcomings in designs and procedures not being observed at the time IDPL was put to a loss of Rs. 1.19 lakhs which had to be written off. The Committee recommend that a careful watch of the consumption of mercury against norms should be kept so that the Management may analyse any abnormal variations from the norms with a view to ensuring that such variations are not on account of any pilferages or wasteful practices etc. The Committee would also recommend that the security arrangements for the mercury in the Ribose Section should be tightened to guard against the possibilities of such pilferages. The Committee would like to be informed of the action taken in the matter within six months.

(Para 3.104 to 3.106)

Reply of Government

As recommended a Technical Committee consisting of Dr. B. Shah, DDG, DGTD, Dr. B. L. Sattur, Regional Research Laboratory, Hyderabad and Dr. P. R. Gupta, Drug Advisor, Ministry of Petroleum & Chemicals had been constituted to review the matter and fix responsibility for the loss of mercury. The Committee visited the plant and had examined all aspects. Its report is awaited.

Continuous electrolytic process for the production of D-Ribose is under stabilisation. Results achieved so far are encouraging. This process involves less handling of mercury which enables a stricter

control being kept on pilferage or wasteful practice. A close watch is also kept on the consumption of mercury by the plant management.

Existing security arrangements provide for maintenance of a complete record, with date and time of entry and departure of every person from the Ribose section, where mercury is handled. All persons leaving the section are thoroughly searched by the Security Guard.

[Min. of P&C O.M. No. 8(25)574—Ch III dt. 23-10-74]

Further information asked for by the Committee

Has the Technical Committee submitted its Report, if so, please give its findings and recommnedations and the follow up action taken thereon by IDPL/Government. Please furnish a copy of the report also.

[Min. of P & C O.M. No. 8(25)574—Ch III dt. 30-10-74]

Further Reply of Government*

A Technical Committee consisting of Dr. B. Shah, DDG, DGTD, Dr. P. B. Sattur, Dy. Director, Regional Research Laboratory, Hyderabad and Dr. P. R. Gupta, Adviser (Drugs), Ministry of Petroleum & Chemicals was constituted to examine the entire matter relating to the theft of Mercury and fixed the responsibility for the loss of Mercury. The Comittee submitted its report and it is now under consideration of Government. A copy of the Report is attached.

Loss of Mercury at the Synthetic Drugs Plant, Hyderabad

The Committee on Public Undertakings in its 56th report on M/s. Indian Drugs & Pharmaceuticals Ltd., had made certain observations and recommendations in connection with the loss of mercury at the Synthetic Drugs Plant Hyderabad. The Committee had also observed that it found it hard to accept the plea of the management that it was not possible to pin-point the responsibility for the loss of mercury. The Committee, therefore, liked Government to review the matter and take action to fix responsibility in this regard.

To examine the matter the Ministry of Petroleum and Chemicals constituted a Committee with the following as members:

(i) Dr. B. Shah, Dy. Director-General, DGTD.

(ii) Dr. P. B. Sattur, Regional Research Laboratory, Hyderabad.

*Not vetted by Audit.

(iii) Dr. P. R. Gupta, Adviser (Drugs), Ministry of Petroleum and Chemicals (Convener).

The above Committee met the officials of the Synthetic Drugs Plant on two occasions—once in September, 1974, and again in May, 1975 (Dr. Sattur was not present at the second meeting as he was on leave then), looked into the papers concerning this matter, and also visited the plant where the loss of mercury took place.

At the time the accident took place, mercury was being used for the production of Sodium Amalgam in batch processes, to be used in the reduction of Ribose-lactone to Ribose, an intermediate, in the manufacture of B-2. It was pointed out by the plant officials that this batch-process was already in operation in the first stream, and the accident took place while the second stream was installed and about to be put into operation. It was also mentioned that this second stream had been tested a week earlier with water and then with mercury and found satisfactory. The plant personnel also informed us that before the inlet tube, to the reaction vessel, was insulated with lagging material, after spot welding of the tracer-pipe, through which steam was to be passed to keep the inlet tube warm, this inlet tube when tested, was found to operate without any leakage and then only the inlet pipe was lagged with insulation material. Before starting the operations, it was again tested with mercury a weak later to make sure of the proper functioning if the plant before the amalgam was prepared and fed into the reactor. It was at this time that the mercury splashed out of the inlet tube connected to the reactor vessel.

Dr. Mukherjee in his report has mentioned that the accident took place around 01 hrs. of 16th morning *i.e.* during C shift working of 15th July, 1968. On a quary made to the plant personnel, it was explained to this Committee that since the first stream, with the same plant design, was working without any problem, no senior official nor the experts of the Soviety collaborators who offered the plant-design, technology etc., were present when the second testing with mercury was done on the 15th night. The Committee was informed that no logging of the test-trials undertaken was made and no proper check list was drawn nor advised by the Soviet experts who furnished the technology, details of drawing etc. It is also observed from the report submitted by Dr. Mukherjee that the loss of mercury was not detected until the 20th when the mercury collected at various points in the plant was drained to the lower tank, after repairing the leaking pipe.

It is also observed that the people working in the plant were not aware of the outlet route through which mercury could have flowed out of the sewerage. It was explained that since the outlet was assumed to be working perfectly when tried with water, no serious doubt was raised about the structure and connection of the sewerage pipe with the plant outlets. It was also explained that since the smaller traps which were provided within the plant were expected by the plant people to take care of any small spillage of mercury, they did not anticipate any large loss of mercury. The provision in the collaborators' drawing in the Layout of the sewerage for collection of any untoward flow of mercury to the sewerage out of the plant was not brought to their notice, nor even was mentioned by the Soviet experts present in the plant. It was stated to this Committee that the Soviet experts also informed about a loss of about 10 tonnes of mercury in their plant in USSR, but only after this mishap took place at the Synthetic Drugs Plant. The plant people, however, could not tell this Committee as to the exact cause of loss that took place in the Soviet plant.

It has also been observed that before the Public Health engineers, who were incharge of the layout and construction of the sewerage line, had gone back to their parent department, they did not give any completion certificates for the jobs they had done. The Public Health engineers also do not appear to have checked whether all the facilities as were provided in the drawings etc., were installed or not before they left the place, nor even the Soviet experts who were incharge of the plant at that time, did check the details of the sewerage line in spite of the fact that they too had lost mercury at their unit in the Soviet Union.

It also appeared to this Committee that the Public Health engineers did not take much care to find out the purpose of all the provisions in the drawings of sewerage. Absence of installation of an outside trap was discovered only after the loss had occurred. It was mentioned that not only the trap outside the plant had not been provided but the construction itself was incomplete and covered with mud etc. These points should have been checked by the Public Health engineers, the administrators and the Soviet experts even before commissioning the first stream of sodium amalgam reduction unit.

The mercury-amalgam preparation vessel which was shown to this Committee as being used in those days, was placed at a great distance and at a higher level far away from the reaction vessel, where the desired reduction process was to take place. It was ex-

plained that this design, furnished by the Soviet collaborators, was possibly with the idea of avoiding any fire hazard.

Dr. Mukherjee in his report has observed that due to lack in the stainless steel valve, acid entered into the reactor and found its way into the mercury-amalgam charging line. This acid could have corroded the pipe and developed holes at the welded spots where the steam tracer pipe had been welded to the charging pipe. It was observed by this Committee that a couple of litres of acid would have to have leaked through the stainless steel valve to reach the point where the supposed corrosion could have taken place. In that case, the plant people would have noticed the corrosive acid, a portion of which would also have come out alongwith the mercury. The people who were present at the time of the accident did not remember any such flow of acid alongwith the mercury. Considering that the first stream, which was already in use, was of the same type and design and no such mishap occurred, the corrosion with acid does not appear to be plausible.

From the description of the reaction process that was adopted then and mentioned by the plant people to this Committee, it was observed that in the reactor, Sodium-amalgam was charged in an atmosphere of nitrogen, and the amalgam was cooled by adding ice-water to it followed by addition of 40 per cent sulphuric acid, to adjust the PH to 3.5 to 4, before any solution Ribono-lactone was charged into the reactor. It appeared that this process was rather defective to the extent that certain quantity of hydrogen would have been lost on acidification of the Sodium amalgam suspension in water, without being utilised for the reduction of Ribono-lactone to Ribose. It was explained by the plant people that initially no changes in the process were made and whatever technology was indicated by the Soviet experts, was followed in toto. It was mentioned that this batch-wise process has, however, been given up with effect from October, 1973 when the plant switched over to the electrolytic reduction process. In this process, the Sodium amalgam from the electrolyser goes to a Y-shaped reactor where it meets the Lactone solution and hydrochloric acid which are fed separately into the line already having Ribose solution in circulation. During the circulation of amalgam alongwith the lactone solution in Y-Shaped reactor line, reduction of lactone to Ribose takes place. The spent amalgam is separated from the working solution and flows back to the olocto-lyser through a washer. It was mentioned that the quantum of mercury now handled is 1/3 of the quantity handled earlier in the

batch-wise chemical method. Consumption co-efficient of mercury per kg. of D-Ribose is less in the electrolytic process and this has decreased from 0.1709 in October, 1973, to 0.1046 as against the Russian standard of 0.155 to 0.167.

Apart from the points as mentioned above, the original design of the plant also was lacking to the extent that valves were not provided at the required places, and that the bigger trap which was provided in the sewerage line, which also had not been completely installed, was in the same line through which sewer/fecal masses also flowed. These defects should have been detected and the exact location of the bigger traps should have been ascertained by the administration as well as the Soviet experts before the Public Health engineers were allowed to leave. Since the Indian operators were to follow strictly the processes of operation supplied, under the guidance of the Soviet experts, they could not raise these points and satisfy themselves to take care of any possible mishap in the spillage of mercury. The Soviet experts who were present at the plant and guided the local operators, should have taken the prime responsibility of checking all the points, particularly when they knew of such possible mishaps based on their own experience at their plant.

Dr. Mukherjee has rightly pointed out that the loss of mercury could have been avoided or minimised to a negligible quantity if proper checks of the equipments, valves and all the traps had been made before commissioning the Ribose section. Evidently, there was no proper coordination between the Civil Engineering Department, Public Health Department and the Soviet and Indian experts. Both the Soviet experts and the administration on the Indian side should have checked if all the provisions for collecting any loss of mercury had been completed, even before starting operations with the first stream of the plant.

In view of the above, it is very difficult to pin-point the responsibility on any individual.

This accident could, however, have been avoided and the loss of mercury also minimised considerably, if the necessary checks were carried out of the equipment and the valves provided and in particular if a check had been made of all the traps provided in the outflow line as per the drawing of the sewerage system, before the manufacturing operations were commenced. A proper check list should have been drawn up for the purpose by the Soviet experts and somebody made responsible for ensuring that they were com-

plied with, and also proper record of the trial runs undertaken were maintained. The plant experts explained that since they were following strictly the advice given to them by the Soviet experts present and also that they were keen to go into production of the various items as quickly as possible, they considered that all possible checks/evaluations would have been met in the design and technology provided by the Soviet experts, and as such they did not take any special or extra precaution to follow the outlet route and ensure whether the necessary trap had been provided.

All the same, great credit should be given to the staff on duty in the night shift who improvised various measures to stop the flow of mercury into the sewerage by putting gunny bags around the place of spillage and started collecting mercury into one of the storage tanks and thereby reduced the loss to about 780 kgs.

We also understand that large quantities of mercury have been lost from this unit in the past by pilferage. While they have provided guards to check and search people who enter and leave the premises to prevent such pilferage, we would suggest that while entering into the Cell house, stores etc. where mercury is handled, the carrying of fountain-pens with barrels should be banned. This is a convenient way of pilfering mercury. Each fountain pen barrel has a capacity of 10 c.c. and the density of mercury being 13.6, each time a person could carry away 136 gms. of mercury un-noticed. If such operation is repeated 10 times, more than one kg. of mercury would disappear in spite of all the watch and ward arrangements. Such a ban should eliminate the possibility of pilferage through this manner.

(Dr. P. B. Sattur)

(Dr. B. Shah)

(Dr. P. R. Gupta)

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 10-8-1975]

Comments of the Committee

Please see para 103 of Chapter I of the Report.

Recommendation (Sl. No. 47)

The Committee find that the Project Report had indicated a loss of 0.0064 tonnes of mercury per tonne of Vitamin B2 but in order to arrive at the extent of loss due to pilferage alone, an exercise was made by the Management by assuming an operational loss of mercury at 0.185 kg. per kg. of Ribose produced. Subsequently the

Committee which was constituted in January, 1971 recommended that the normal consumption of mercury should be 0.2 kg. of mercury per 1 kg. of Ribose.

The Committee feel that in order to inspire confidence, refixation of norm should have been done by an independent agency after taking into account norms followed in similar plants in the collaborators country, lost upward revision of norm by the Management themselves should be construed as an indirect regularisation of a loss.

(Para 3.107)

Reply of Government*

As mentioned in reply to Recommendation No. 46, continuous electrolytic process is under stabilisation at present. Norm will be fixed in consultation with an independent agency after the process stabilises.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 30-10-1974]

Comments of the Committee

Please see para 107 of Chapter I of the Report.

Recommendation (Sl. No. 48)

The Committee find that the DPR did not give any indication either about the cost of production or the profitability of products. The plant prepared product-wise estimates of cost first in March, 1967 and these were revised in November, 1967, October, 1969 and July, 1970. After taking into account the changes in the raw materials input as a result of modification, process changes, revision in the prices of raw materials etc. The Committee find that even in 1971-72 and 1872-73, the actual cost of production was signficantly higher than the estimated cost in all the items except two. The Committee note that excess consumption of raw materials alone over the standards laid down in July, 1970 accounted for Rs. 29.73 lakhs during 1970-71 and 1971-72. The Committee recommend that IDPL should analyse the cost of production to examine as to how far these norms are adhered to. The Committee understand that departmental committee is examining the question of fixation of norms of consumption of raw materials on scientific basis. The Committee hope that departmental committee would finalise its work soon so that reliable data may be available to enable the management to review the cost of products. The Committee need hardly stress that the aim should be to achieve an economic and competitive cost of production.

*Not vetted by Audit.

The Committee find that the plant will continue to incur losses even on attaining the rated production unless selling prices are revised. The committee have no doubt that the Departmental Committee would look into this aspect as well and suggest concrete measures for improving the profitability of the project. The Committee recommend that the plant should endeavour to bring down its cost of production so that it may be possible to reduce the selling prices and make available drugs to the common man at reasonable prices.

(Para 3.123)

Reply of Government*

The Consumption co-efficient of raw materials for the production of various drugs/intermediates have been finalised by the Departmental Committee and they are under examination for according necessary approval by the company.

Excess consumption of raw materials is analysed by IDPL every month with a view to ascertain the reasons therefor and to take remedial measures.

Since the sale prices of the drugs in the production range of the pplant have been revised by Government the profitability of the plant has improved. The plant authorities are examining further measures for improving the profitability of the plant. The recommendation of the Committee that the plant should endeavour to bring down the cost of production with a view to reduce the selling prices have been noted for guidance.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 30-10-1974]

Further information asked for by the Committee

(a) Is the examination of consumption co-efficients of raw-materials as finalised by the Departmental Committee for according necessary approval over?

(b) It is stated that the sale prices of the drugs in the production range of the plant have been revised by the Government and the profitability of the plant has improved? When and to what extent is the improvement in the profitability of the plant?

(c) What specific measures have been taken or are proposed to be taken to bring down the cost of production with a view to reduce the selling prices? Please give details?

[LSS O.M. No. 26—PU/74, dt. 21-5-1975]

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*Not vetted by Audit.

Further Reply of Government*

(a) The consumption coefficients of raw materials for the production of various drugs/intermediates have been approved by the company and implemented. The excess consumption of raw materials is analysed every month by Chief Technologist, Works Manager and Cost Controller, and steps are being taken to bring down the consumption of raw materials to the standard norms, where necessary.

(b) Government have revised the selling prices of various drugs, as indicated in Appendix IX with effect from dates noted against each.

Further, the Bureau of Industrial Costs and Prices had visited the plant during the period October-November, 1974 and carried out cost examination in respect of Folic acid, Sodium PAS, Amidopyrine, Acetazolamide, Sulphamethazole. Their recommendations are awaited. As regards improvement in profitability of the plant due to revision of prices, the price revision is based on formula designed by the BICP taking into account the prevalent cost of various inputs. As such, the revision of prices has helped the plant to meet the cost of inputs to reduce the losses and thereby improve the financial status of the company which is being reflected in the annual accounts. The profit achieved in 1974-75 is Rs. 407 lakhs as against Rs. 98 lakhs earned in 1973-74.

(c) Extensive efforts have been made through R & D to reduce the consumption coefficient and increase the yields. Changes have been made in the process by using catalysts, etc., with a view to increase the yields. Steps have been taken to cut down some steps in the process so that the cost of production is reduced. Changes have been made in the process to reduce the time cycles so that more production can be obtained in the existing capacity. These efforts have shown promising results in some drugs like Vitamin B-1, Analgin, Folic Acid etc.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 10-8-1975]

Recommendation (Sl. No. 51)

The Committee note that on the basis of the provision in the Project Estimate and contemplated production programme of 1967-68, the undertaking procured from March, 1967 to April, 1968, bottles costing Rs. 4.16 lakhs for packing of finished products. In addition it procured 11.31 lakhs pilfercaps of the value of Rs. 80,000 for use in the bottles. The Committee regret to note that because of indenting packing materials prior to commencement of production

*Not vetted by Audit.

bottles worth Rs. 3.75 lakhs and caps worth Rs. 50,000 approximately are lying in stock. The Committee were informed that since most of the pharmaceutical suppliers have switched over to other modes of packing, response for the purchase of the bottles and pilfer-caps is poor, but efforts are being made for their disposal. The Committee would like to be informed of the developments. In the opinion of the Committee the transaction is likely to result in a loss.

(Para 3.147)

Reply of Government

The availability of Amber coloured bottles which are surplus to our requirements is being circulated periodically to the consumers. Suitable offers are not received. They are also being included in the public auction every time for disposal. Efforts are being continued to dispose them off as early as possible.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 10-2-1975]

Recommendation (Sl. No. 53)

The Committee note that the undertaking decided in August, 1966 to set up an Ammonia receiving and storage station with a capacity of 100 tonnes for ensuring uninterrupted supply of liquid Ammonia and to avoid extra expenditure involved in its procurement in cylinders. The Fertilizer Corporation of India agreed to provide the design technical assistance in the procurement, inspection, erection and commissioning of the equipment for a remuneration of Rs. 96,750. After invitation of tender, the Undertaking accepted the tender of M/s. ISGEC at the cost of Rs. 2.8 lakhs. The tender was subsequently increased to Rs. 3.14 lakhs due to some additional items of work allotted. The firm was to complete delivery within nine months from the date of the receipt of the order, clearance of technical details and receipt of approved drawings etc. Because of frequent revision of drawings by the Fertilizer Corporation of India at the instance of the firm there was a delay in completing the supplies and the supplies were actually received by the Undertaking on 31st May, 1973. As a consequence of this delay, the Undertaking had to bear an extra expenditure of nearly about Rs. 5 lakhs during 1969-70 to 1971-72 by way of price differential between supply of cylinders and tank wagons. The Committee note that one of the considerations for the selection of this firm was its past experience and standing in the fabrication of pressure vessels. It is surprising that the Fertilizer Corporation which recommended the award of work to this firm stated that their experience with the firm was in no way unique and they had similar problems with them. The Committee fail to understand as to how, in spite of their experience with the firm they had recommended the firm to the Undertaking.

The Committee were informed that the storage tank had since been erected and trials were in progress. A sum of Rs. 30489 was held back and the question of levying penalty for delay in delivery was under consideration. The Committee recommend that the matter should be fully investigated and the Committee apprised of the results.

(Paras 3.159 and 3.160)

Reply of Government

The observations made by the Committee have been noted. The matter is being examined in consultation with Fertilizer Corporation of India and the IDPL.

The tanks have since been commissioned and put to use and they are functioning quite satisfactorily. For the delay in supply 5 per cent of the ordered value was recovered towards liquidated damages as penalty as per the provisions of the purchase Order and transaction was treated as closed. The security deposit is being released to the firm.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 10-2-1975]

Recommendation (S. No. 56)

The Committee note that the plant had 5,000 million tabletting capacity per annum. In reply to an earlier recommendation of the Committee (para 3.39 of their 46th Report 1968-69 4th Lok Sabha, the Ministry of Petroleum and Chemicals had informed the Committee in November, 1970 that after taking into account stand by capacity and time required for change over from one product to another, effective capacity of the tabletting would be 3051 million tablets per year based on two shifts machines working. The Committee find that in September, 1973 the achieveable capacity was reduced to 2,000 million tablets per annum keeping in view the change in the product mix size of the tablets, physical characteristics, capacities at various stages like mixing, granulation and drying. The Committee find that as against these capacities, the product mix indicated in the Project Report for formulation was only 666 million tablets per annum. It will thus be seen that the management has been revising the formulation capacity downwards from time to time.

The Committee also note that actual production fell short of even the reduced capacity. The percentage of actual formulation to capacity (3000 million tablets) ranged from 9 per cent in 1968-69 to 60 per cent in 1972-73. The Committee were informed that the plant is now working at a capacity of 2,000 million tablets per annum and production of formulation during the year 1972-73 is of the order of 1731 million tablets.

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The Committee regret to note that the economics of formulation section on the basis of reduced capacity of 2,000 million tablets per annum has not been worked out, as it is stated it would vary greatly with the product-mix. The Committee were also informed that plant is being allowed imports or releases of bulk drugs imported through STC to enable them to take up formulations based on new products. As the main margin of profit is in formulations, the Committee stress that Undertaking should carefully assess demand of drug and medicines commonly in demand and on which foreign firms are making sizeable margins so as to undertake their manufacture marketing at the earliest and thus bring about more competitiveness in drugs and bring down the rates.

(Paras 3.186—3.188)

Reply of Government

The recommendation has been noted for guidance and compliance. Please also see reply to recommendation No. 25. The profitability of the plants including the formulation activities will be worked out as recommended by the Committee in its Recommendation No. 31.

The plant has developed new formulations, namely, Sukcee (Vitamin C in chewable tablets) Calmod (Diazepam) Compeba (Metronidazole) Cebaxin (Vitamin B Complex Forte with Vitamin C) in competition with foreign and other Indian units. Further development of new formulations is in progress. IDPL are already marketing the following formulations, namely, APC, APC with Codeine, Apidin, Cemizol, Hexavitamin/Hexavit, Multivitamin, Cough tablets and Primaquine Phosphate, in competition also with foreign firms.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 4-12-74]

Recommendation (Sl. No. 57)

The Committee in paragraph 5.3 of their 46th Report (1968-69) on IDPL had pointed out that the estimates of the Surgical Instruments Plant had been revised 5 times during a period of 8 years from 1961 to 1968. The Committee note that estimates revised in August, 1968 were approved by Government in August, 1971 for Rs. 464.71 lakhs as against the estimate for Rs. 476.69 lakhs approved by Government in October, 1966 for the first time. The Committee find that the actual expenditure up to 30th September, 1973 was Rs. 469.66 lakhs which is more than even the final estimate approved by Government. Apart from the increase of over Rs. 2 lakhs in administrative and general expenses the Committee find that there has also been an excess of over Rs. 2 lakhs on Plant and equipment. The Committee are surprised that estimates revised and approved

in 1966 i.e. after the plant had been commissioned had again to be revised in August 1968 and approved by Government in August 1971 and the actual expenditure had however exceeded the approved estimates of 1971. The Committee are not sure whether even now the liabilities to be adjusted against the project had been taken into account and there would be no further revision of project estimates. The Committee would like to be informed of the position.

(Para 4.6)

Further Reply of Government*

All works included in the project estimates have been completed and capitalised. No liabilities against these works are pending and as such the expenditure on the project already reported is final.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 30-10-1974]

Recommendation (Sl. No. 58)

The Committee regret to note that SIP was commissioned in September, 1965 to produce 2.5 million instruments for stock without a proper market survey with the result that the instruments did not command a ready indigenous market because of high prices, restricted number of varieties and pattern of instruments not carrying conviction with Indian Surgeons. Consequently the Plan was faced with an accumulated stock of Rs. 2.57 lakhs at the end of March, 1968. The Committee find that in April, 1966 a market survey was conducted by the NCAER. Subsequently in 1967-68, the Marketing Division of IDPL conducted a "Quick Demand Survey". According to both these surveys, the original product mix in the DPR needed to be modified. In 1967-68, a Committee of Surgeons recommended that only about 25 per cent of the original product-mix could be acceptable in the Indian market and the remaining are either to be modified or given up and instead new types of instruments were to be developed. No exercise was done by the Company to determine the rated capacity of the Plant in the light of the changes in product-mix based on this survey till May 1972 when the rated capacity was brought down from 2.5 million instruments to 1 million instruments and Rs. 30 lakhs of job orders.

The Committee were informed that the reduction in the rated capacity was not placed before Government for approval.

It has been admitted by the Management that "The market demand for surgical instruments in the country is not expected to meet

*Not vetted by Audit.

fully the break even requirements of the Plant". The Committee are of the opinion that all the problems of the Plant are due to the absence of a market survey before deciding upon the product-mix for this plant. The Committee feel that even now it is not too late to ascertain the types of surgical instruments which would be suited to the Indian market and re-determine the existing product-mix suitably so as to make the plant economically viable.

The Committee would like Government to go carefully into the question of export possibilities from this plant to East European and other countries and have a long term arrangement so that the built-in capacity which is surplus to requirements can be put to profitable use. The Committee would like to be informed within six months of the concrete steps taken in pursuance of this recommendation.

(Paras 4.22 to 4.25)

Reply of Government*

A Committee consisting of Adviser (Medical), Chief Marketing Manager and the General Manager of the Surgical Instruments Plant has investigated the demand for surgical instruments in the indigenous market and a total of 289,000 instruments is expected to be produced during the current year. In addition job works to a value of Rs. 10 lakhs will be executed during the current year.

The Company has been asked to place before the Board for its consideration notes in regard to reduction in the rated capacity as well as the demand now estimated by the Committee referred to above.

A note on the instruments produced at the plant and their prices etc. has been circulated to the Indian Embassies in Europe and USA to explore the possibilities of their exports to these countries. The Company on their own also are exploring such possibilities.

[Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 8-11-1974]

Further information asked for by the Committee

(a) What will be the utilisation and is there any improvement as a result of the investigation made by the Committee consisting of Adviser (Medical), Chief Marketing Manager and the General Manager of Surgical Instruments Plant into the demand for surgical instruments in the indigenous market?

*Not vetted by Audit.

(b) Has the IDPL placed before the Board and the Government for consideration notes in regard to the reduction in the rated capacity. What is the result of the consideration of the Board and the Government? Please state in detail indicating whether the reduction in the rated capacity was justified.

(c) What specific action has been taken by IDPL/Government for exploring the possibilities of export of Surgical Instruments of IDPL to East European and other Countries? Please state in detail.

[LSS O.M. No. 26-PU/74 dt. 21-5-75]

Further Reply of Government

(a) The production plan for 97 types of instruments was drawn up in July, 1974. However, this could not be fulfilled because of the power cut imposed by the Tamil Nadu Government. This power cut ranging from 2/3rd to complete power cut in that area also affected the export agreement for the instruments numbering 296,000 valued at Rs. 33,71,640. Out of this agreement, only 123,000 instruments worth Rs. 12,34,780 could be supplied.

(b) There has been no reduction in the rated capacity. However there has been change in the product mix. The earlier higher capacity of production pertaining to simpler items whereas the present rated capacity of 1 million instruments is for a specific product mix.

(c) The Ministry of Petroleum and Chemicals have issued circular letters to the Indian Embassies located in East European and other countries. Accordingly, the IDPL received enquires from a few Embassies and have also submitted to them their quotations together with samples. Negotiations are afloat and IDPL are awaiting orders. However, the Plant Committee has also pointed out that the export might not be remunerative as the international prices are low and have stated Pakistan Industry is being subsidised to the extent of 40 per cent for export of surgical instruments.

[Min. of P&C O.M. No. 8(25)/74—Ch. III, dt. 10-8-75]

Comments of the Committee

Please see paras 126 and 127 of Chapter I of the Report.

Recommendation (Sl. No. 59)

The Committee note that the Surgical Instruments Plant was commissioned in September, 1965 and was designed to produce 2.5 million surgical instruments of 166 types according to the Detailed Project Reports. As only 46 types were acceptable to the Indian Market, the Plant was faced with the problem of unsold stock worth Rs. 25 lakhs. In July, 1967 the Board of Directors decided that no further production should be undertaken unless there were definite orders for the same. The Committee find that since the Plant was essentially designed for bulk production of small number of intsruments and the orders received by the Plant were only in small lots, with the results there was diversion of customers to other sources. Since 1970-71 the Plant had been mainly dependent on export orders. The Committee recommend that as the Plant is designed to produce large bulk of a restricted number of varieties of instruments, the Government/IDPL should pool in coordination with the State Governments, the requirements of Surgical Instruments for the Government Hospitals all over India so that the Plant can take up the production of such instruments in economic lots. This may be of some help in finding orders for the utilisation of the existing capacity of the Plant.

(Para. 4.38)

Reply of Government*

The question of assessment of surgical instruments required by Hospitals, etc. has been taken up with the Ministry of Health & Family Planning. In the meantime, as already mentioned in reply to recommendation No. 58, demand survey of instruments has been made by a Committee of IDPL and the programme for 1974-75 envisages the manufacture of 97 types of instruments including 68 newly developed and 29 types of instruments from the original product-mix of 166 types.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dt. 8-11-1974]

Further information asked for by the Committee

(a) Has the IDPL/Government taken up with State Governments the question of assessment of surgical instruments required by Hospitals etc. all over India? If so, what is the outcome thereof? Please state in detail.

(b) It is stated that a demand survey of instruments has been made by a Committee of IDPL and the programme for 1974-75 envisages the manufacture of 97 types of instruments including 68 newly

*Not vetted by Audit.

developed and 29 types of instruments from the original product-mix of 166 types.

What about the remaining types of instruments?

(LSS O.M. No. 26-PU/74 dt. 21-5-75)

Further Reply of Government

(a) It is extremely difficult to earmark specific requirements on yearly basis as the same are changing. However, the State Governments have been asked to issue directives to their respective departments to buy their requirements only after obtaining a non-availability certificate from IDPL. A few State Governments have already issued such instructions.

(b) The Company had already constituted a Committee which gave its findings that certain diversification has to be done. For further scrutiny, these reports have been submitted to the Director General, BPE. In the meantime, Government has also appointed a Committee to study the working of surgical instruments Plant, in pursuance of the recommendations made by the Committee on Public Undertakings.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 10-8-1975]

Comments of the Committee

Please see paras 126 and 127 of Chapter I of the Report.

Recommendation (Sl. No. 60)

The Committee also find that actual production of the SIP fell short of the planned production in all the years and under all the categories despite the fact that the planned production itself was much lower than the reassessed capacity of one million pieces of instruments. Apart from the disturbed labour situation the shortfall in production particularly during 1971-72 has been attributed to production deficiencies especially in the Assembly and Grinding shop. The Committee also find that though no production was planned for a number of items yet the actual production thereof was undertaken. Similarly production of a number of items was also more than the planned targets. In this connection it has been admitted by the Management that "this incidentally will continue to be a feature so long as a fairly stable production is not achieved." The Committee recommend that in the interest of stabilising production, existing

system of planning and control of production should be placed on a more rational feeting so that the Plant is in a position to plan its production keeping in view the pattern of demand in the country.

(Para 4.39)

Reply of Government*

The plant did not have the advantage in the past to have sufficient lead time for planning the production and keep the drawings and toolings ready in time. This has resulted in planning for items on emergency basis resulting in turn in taking for production items for which materials were available in hand.

The recommendation for putting the planning and control of production on a more rational basis has been noted for implementation. Presently a sales projection is under way and this should ensure a continued production of a few specific types of instruments in large quantities. The plans for 1974-75 drawn up by the Committee of the Company mentioned in reply to recommendation No. 58 has been taken into account for proper planning of the production.

[Min. of P & C O.M .No. 8(25)/74-Ch. III dt. 8-11-1974]

Recommendation (Sl. No. 62)

The Committee note that the SIP has not been able to use all the machine in the Plant. The Committee regret to note that no machine utilisation statements were prepared by the plant till 1970-71. It has been reported that, at the end of August, 1972, the plant had 15 surplus machines valued at Rs. 9.35 lakhs awaiting disposal. The Committee understand that the management had already circulated the list of surplus machines to all the public sector undertakings and also given necessary publicity in "Lok Udyog". The Committee hope that the plant would be able to dispose off the surplus machinery soon in the best interest of the unit.

(Para No. 4.69)

Reply of Government*

Efforts for the disposal of surplus machines are continuing. All representatives of public undertakings visiting the plant are also given the lists of the surplus machines with complete specifications to enable them to procure them if need be. So far however there has been no disposal.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 8-11-1974]

*Not vetted by Audit.

Further information asked for by the Committee

What specific efforts are being made by IDPL/Government for the disposal of 15 surplus machines valued at Rs. 9.35 lakhs and what is the result thereof? Please state in detail.

(LSS. O.M. No. 26-PU/74 dt. 21-5-75)

Further Reply of Government

A list of 15 equipments which have been declared surplus for disposal was circulated to various public sector undertakings and an advertisement was also given in the leading dailies. The response received against the advertisement was however not encouraging. Efforts are still being made for disposal.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 10-8-1975]

Comments of the Committee

Please see para 137 of Chapter I of the Report.

Recommendation (Sl. No. 63)

The Committee note that in order to utilise idle capacity available with the plant, the plant had been accepting job orders. Job Orders accepted ranged between Rs. 1.55 lakhs and Rs. 12.76 lakhs during 1966-69 to 1971-72 as against the capacity of Rs. 30 lakhs. The Committee find that the costing of the job orders had been defective in that the value of the jobs executed did not include the direct labour cost which was being treated as part of the fixed cost with the result that cost total of orders had not been correctly worked out.

The Committee recommend that the procedure of job costing which is being followed so far should be reviewed and put on more scientific line so that the true cost of the job is available for effecting recoveries.

(Para 4.70)

Reply of Government*

The procedure for job costing has been reviewed and with effect from May, 1974, offers for job orders are made on the basis of Direct labour, Direct material, Factory overheads plus 30 per cent extra of the Direct labour and overheads. Cost sheets of job orders reflect the expenditure incurred under all the elements referred to above.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 8-11-1974]

*Not vetted by Audit.

Recommendation (Sl. No. 64)

The Committee find that as a part of diversification programme the Surgical Instruments Plant had taken up the manufacture of family planning instruments. An analysis of production performance indicates that the production of Family Planning Instruments has declined from 1.60 lakhs in 1968-69 to 30,000 in 1972-73. The percentage of these instruments with reference to total instruments produced come down sharply from 68 per cent in 1968-69 to 4.4 per cent in 1972-73. The Committee were informed that based on past experience, Management assessed the requirements for Family Planning instruments not exceeding Rs. 15.20 lakhs per annum, out of which share of surgical instruments plant would be around Rs. 10.12 lakhs per annum. This would work out to 10-12 per cent of the total production of instruments (1 million capacity). The Committee recommend that Government should pool their requirements for Family Planning instruments in advance so that there is steady flow of orders and the plant is able to utilise its spare capacity to the maximum extent possible. The Committee would like Government to take up the matter with the State Governments "the interest of securing firm orders for Family Planning Instruments."

(Para 4.71)

Reply of Government*

The production of Family Planning Instruments declined from 1.6 lakhs in 1968-69 to 30,000 in 1972-73 because of diversion of capacity to meet the export orders from Russia. The production of family planning instruments during 1973-74 was 24,223 valued at Rs. 2,292,17/-. It may be mentioned that the emphasis, in the family planning programme has since shifted to other methods like Norodh and pills etc. and this has affected sale of instruments. Also earlier, supplies of family planning kits were being made while now only individual instruments are required. During 1974-75, the programme of the plant is to manufacture 36,300 instruments valued at Rs. 5,95,900/-.

The Company has already approached the Central Government Departments in regard to the orders for family planning instruments being placed on Indian Drugs & Pharmaceuticals Limited. They have also approached State Governments, for the issue of necessary directives to their departments for purchase of instruments from IDPL without calling of quotations.

*Not vetted by Audit.

The assessment of requirements of family planning instruments has also been taken up in consultation with the Ministry of Health and Family Planning.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 30-10-1974]

Further information asked for by the Committee

What is the result of approaching the State Governments for the issue of necessary directives to their Departments for purchase of instruments from IDPL without calling of quotations? Please state in detail indicating the latest position.

(LSS O.M. No. 26-PU/74 dt. 21-5-75)

Further Reply of Government

Please see reply to S. No. 59.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 10-8-1975]

Comments of the Committee

Please see paras 126 and 127 of Chapter I of the Report.

Recommendation (Sl. No. 67)

The Committee note that so far no standard cost has been worked out in respect of the products of Surgical Instruments Plant and only a system of job costing is in vogue by which the cost of production of each type of instrument is worked out. The Committee find that even under the system of job costing, the cost of production of all instruments in 1970-71 was higher than the selling prices both in respect of local sales and also for external market. The Committee were informed that during 1971-72 the sale value covered the direct cost although in 1972-73 there were as many as 20 items whose selling prices did not cover even the prime cost of production. The main reasons for such a situation were stated to be that fixed overheads of the Plant were of the orders of 42 per cent of the breakeven expenditure of Rs. 160 lakhs; the selling prices have been following a uniform pattern for the indigenous as well as for exports in spite of abnormal increase in the cost of material and wages. Lower productivity in grinding and Assembly shop is also stated to be one of the reasons for high cost.

The Committee find that there is a wide variation as between the total cost of production and the selling prices of various instruments.

The Committee recommend that the plant should take concerted measures to bring down the cost of production and raise the level of productivity, particularly in the Grinding and Assembly shop.

(Para 4.101)

Reply of Government*

The prices of instruments were revised with effect from the Ist May, 1974 and in this full costs including depreciation and interest are covered for 11 types of instruments, and overhead charges partially covered in respect of 76 other items.

As regards raising the level of productivity and also reducing the cost of production, the Government proposes to appoint a Committee/ Consultant to examine all aspects of the Plant.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dt. 10-2-1975]

Further information required by the Committee

Has the Committee/Consultant been appointed? If so, when and what are the terms of reference? Has the Committee/Consultant submitted its report, if so, the salient features thereof and the action taken by Government/IDPL thereon, and if not when is it expected to submit its report?

(LSS O. M. No. 26-PU/74 dt. 21-5-75)

Further Reply of Government

After detailed consideration and in consultation with the Planning Commission, a Committee consisting of the following was set up in this Ministry's Memorandum No. 8(85)/74Ch. III dated the 27th June, 1975:—

1. Shri H. R. Verma, Director (Engg) Planning Commission.
2. Shri Bazle Karim, Adviser (Production) BPE.
3. Shri K. N. Ramaswamy, IA, DGTD.
4. Shri M. S. B. K. Rao, Tech. Manager, Hindustan Tele-Printers Limited, Madras.
5. Dr. P. P. Goel, Consultant in Surgery, Safdarjang Hospital, New Delhi.
6. Dr. B. N. Sinha, 9—A. P. Sen Road, Lucknow (U.P.)
7. Shri Inderjit Singh, N—246, Greater Kailash, New Delhi.

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*Not vetted by Audit.

8. Shri S. K. Sachdeva, FA&CAO, IDPL, N—12. NDSE, Part—I, New Delhi-110049.
9. Dr. Kameswaran, Director, ENT, General Hospital, Madras.
10. Representative of Min. of Finance (Cost Accts. Br.).
11. Representative of Association of Surgeons, Madras.
12. Shri R. Grover, Director, Min. of P & C—Convenor.

The terms of reference are as follows:—

(i) To examine the working of the Surgical Instruments plant to identify the areas where the cost of production can be reduced and to suggest viable selling prices for each type of instrument;

(ii) To examine the adequacy of technical build up and organisation of the plant to achieve the capacity envisaged by the Management;

(iii) To examine the economics of the plant, scrutinise its product mix *de-novo* to increase the prospects of increasing sale of instruments in the domestic markets so as to make the plant economically viable;

(iv) To explore the scope for diversification and for exports to other countries at remunerative prices;

(v) To examine the adequacy of the present Management both administrative and technical, productivity level of workers adequacy of the present systems of management and to suggest scope for improvement, administrative reorganisation, etc., and

(vi) To suggest future set up for the plant.

The Committee is required to submit its report within three months.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 10-8-1975]

Comments of the Committee

Please see para 150 of Chapter I of the Report.

Recommendation (Sl. No. 68)

The Committee find that the prices of Surgical Instruments were fixed in 1966 on the basis of estimated cost of 1966-67 when only a fraction of the capacity of the Plant could be utilised. The prices

were consequently very high compared to the corresponding instruments manufactured in the private sector. It has been claimed by the company that Instruments of this plant were superior in quality. The Committee regret to note that inspite of the revision of the prices of instruments substantially in July, 1967, taking into account changes in product mix, current cost and market prices, the selling price continue to be lower than the cost of production in all items except one and the extent of difference in the case of individual instruments varied from Rs. 2.24 to Rs. 206.20.

The Committee are not however convinced that the cost of production was high due to lack of orders. The Committee have already pointed out elsewhere in this Report that the plant had pending orders worth lakhs of rupees which could not be executed. The Committee fail to understand as to why in spite of existence of such orders, there had been shortfall in production leading to under-utilisation of capacities with consequential higher cost of production.

The Committee also find that during 1972-73 the plant produced 2892 instruments (code No. 05-01) at a total cost of 55.60 rupees per instrument and sold the same at only Rs. 11 per instrument. The prime cost of this instrument was stated to be Rs. 12.93. There are number of other instruments where the selling price was not only far below the overall cost of instruments but did not cover even the prime cost of the instrument. The Committee feel that if selling prices continue at the present level without any reduction in cost of production the working of the plant cannot be expected to become economically viable in the near future. The Committee, therefore, recommend that a high power Committee should be appointed to go into the entire working of the Surgical Instruments plant to identify the areas where the cost of production can be reduced and to suggest viable selling prices for each type of instruments, including scope for diversification.

(Para 4.102)

Reply of Government*

A Committee of the type suggested by COPU is proposed to be appointed shortly. That Committee would also go into the cost aspects of the products of Surgical Instruments Plant with a view to formulating norms for fixation of realistic sale prices.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 8-11-74]

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*Not vetted by Audit.

Further information asked for by the Committee

Has the said Committee since been appointed, if so, when and what are its terms of reference? When is the Committee likely to submit its report?

(LSS O.M. No. 26-PU/74 dt. 21-5-75]

Further Reply of Government

Please see reply to Sl. No. 67.

[Min. of P & C O.M. No. 8(25)/74-Ch. III dt. 10-8-75]

Comments of the Committee

Please see para 150 of Chapter I of the Report.

Recommendation (Sl. No. 70)

The Committee find that the plant is holding huge stocks of raw materials, stores and spares, compared to the overage annual rate of consumption. The stock of indigenous raw materials as on 31st March, 1973 represented 150 months consumption while the indigenous stores and spares 144 months consumption. The stock of imported raw materials represented 5 months consumption while the stock of imported stores and spares represented 100 months consumption. An analysis of some of the individual items indicated that stainless steel and alloy steel valued at Rs. 40 lakhs imported from USSR during 1965-66 to 1967-68 had been lying unused. It was stated that this had been ordered even before the plant went into production taking into account the product mix and capacity envisaged in the project report.

The Committee regret to note that even though the unit came into existence in September, 1965 no maximum and minimum limits have been fixed for the items. It has been indicated that the original stocking of spares was based on the advice of the collaborators and because of less utilisation of the equipment there has not been much out-go or replacement of the spares.

The Committee were informed that a Technical Committee had been appointed early in 1973 to go into the requirements of the spares and assess the inventory holdings under three categories (a) insurance items (b) stores which may be possibly required during the next five years; and (c) spares which could be straightway declared as surplus and disposed of.

The Committee were also informed that this Technical Committee have now recommended declaration of stores worth Rs. 50,000/- as surplus and the management is now taking action for their disposal and also maximum and minimum limits have been fixed in respect of certain items. The Committee recommend that the Technical Committee should complete its work soon and identify stores which are really surplus to the requirements so that the undertaking can take immediate action to divert the surplus to more profitable use to other undertakings or dispose them of to the best interest of the undertaking. The Committee would like that Management should take action to fix maximum and minimum limits for all the stores without further delay so that the risk of high inventory holding is avoided.

The Committee find that stainless steel and alloy steel valued at Rs. 40 lakhs imported from USSR during 1965-66 to 1967-68 had been lying unused. The Committee are not sure whether the stainless steel and alloy steel has been used or disposed of. The Committee would like to be informed of the latest position.

(Para 4.113-4.114)

Reply of Government*

The Technical Committee has not yet finalised the requirement of spares and assessed the inventory under the three categories indicated. The necessary action on the basis of their recommendations will be taken by the plant management, and the maximum and minimum limits will be fixed.

A statement showing the inventory of imported stainless and alloy steels lying unutilised is attached. It will be seen therefrom that the inventory of Rs. 40 lakhs as on 31-3-1972 has been reduced to Rs. 37.72 lakhs as on 31-3-73 and Rs. 35.19 lakhs as on 31-3-74 and to Rs. 34-44 lakhs as on 31-8-74.

Out of the stock of Rs. 34.44 lakhs, materials to the extent of Rs. 10.72 lakhs have been declared as surplus as they were not required by the plant. The list of surplus stores/materials has been circulated to all the public sector undertakings and Defence organisations. The disposal of these stores would also require the buyer to obtain the permission of the Import Control authorities. Deducting the value of surplus stores, the value of stock items will be

*Not vetted by Audit.

Rs. 23.72 lakhs which represents 24 to 60 months consumption depending on the product mix.

Imported raw materials (stainless & alloy steel)
(Value in lakhs)

Sl. No.	Description	As on 31-3-72	As on 31-3-73	As on 31-3-74	As on 31-8-74
1.	H.R. Stainless Steel . . .	8·10	6·64	6·09	5·70
2.	C.R. Sheet	3·15	3·06	3·01	3·00
3.	Alloy Tool Steel	13·17	12·70	11·49	11·47
4.	Silver Steel	16·50	15·32	14·60	14·27
		40·92	37·72	35·19	34·44

[P&C Min. O.M. No. 8(25)|74-Ch. III, 8-11-1974]

Further information asked for by the Committee

(a) Has the Technical Committee which was appointed in early 1973 to go into the requirements of the spares and to assess the inventory holdings under the said three categories, submitted its report? If so, what are its salient features and what follow up action has been taken thereon. If not, when is the Committee likely to submit its report and what are the reasons for such a long delay?

(b) The statement showing the inventory of imported stainless steel and alloy steels lying unutilised, stated to have been attached with the reply to this recommendation has not been received. Please furnish requisite number of copies thereof.

(c) What is the latest position of the disposal of stainless steel and alloy steel? Why such a huge quantity thereof was imported at all?

(d) Even now the 24 to 60 months consumption is examined. Please comment.

(LSS O.M. No. 26-PU/74 dated 21-5-75)

Further Reply of Government

(a) The Technical Committee went into the study of non-moving stores and have listed out items worth Rs. 53,314 to be disposed of.

All the spares available other than one item (Piston rods for drop forge hammers) are considered as insurance items.

(b) The Statement showing the inventory of imported stainless steel and alloy steels lying unutilised is attached at Appendix X.

(c) The stainless steel and alloy steel was imported originally based on the product-mix and the capacity envisaged in the project report. However every effort is being made to dispose of these surplus items. Recently, we have advertised for sale and tenders are yet to be opened.

(d) Since the product-mix has not yet been established, the inventory figures appear to be excessive. IDPL have taken suitable steps to dispose of these items. In this connection, a separate cell has already been formed for the disposal of surplus items.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dated 10-8-1975].

Comments of the Committee

Please see para 160 of Chapter I of the Report.

Recommendation (Sl. No. 71)

The Committee note that the percentage of labour efficiency has increased from 21.85 per cent in 1968-69 to 69.27 per cent in 1971-72, correspondingly the value of production per employee has also increased from Rs. 1292 in 1968-69 to Rs. 6328 in 1971-72. The increase in productivity was however accompanied by an increase in salaries and wages, per employee. The Committee, find that the percentage of labour efficiency has decreased to 68.49 in 1972-73 and the idle time has also increased to 6645 hours in 1972-73 as against 3797 hours in 1971-72. The Committee regret to note that though the overall man-hours available were more than the standard hours and production was less than the plan targets, heavy expenditure on honorarium was incurred during 1970-71, 1971-72 and 1972-73. The Committee were informed that increased payment of honorarium was due to the need to diversify the production in Surgical Instruments Plant and job orders which pose an urgent problem to man more equipment days with the existing staff.

The Committee need hardly stress that with the increase in labour efficiency and in the level of technical skill developed during the course of years, it should be possible for the Undertaking to keep the

expenses on honorarium to the minimum. The Committee recommend that staff already available should be usefully desployed for productive purposes so as to improve the labour efficiency and obviate the necessity for payment of honorarium.

(Para 4.126).

Reply of Government*

Payment of honorarium to the workers has since been stopped. No honorarium was paid during 1973-74.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dated 8-11-1974].

Further information asked for by the Committee

(a) As recommended by the Committee on Public Undertakings in their recommendation, has the staff already available been usefully deployed for productive purposes so as to improve the labour efficiency and obviate the necessity for payment of honorarium?

(b) If so, has there been any improvement in labour efficiency and utilisation of labour for productive purposes? Please state the latest position.

(LSS O.M. No. 26-PU/74, dated 21-5-1975).

Further Reply of Government

Payment of honorarium has been stopped in 1973. The useful deployment of labour with efficiency can be obtained only when requirements of mass production technology are met with. The major requirement for this is a steady product-mix. Production has to be market oriented and as there is not sufficient market for the surgical instruments diversification programme has already been taken up.

[Min. of P&C O.M. No. 8(25)/74-Ch.III, dated 10-8-1975].

Recommendation (Sl. No. 73)

The Committee find that although the Surgical Instrument Plant should have come within the purview of the Employees State Insurance Act, 1948 as early as September, 1965 and should have atleast registered itself under the Act with effect from June, 1966 when it was asked by the Employees State Insurance Corporation to do so, it actually decided to implement provisions of the Act only in April, 1967. The result was that the Unit had to pay an amount of Rs. 1.16 lakhs as arrears of contributions from September, 1965 to October,

*Not vetted by Audit.

1967. The Committee need hardly point out that had the Company brought the Surgical Instrument Plant within the scope of the Act right from the beginning, it would have avoided an expenditure of Rs. 77,331 incurred by it on reimbursement of medical expenses under the company's rules. The Committee were informed that delay in the registration of the Unit under the act was on account of the medical facilities provided by the Unit being more favourable to its employees than would be available under the Act.

The Committee feel that because of the delay in the implementation of the statute payment of medical expenses to the extent of Rs. 77,331 has become avoidable.

(Paras 4.136, 4.137)

Reply of Government*

The observation made above has been noted for guidance in order to avoid such lapses in future.

[Min. of P&C O.M. No. 8(25)/Ch.III, dated 8-11-1974].

Recommendation (Sl. No. 74)

The Committee note that the prices of products of the Antibiotics Plant and the Synthetic Drugs Plant were fixed for drugs likely to be on sale in 1968 on the basis of the then ruling maximum prices in the market, even though the cost of production at that time warranted higher prices. The Undertaking had, however, to reduce the prices to lower levels and to sell the products at reduced prices to secure fair span of the market. With the tapering of imports, the Company was able to progressively increase its prices of Sulphas and penicillin when the Drugs (Prices Control) Order came into effect from the 16th May, 1970 and certain drugs were defined as "essential bulk drugs". The prices of bulk drugs were, however, frozen at the rates ruling on 15th May, 1970. The Committee was informed that the prices fixed did not take into account the actual cost of production in the Antibiotics Plant with the result that the recommendations of the Drugs (Price Control) Order proved uneconomical to I.D.P.L. A similar difficulty was also felt in the case of Synthetic Drugs Plant since the process of rationalisation of the prices had not been com pleted. There had also been a number of escalations in the prices of raw materials, wages, services etc. As bulk drugs are sold mostly to the private sector for formulation purposes the Committee feel that

*Not vetted by Audit.

as a result of transfer of bulk drugs to formulators in the private sector, they were allowed to earn a greater margin of profit.

The Committee also note that the Company approached Government for fixing the selling prices after taking into account its ultimate cost of production including return on capital. The Committee understand that on the 11th September, 1970, Government constituted a Working Group of Bureau of Industrial Costs and Prices for settling the cost structure on 25 bulk drugs and to recommend fair selling prices therefor. The Committee regret to note that though the recommendations of the Bureau were received by Government as far back as October, 1972. Government took an unduly long time in taking a decision on these recommendations.

In one of the Inter-Ministerial Meetings held on 7th December, 1973, it was decided by the Government that the Bureau should advise on the revised selling prices, keeping in view the current costs of raw materials and other pharmaceuticals aids and services.

The Committee need hardly emphasize that IDPL should improve efficiency and effect economics to make their products most competitive.

(Paras 5.22, 5.23, 5.24 and 5.25)

Reply of Government

Government have since taken a decision on the Report of the Working Group constituted under the Chairmanship of the Chairman, BICP in so far as the revision of prices of bulk drugs and revision of norms for conversion costs and packaging are concerned. These cover the specific terms of reference to the Working Group. A statement on this was laid on the Table of the Lok/Rajya Sabha on the 19th/24th April, 1974. Other recommendations which the working group has made under the residuary terms of reference are under examination of Government.

Government have also allowed increases in prices further on the basis of the recommendations of the BICP to the extent of increases in the cost of raw materials. A statement indicating the previous prices and the present selling prices of drugs in the range of the IDPL is attached at Appendix XI. The revised prices are expected to improve the economics of the Plants.

Efforts are being made to secure improved technologies and strains. With this aim in view, a team consisting of Deputy, DGTD, Adviser (Drugs) Ministry of Petroleum and Chemicals and the Managing Directors of IDPL and HAL visited various countries from the last week of February to the first week of April, 1974. The matter is being further pursued with the parties who showed positive response.

[Min. of P&C O.M. No. 8(25)|74-Ch.III, dated 30-10-1974]

Comments of the Committee

Please see para 166 of Chapter I of the Report.

Recommendation (Sl. No. 76)

The Committee note that the marketing organisation of I.D.P.L. was set up in March, 1967 for the purpose of carrying out market surveys and undertaking distribution of the products of the plants. As a result of Government's decision to entrust to the Company distribution of imported drugs within the production range of the Company, the activities of the Marketing Division were expanded in 1970-71 to include the sale and purchase of imported drugs as well. With effect from 1st January, 1971 marketing activities of surgical instruments were transferred back to the Surgical Instruments Plant, Madras. The bulk products and intermediate chemicals are generally sold by the plants to the pharmaceuticals/chemicals companies. In the case of imported bulk, however, the sales are centralised at Bombay Depot of the Company. The sale of pharmaceuticals formulations to Government institutions is mainly through rate contracts entered into with D.G.S. & D/State Governments etc. The sales to trade are, however, executed by the regional offices through distributors. The total staff strength of the Marketing Division as on 31st March, 1973 was 364 (including 49 officers). The Committee recommended that organisational set up and arrangements for the sale of I.D.P.L. products may be kept under-review and improvements effected from time to time so as to push up the sales of I.D.P.L. products in the best interest of the Company and at the same time keep the selling cost to the minimum.

(Para 6.11).

Reply of Government*

The recommendation of the committee have been noted for guidance. As recommended by the Committee *vide* recommendation No. 78 the company is effecting a change in the marketing of Indian Drugs and Pharmaceuticals Limited products. The effort is now to secure

*Not vetted by Audit.

increased share of the trade sales. For this purpose, field staff is being strengthened and the number is likely to increase to 200 by the end of 1974.

[Min. of P & C O.M. No. 8(25)/74-Ch.III, dated 30-10-1974].

Recommendation (Sl. No. 78)

The Committee find that during 1972-73, IDPL's sales were 62.4 per cent of bulk and 37.6 per cent of formulations. Out of its total sales of formulations, the percentage sale to Government Departments was 80.6 per cent and to trade 19.4 per cent during that year. The Committee further find that during 1973-74 (up to November, 1973) the percentage sales to Government Departments was 72.3 per cent and to trade 27.7 per cent. The Committee recommend that IDPL should strive to change its sales pattern so as to increase the percentage of its sales to the trade and reduce its dependence on the purchases by Government Departments.

(Para 6.16)

Reply of Government

The IDPL as already mentioned in reply to recommendation No. 77 is already taking steps to secure a better share of the trade sales. Greater emphasis is being placed on the sale of items such as analgin in the trade market which have a better margin of profit. More sophisticated formulations are being introduced under brand names to capture share of trade market.

Simultaneous introduction of a number of products is undesirable as it affects the sale of products and the 'detailing time' allowed by the medical profession to a representative is limited making it difficult to handle too many products at the same time.

However, the IDPL propose to introduce gradually a number of formulations indicated below:—

Ampicillin capsules & injection

Idifulvin (Griseofulvin)

Compeba (Metronidazole)

Cabexin (B-Complex Plus C)

Doxycycline Capsules

Sulphamethaxazole plus Trimethoprim

Indomethacin Methyl Dopa

Frusemide Tablets & Injection

Prenylamine lactate.

[Min. of P&C O.M. No. 8(25)|74-Ch.III, dated 30-10-1974]

Recommendation (Sl. No. 79)

The Committee find that with a view to exploit the vast trade market, IDPL has introduced some branded products like Apidin, Cemizol and Hexavit, Sulphadimidine, Sulphaguanidine and Chloroamphenicol. The Company has also introduced its first liquid injectable product under the brand name 'OTCIM' for sale to the trade. The Committee have been informed that a number of new drugs are under development and are likely to be introduced by the end of 1973-74 or in the early of 1974-75.

While the Committee appreciate the efforts being made by IDPL to make available medicines to the people at reasonable prices, the Committee feel that in order to improve its profitability IDPL should also introduce some more sophisticated formulations in order to increase its share of trade in market.

(Paras 6.17 and 6.18)

Reply of Government

As in recommendation No. 78.

[Min. of P & C O.M. No. 8(25)/74-Ch.III, dated 30-10-1974].

Recommendation (Sl. No. 81) ..

The Committee note that in July, 1970, Government introduced a canalisation scheme under which the import of bulk drugs to make good the shortfall/supplement indigenous production was permitted. IDPL was designated as the canalising agency for 10 items which fell within its production range. The number of items canalised for imports through State Trading Corporation was 36 in 1973-74. A system of pooling prices was also evolved by Government under which pooled price was fixed by taking the weighted average of the prices allowed to indigenous manufacturers and the price of the imported

material inclusive of CIF price, Customs and Clearance charges etc. The Scheme envisaged that the difference between the price notified by Government for the indigenous production and the pooled price would be reimbursed by IDPL out of profits earned under the schemes. It has been claimed that with the introduction of system of canalising, it has been possible to ensure uniform prices for all sections of the industry and it has enabled the State Trading Corporation to procure such drugs in bulk quantities from sources which offer the lowest price. Another advantage was that the small-scale sector companies were able to undertake formulation of a large number of drugs which brought down the prices of such formulations. The benefit of canalisation thus passed on the consumer. The Committee find that a comprehensive review of pooled prices had not been carried out by Government since the canalisation system was first introduced in July, 1970. The Committee, therefore, recommend that Government should keep the present system of canalisation under constent review and ensure that the system of price based on the principle of weighted average, is worked out in such a way that it is equitable to all concerned especially to companies in the small-scale sector.

(Para 6.48)

Reply of Government

The import plan for drugs and drug intermediates whose import are canalised through the STC is discussed at interministerial meetings in the Ministry of P&C, taking into account the requirements for the ensuing year and estimated indigenous production. These estimates are further discussed at meetings of the STC's Drug Imports Advisory Committee in which all sectors of Industry are represented. Further periodical reviews, are made in the Ministry of P&C with the representatives of the DGTD, DGHS, STC and the IDPL. It may be mentioned that only the gap between the actual requirements and the indigenous production are met by imports. It is also ensured that there is proper distribution to all sectors, including small scale of the Industry which is given substantial increment allocation each year.

The pooled prices of drugs were reviewed by the Drugs prices Revised Committee under the BICP and by Govt. in the middle of 1974 and revised pooled prices were fixed on the weighted average basis for the following drugs based on the imported prices and the

quantities proposed to be imported, indigenous selling prices and the estimated indigenous product.

	Pooled prices (Rs. per kg.)
Analgin	175·02
Amidopyrine	132·43
Folic Acid	1527·02
Sulphaguanidine	115·61
Phenobarbitone	276·11
Vitamin B1	592·48
Streptomycin	343·00
Vitamin B2	935·48
Chloromphenicol Powder	646·00

It may be mentioned that the IDPL have been asked to maintain separate account for trading activity under the pooling system from this financial year onwards.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 4-12-74]

Recommendation (Sl. No. 82)

The Committee note that a major portion of the surgical instruments produced at the Surgical Instruments Plant of IDPL are being exported, to the U.S.S.R. The value of export has arisen from 1.01 lakhs 1968-69 to Rs. 50.72 lakhs in 1972-73. The percentage of exports to total sales increased from 57 per cent in 1968-69 to 87.1 per cent in 1972-73. The Committee also note that the export prices at which these surgical instruments were exported were much lower than the cost of their production and local sale prices with the result that these exports have resulted in significant losses to the Company. During the period 1968-69 to 1972-73, Surgical Instruments produced at a cost of Rs. 319.48 lakhs were exported at Rs. 131.64 lakhs thus resulting in a total loss of Rs. 187.84 lakhs to the Company. The Committee understand that while the prices of comparable instruments produced in West Germany were higher, the prices of such instruments produced by Pakistan were lower because Pakistan gave about 50 per cent subsidy on such exports. The idea of giving subsidy to IDPL, however, has not found favour with the Ministry because "a subsidy would merely imply a transfer of loss" and would give a distorted picture of the performance of Surgical Instruments Plant, Madras. The Committee were informed that the matter is,

however, still under examination and the IDPL had been asked to work-out a paper as to the degree of assistance which would be required by it to become self-supporting over a period of year. The Committee deeply concerned to note that the Plant will have to continue to incur heavy losses by exporting surgical instruments produced by it at unremunerative prices. The Committee are sure that a plant which exports its products at a price which is substantially less than the cost of production would continue to be a drain on the financial resources of the Company as a whole and may jeopardise the economic stability of the Company. The Committee, therefore, feel that it is high time for Government to undertake a thorough probe of the economics of the Surgical Instruments plant, Madras and scrutinize its product mix to increase the prospects of increasing sale of instruments in the domestic market and to explore the scope for exports to other countries at remunerative prices in order to avoid dependence for such exports on a single country.

(Para 6.65)

Reply of Government*

The recommendation has been noted and as mentioned in reply to Recommendation No. 68, a Committee is proposed to be appointed shortly to examine the various aspects of the working of this Plant.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 10-2-75]

Further information asked for by the Committee

Has the Committee been appointed to examine the various aspects of the working of SIP? If so, when and what are the terms of reference? Has the Committee submitted its report, and if so, what are the salient features thereof and what action has been taken by the Government/IDPL on the recommendations thereof or when is it likely to submit its report?

[LSS O.M. No. 26-PU/74 dt. 21-5-75]

Further Reply of Government

Please *see* reply to Sl. No. 67.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 10-8-75]

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*Not vetted by Audit.

Recommendation (Sl. No. 83)

The Committee note that in order to compete with private manufacturers, IDPL has introduced lucratics scheme for development of dealers under which a specific commission on distribution of IDPL products is allowed and a periodic incentive through a companies scheme or quantity discount is given from time to time. The Committee recommend that IDPL should review the position from time to time and to see that other measures are necessary in order to push up its sales in the indigenous market and to offer fair competition to the private manufacturers in the field.

(Para 6.67)

Reply of Government*

The recommendation of the Committee has been noted. Periodic review is being made by IDPL of the various measures taken to improve the sale of its products. As already mentioned reply to recommendations Nos. 78 and 79. IDPL are introducing a number of sophisticated formulation to improve their share of drugs in the market.

[Min. of P. & C. O.M. No. 8(25)/74-Ch. III dt. 10-2-75]

Recommendation (Sl. No. 84)

The Committee note that the Authorised and Paid up Capital of the IDPL as on 31st March, 1973 stood at Rs. 40 crores and Rs. 33.70 crores respectively. The debt equity ratio of the Company on that date was 1.6:1. On 22nd September, 1972, the Government of India granted a moratorium for a period of four years with effect from the 1st April, 1972 on the repayment of loans and loan instalments amounting to Rs. 24.85 crores which had fallen due for repayment upto July, 1972. Besides Government also agreed to treat the working capital loans to the extent of Rs. 24.85 crores drawn to finance the cash losses sustained by the Company upto 31st March, 1972 as "interest free" for a period of 5 years from 1st April, 1972. The treatment of the working capital loans amounting to Rs. 24.85 crores as interest free loans, it has been stated, would give company an annual relief of Rs. 150.53 lakhs for five years. In August, 1973, Government also waived an amount of Rs. 180.05 lakhs due from the Company on account of penal and compound interest on delayed repayment of loan instalments and delayed payment of interest.

The Committee are deeply concerned to note that by 31st March, 1973 IDPL has incurred a cumulative loss of Rs. 38.25 crores and

*Not vetted by Audit.

had thus eaten up its entire paid up capital of Rs. 33.7 crores. The Committee note that the loss has increased from Rs. 56.45 lakhs in 1965-66 to Rs. 369.95 lakhs in 1972-73. Considering the individual plant, Division, the Committee find that Surgical Instruments Plant has suffered a loss of Rs. 602.36 lakhs, Synthetic Drugs Plant of Rs. 1047.70 lakhs, Antibiotics Plant Rs. 2103.91 lakhs and the Marketing Division Rs. 71.93 lakhs. The Committee feel that in order to judge the performance of the trading operations of these plants, it is essential that the accounts are kept in such a manner that the working results of manufacturing activities of each plant and trading results on the purchases and sale of imported drugs can be prepared separately.

The Committee have been informed that these losses were mainly due to long construction and gestation period, under utilisation of capacity due to lack of technical expertise, deficiencies of equipments and process shortage of critical raw materials, power cuts, losses due to export of surgical instruments. The plant is stated to be taking steps to improve the technology by introducing new equipment, machinery and processes. The Committee recommend that IDPL should take concerted measures designed to improve its profitability rather than depend on financial relief granted by the Government from time to time.

(Paras 7.37-7.38)

Reply of Government*

The recommendation of the Committee has been kept in view by the IDPL and all efforts are made to improve the working of the plants. Even though there was a shortfall in production in the Synthetic Drugs Plant due to short supply of raw materials, set-back in production in Antibiotics Plant, Rishikesh in July, 1974 due to the contamination problem and severe power cut in the surgical instruments plant, the working of the Company shows an improvement over the previous year. The operating results of the Company as estimated during the current year and budget estimates for 1975-76 are given below:

(Rs. in lakhs)

Particulars	1974-75		1975-76
	Budget	Revised Estimate	Budget
Profit before depreciation and interest	558·33	818·02	940·15
Depreciation	265·46	266·75	273·82
Interest	312·89	348·41	323·95
Profit after depreciation and interest	(—)20·02	(+)202·86	342·38

*Not vetted by Audit.

From the above it will be seen that the financial position of the Company is improving.

The Company however carries a substantial amount of loans granted by the Govt. and it will be necessary for Govt. to provide financial relief to the Co. in the form of further loans to repay the existing loans which fall during this year.

As regards trading activities on the sale of imported drugs, as mentioned in reply to Recommendation No. 81, the IDPL have been asked to maintain separate account for trading activities under the pooling system from this financial year onwards.

[Min. P & C O.M. No. 8(25)/74-Ch. III dt. 19-6-75]

Recommendation (Sl. No. 85)

The Committee find that though the items to be covered in the Internal Audit Programme have been laid down, the quantum of Audit to be applied to such items has not been prescribed therein. As Internal Audit is an important aid to Management, the Internal Audit Department should be strengthened to enable it to critically review policies, practices and procedures concerning all fields of activities and Departments of the Plants|Units in terms of adequacy, soundness and effectiveness.

(Para 7.39)

Reply of Government*

Staff, strength of Internal Audit Department is carefully reviewed by the Management from time to time keeping in view its important role as an aid to Management. For instance, in August, 1972 it was decided to introduce physical verification of the stocks of drugs lying in the Regional Sales Offices and depots of Marketing Division by a stock verified from the Internal Audit Deptt. for which a new post was created. Also in October, 1972 it was decided to increase the frequency of Internal Audit on the basis of two cycles of audit in a year of the aforesaid offices instead of 'one cycle in a year' by further strengthening the Internal Audit Deptt. by two posts of accountant. Critical review of policies, practices and procedures concerning all fields of activities and departments of the Plants/Units in terms of adequacy, soundness and effectiveness is one of the activities of the Internal Audit Department. Management specifically directs the Internal Audit Department to conduct special studies with a view to ascertain areas in which improvements are possible/considered necessary.

[Min. of P&C O.M. No. 8(25)|74-Ch. III dt. 22-11-74]

*Not vetted by Audit.

Recommendation (Sl. No. 86)

The Committee note that the Managing Director is the Chief Executive of the Company. At the Unit level the General Manager functions as Chief Executive of the individual Unit and is responsible for the efficient performance of the Unit in accordance with the policies and Plans approved by the Board. The IDPL has three Plants, one at Rishikesh, the second at Hyderabad and the third at Madras. Though these are distinct units each specialising in a special field of production these are under one Management. The General Managers are not invited to participate in the meetings of the Board although according to general directions issued by the Bureau of Public Enterprises such an arrangement might be considered in the interest of the working of the units and the Undertaking as a whole. The Committee are informed that the Ministry is already examining the future set up of the IDPL and HAL with a view to coordinate their activities and rationalise the management of the units in the context of the targets envisaged in the Fifth Plan and ensure that the Plants manufacturing similar products are under the same management. The Committee desire that the Ministry should complete its examination soon and rationalise the Management so as to have a more broad based Board.

(Para 8.30)

Reply of Government*

The recommendation has been noted and the question of having a common marketing organisation for both the Public Sector Units is under consideration.

The Committee on Drugs and Pharmaceuticals Industry constituted under the Chairmanship of Shri Jaisukhlal Hathi has made certain recommendations on the various antibiotics to be manufactured by the IDPL and HAL and also the organisational structure. These are also under consideration and an early decision is expected to be taken.

[Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 19-6-75]

Comments of the Committee

Please *see* para 170 of Chapter I of the Report.

Recommendation (Sl. No. 87)

The Committee find that in pursuance of the recommendation of the Committee on Public Undertakings in their Fifteenth Report (Fourth Lok Sabha—April, 68) the B.P.E. Government of India issued

*Not vetted by Audit.

broad guidelines defining the main functions, responsibilities and powers of Financial Adviser. It was also mentioned in the guidelines that the Board of Directors should lay down detailed powers and functions of Financial Adviser particularly in regard to matters which should be reserved for concurrence or consultation with Financial Adviser, etc. In spite of these directions no such demarcation has been made so far. The Committee were informed that the existing practice has been working smoothly during all these years and therefore, it was not considered necessary to modify them. The Committee, however, feel that financial demarcation of areas for prior consultation/concurrence with the Financial Adviser as laid down by the Bureau of Public Enterprises, would be advantageous, instead of being the matter to be decided by the practices which may vary from time to time. The Committee also find that no Hand Book of Financial Powers delegated from time to time has been compiled. The Committee need hardly stress the importance of compiling early a suitable Guide Book containing in detail the duties and powers of the Financial Adviser, in the interest of expeditious disposal of business. (Para 8.31).

Reply of Government

The Handbook of Financial Powers is under compilation by IDPL and is expected to be completed shortly. The areas of expenditure for which prior consultation/concurrence with Financial Adviser/CFA, etc. would be necessary will be specified in the proposed Handbook.

[Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 8-11-74]

CHAPTER III

RECOMMENDATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF GOVERNMENT'S REPLY

Recommendation (Sl. No. 4)

In paras 4.02 and 4.03 of their 46th Report (1968-69) the Committee had pointed out that the Detailed Project Reports did not contain any time schedules for completion of the plants. The Committee find that according to schedule time for commissioning fixed in September, 1966. Tetracycline, Oxytetracycline and Nystatin Sections were scheduled to be commissioned in December, 1967, February, 1968 and in May, 1968 respectively. In April, 1967, the scheduled dates of commissioning were revised to March, 1968, September, 1968 and July, 1968 respectively. Tetracycline Section could be commissioned only in January, 1969 resulting in a delay of 12 months with reference to the 1966 schedule and nine months with reference to the revised schedule of 1967. Oxytetracycline Section was actually commissioned in December, 1969, the delay being 22 months with reference to the original dates and 15 months with reference to the revised schedule. In the case of Nystatin Section which was commissioned in January, 1971 the delay has been the maximum, that is, 32 months with reference to the original schedule and 30 months with reference to the revised schedule of April, 1967. The Management had attributed these delays to the late receipt of drawings and change in the layout introduced after the arrival of the Soviet Experts; changes in technology; difficulties regarding sterility conditions, and difficulties in the air-conditioning system. The Committee were informed that the management were taking remedial measures for modfication in the air supply system, reduction in the sterility areas, change in technology etc. The Committee are distressed to find the long delays in the actual commissioning of important product sections like Tetracycline, Oxytetracycline and Nystatin Sections. The Committee recommend that every effort should be made to minimise such delays so as to avoid any loss in production. (Para 2.30).

Reply of Government

This recommendation has been brought to the notice of the Indian Drugs & Pharmaceuticals Ltd. Care will be taken in future to ensure that delays in commissioning resulting in loss of production are kept to the minimum.

[Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 30-10-74]

Recommendation (Sl. No. 16)

In the case of Tetracycline, the ratio of batches harvested to seed vessels charged has ranged between 0.33 to 0.72 during 1969-70 and 1973-74 (upto September, 1973). In the case of Oxytetracycline, the ratio of batches harvested to seed vessels charged ranged from 0.50 to 0.84 during the same period. The management have neither fixed any norms nor assessed the loss on account of the harvesting of inoculator seeds vessels, percentage of batches contaminated to batches harvested in the case of Tetracycline ranged between 6.90 per cent in 1973-74 (upto September, 1973) to 23.18 in 1971-72. The percentage of batches contaminated to batches harvested in respect of Oxytetracycline ranged between 17.65 in 1973-74 to 43.27 in 1971-72. The Committee also find that as against protocol norm of 128.5 mlrds of native solution per batch, the higher achieved in November, 1970 in case of Tetracycline was 135.44 mlrds. The average yield of native solution per batch was, however, only 81.72 mlrds in 1969-70, 105.49 mlrds in 1970-71, 101.67 mlrds in 1971-72 and 102.3 mlrds in 1972-73. As against the protocol norm of 95 per cent filtration efficiency for Tetracycline was 84.60 in 1969-70, 85.61 in 1970-71 and 86.88 per cent in 1971-72 and 84.5 in 1972-73. In the case of Oxytetracycline the conversion efficiency from base Hydrochloride as indicated in the protocol is 83 percent. But the conversion efficiency actually achieved ranged between 50.84 per cent to 90.63 per cent in 1969-70 to 1973-74 (September, 1973). The plant has been able to achieve conversion efficiency of 93 per cent. The Committee were informed that the Russians had provided some balancing and additional equipment free of charge to overcome the shortcomings. The Committee would like to know the results achieved after installation of this balancing equipment. (Para 2.184)

Reply of Government

After installation of the balancing equipment, the protocol capacity has now been achieved, Production of Tetracycline and Oxytetracycline during 1973-74 was 12,303 and 10.899.5 mlrds respectively against the protocol capacity of 12500 mlrds and 25000 mlrds respectively. In addition, 1252.7 mlrds of Oxytetracycline USSRP and 2350 mlrds of Tetracycline USP were produced. The production of these two Antibiotics during the year 1974-75 is expected to be around 25000 mlrds for each of the products.

(Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 22-11-74)

Recommendation (S. No. 17)

The Committee find that in the case of Nystatin, antifungal antibiotic, produced by Antibiotics Plant, the ratio of batches harvested to inoculators charged was 0.29 in 1971-72. The percentage of batches contaminated to the batches harvested was 23.2 in 1971-72. The Management have neither laid down any norms nor have assessed the loss on account of drainage of inoculator. The Committee note that in the case of Nystatin, the average activity was better than even the protocol norm in 1971-72, though the total time cycle was much more than the protocol norm of that planned by the Management.

The recovery efficiency, however, was only 23.36 per cent as against efficiency of 45 per cent indicated in the protocol resulting in shortfall in production to the extent of 3310 mlrds valued at Rs. 18.2 lakhs. The Committee note that production of Nystatin has not been maintained on a continuous basis on account of lack of adequate market. As a result the technology of manufacture has not yet established, resulting in poor efficiencies. The Committee would like to be informed about the sales prospects of Nystatin.

(Paras 2.201 and 2.202)

Reply of Government*

The Antibiotics Plant, Rishikesh has a licensed capacity of 10 tonnes of Nystatin per annum and according to the assessment made by the Company, the present market demand works out to approximately 800 kgs. It is likely to go upto approximate figure of 1.5 tonnes per annum by 1978-79. This is for short of the installed capacity, and it is highly uneconomical for the plant to manufacture small batches to meet a very limited demand. The newer antifungal drugs like Amphotericin and Griseofulvin which are more stable and products with wider range are more acceptable in the market and the demand for these products is likely to grow at the cost of Nystatin. The Task Force demand estimate of 3 tonnes per annum by 1978-79 might be on the high side. Even at the level of demand estimated by the Task Force, the capacity utilisation will only be 30 per cent of the installed capacity and the plant will not be able to establish production on a continuous basis.

(Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 27-1-75)

*Not vetted by Audit.

Recommendation (S. No. 21)

The Committee find that the plant management had with the approval of the Uttar Pradesh State Electricity Board fixed in December, 1966 their maximum contract demand on 6.6 KVA supply. Owing to non-attainment of capacity the actual demand was, however, much less and varied between 2,033 KVA and 13,600 KVA during the period from March, 1967 and 31st March, 1972. As the actual consumption was less than the 60 per cent of the contracted demand (on the basis of which payment had to be made to the Electricity Board the Company had to incur an extra expenditure of Rs. 22.12 lakhs) upto 31st March, 1973. No extra expenditure was, however, incurred during 1973-74 (upto September, 1973) as the plant was subject to a continuing power cut of 40 per cent. The Committee have been informed that the present demand of 20,000 KVA does not need any downward revision and would be sufficient to take care of the plant expansion programme. It has been stated that the problem of ensuring adequate power supply to the plant cannot be resolved by going in for a small captive power plant because of the huge cost involved and in view of the steep increase in the price of crude oil. The Committee recommend that plant authorities may examine the matter in depth in consultation with the Ministry of Irrigation and Power/ UP State Electricity Board so that the production in the plant is not affected due to shortage of power supply. (Para 2.245).

Reply of Government*

Presently the power supply in the Antibiotics Plant, Rishikesh is satisfactory and the number of failures, voltage fluctuations etc. have been reduced.

The Plant's contracted demand on 6.6 KV and 11 KV systems are 20 MVA and 2.5 MVA respectively (i.e. total of 22.5 MVA). It is sufficient to cover the expansion schemes envisaged in the Plant. In order to improve and consolidate the power supply, the following suggestions were mooted:

1. *Setting-up of a thermal generating Plant by UP SEB in the vicinity of IDPL.*

The Managing Director, IDPL had requested the UP SEB to consider the installation of a thermal power plant near Antibiotics Plant. This was not agreed to, due to the distance from the sources of coal.

*Not vetted by Audit.

They have, however, some hydel schemes coming-up near Rishikesh. The UP SEB is also erecting 220/400 KV Sub-Station adjoining Rishikesh Plant to receive power from Hydel schemes. The commissioning of these installations would improve the power stability to Antibiotics Plant considerably.

2. *Linking-up BHEL generation with Antibiotics Plant.*

This matter was also discussed with UP SEB Engineers and the scheme was found not practicable besides needing costly imported relays.

3. *Setting up of* 2 × 10 *MW Thermal Plant*:

This will involve a capital outlay of Rs. 8.10 crores and in view of the heavy cost the possibility of providing emergency power supply by having a small diesel power plant was examined. But since the operation-cost of the diesel Plan is high, the proposal was dropped. Now plant is arranging procurement of smaller air compressors so that the operation of the second big air compressor is not necessary at the present production level. The possibility of procuring a diesel Power Plant with automatic starting arrangement to run these small compressors in the event of a power failure is also being examined.

(Min. of P&C O.M. No. 8(25)/74-Ch. III dt. 22-11-74)

Recommendation (Sl. No. 23)

The Committee find that it has not been found feasible by the Company to install individual meters for each product and in the absence of these meters the allocation of consumption of services is being made, at present, on the basis of running hours of each equipment consuming the service and as such the comparison of the actual consumption of these services with the norms laid down in the Detailed Project Report has not been possible. The Committee feel that the present procedure is neither scientific nor accurate for the allocation of consumption of services and therefore recommend that this aspect may again be reviewed with a view to ensure control on consumption of services and affecting economy wherever feasible.

(Para 2.255)

Reply of Government

Unlike other Antibiotics manufacturing plants in our country like Hindustan Antibiotics Plant, Pimpri etc. where one product is manufactured in one block of buildings, this plant has been designed to

operate on a functional basis *i.e.* all the media storage and media preparation is done in one block; Fermentation and filtration of all Antibiotics is done in the 2nd block and similarly chemical purification and recovery of all antibiotics is done in the 3rd block and so on. All the service lines are drawn Block-wise where in each block production vessels of all the various products draw their requirements of water, steam, brine etc. from the common headers. Product-wise meters could have been installed if the lay-out was product-wise. Such a step at this stage would involve large scale relaying of pipelines involving stoppage of production. Results may not be commensurate with the expenditure involved. However, recommendation of the Committee has been noted and will be kept in view in executing expansion schemes involving new building etc. Further, repairs/replacements in the existing buildings will be made keeping this aspect of separate product-wise meters. in view.

[Min. of P&C O.M. No. 8(25)|74-Ch. III dated 22-11-1974]

Recommendation (Sl. No. 36)

The Committee note that the Detailed Project Report had indicated the manpower norm on the basis of optimum production. But as the operational practices and labour efficiencies in the USSR were different from those in India the Board of Directors appointed a Committee in November, 1966 to assess the requirements of manpower. The Committee, however, did not do any investigation. In August, 1967, the Industrial Engineering Department was set up by the Company for the assessment of the manpower requirement of the Plant. The Department assessed the requirement at 2174 within the peremeter wall of the plant. In September, 1972 a revised assessment was made by the Industrial Engineering Department. The revised strength fixed for the plant was 2297. For five out of the six blocks the present strength of staff on 30-6-1973 is 30.43 which includes the staff employed on work charge and muster roll basis. The regular strength is 2346 including 47 personnel for the 6th Block for which study is still to be completed and it does not exceed the overall strength recommended by the Industrial Engineering Department. The Committee recommend Government IDPL should ensure that unless the requirements of higher production demand staff strength of the plant may be kept within the assessed level.

The Committee would also like to be informed in due course of the staff for the sixth block, *i.e.* Administrative Block-Technical and Research and Development Department. (Para 2.61)

Reply of Government

With reference to the revised industrial engineering studies conducted in Sept, 72, the position of the staff in various departments inside the peremeter wall of the plant is indicated in the following table:

S.No.	Department	DPR	Revised recommendation by I.E.D.	Persons in position as on 31-7-1974. Regular	W/C	M/R	Total
1.	Fermentation & Media Block	416	385	399	1	59	459
2.	Recovery & Purification Block	395	336	407	9	63	479
3.	Sterile of Fir ishir g Block .	400	412	451	7	38	496
4.	Laboratories, Quality Control Pilot Plant & Ar imal House	265	266	294	3	34	331
5.	Main & Auxiliary Services Block	507	998	929	49	307	1283
6.	Administrative Branch (Tech.)	197	69	62	..	3	65
	TOTAL . .	2180	2466	2540	69	504	3113

It would be seen that the total manpower on the regular establishment is within the assessed limits. However, the excess staff on workcharge (67) and the muster roll (412) still continues because of additional jobs of temporary nature which were not specifically included in the detailed study and also the lower level of productivity of workmen than assumed. Efforts are being made to reduce the staff and there has been a reduction of 32 M/R and 186 W|C employees during the period after 30-6-73.

The industrial engineering studies of the administrative staff in the 6th Block are in progress and the departments dealing with the purchase and stores, commercial and personnel and administration have already been covered. The requirement of the staff for Research & Development Department depends on the level of activity and scope of functions. A constant watch on staff will be kept so as to maintain a good level of utilisation of scientific talents available to the Research & Development Department.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III dated 22-11-1974]

Further information asked for by the Committee

(a) When are the industrial engineering studies of the administrative staff in the 6th Block likely to be over? If already over please furnish details of the result.

(b) What is the present position regarding surplus staff and how is this surplus staff regularised? Please state in detail.

[LSS O.M. No. 26-PU/74 dated 21-5-75]

Further Reply of Government*

(a) Studies are expected to be completed within a period of six months.

(b) The surplus staff is expected to be utilised in the expansion schemes being taken up by IDPL during the 5th Five Year Plan.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III dated 10-8-1975]

Recommendation (Sl. No. 39)

The Committee also note that actual expenditure on the Project including a sum of Rs. 78 lakhs on the execution of effluent disposal scheme. According to the arrangements entered into with the State Government, the latter would bear the cost of effluent disposal scheme upto Rs. 30 to 40 lakhs. In 1961 the Ministry informed that a simpler and economical scheme for effluent disposal was suggested by the collaborators involving an expenditure of Rs. 15 lakhs. When this scheme was communicated to the State Government they agreed in August, 1961, to bear the full cost of the effluent scheme. The Committee note that this simpler scheme could not be implemented after considering various proposals for effluent disposal and ultimately a scheme prepared by the Central Public Health Engineering Institute Nagpur for Rs. 58 lakhs, was adopted by the undertaking, in February, 1966. When the State Government was approached in 1969 for reimbursement of the expenditure incurred on the scheme the State Government repudiated any liability in excess of Rs. 15 lakhs on the ground that the State Government had to incur extra expenditure to the extent of Rs. 25 lakhs for payment of enhanced compensation for the land acquired by it and gifted to the Undertaking. The result was that the expenditure on the scheme had to be borne by the Undertaking itself.

*Not vetted by Audit.

Subsequently, efforts to get reimbursement of money from the State Government were not fruitful. The Committee were informed that the matter is now being pursued at Government level. The Committee would like to be informed of the development in the case.

(Para 3.26)

Reply of Government*

As indicated in the recommendation, the State Governments are agreeable to accept a liability of Rs. 15 lakhs only on the effluent scheme but have put in a counter claim for expenditure incurred by them as payment of compensation on the land acquired for the Synthetic Drugs Plant. In a recent communication, they stated that this amount is Rs. 58.49 lakhs and have requested Government of India to reimburse it after deducting the amount payable by them to the Central Government towards effluent disposal scheme.

2. This was considered by this Ministry in consultation with the Ministry of Finance and as both the parties have incurred considerable expenditure, that is, by the Indian Drugs and Pharmaceuticals Ltd. on the effluent disposal scheme and by the State Government on the acquisition and payment of compensation for the land gifted by them to the Indian Drugs and Pharmaceuticals Ltd., it has been decided that the matter may be treated as closed and both the parties not press for their respective claims however justified as they may be. This decision has been communicated to the Government of Andhra Pradesh.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dated 30-10-74].

Recommendation (Sl. No. 44)

The Committee find that IDPL has gone in for expansion of the plant at Hyderabad to be executed in two phases. The first phase of expansion to 2,000 tonnes is stated to be based on the Market Survey and the demand for the products as known in the undertaking as it is the sole distributing agency for these products, while the 2nd phase of expansion is stated to be based on the target fixed by the Task Force of Planning Commission and Ministry of Petroleum and Chemicals. The Committee find that the estimated cost of Rs. 525 lakhs for the expansion scheme has been reduced to Rs. 478 lakhs because of over-lapping of some items included both in the expansion scheme and the revised project estimates of the

*Not vetted by Audit.

first phase. The actual expenditure upto 31st March, 1973 was Rs. 162 lakhs. Although the scheme was scheduled to be completed by 1972-73, according to present anticipation, it is expected to be completed by 1974-75. The Committee are of the opinion that IDPL instead of going in for expansion on a large range of product-mix should make a selective approach consistent with the demand of products in the market in order to utilise its available capacity to the maximum.

(Para 3.76)

Reply of Government

The expansion scheme envisages expansion of existing capacities in respect of 11 drugs and production of 9 new drugs.

The expansion of the capacities of the existing drugs has been based on full utilisation of the existing capacities with due regard to the requirements envisaged by the Task Force in the Fifth Five Year Plan.

As for new drugs, they have been selected keeping in view the following:—

(a) demand and marketability;

(b) technological experience gained by the plant in certain specific fields such as Sulphas, barbiturates and vitamins; and

(c) maximum utilisation of existing equipment.

Further, the IDPL alongwith HAL has been assigned a predominant role in the pharmaceutical field to increase significantly its share in drugs market during the Fifth Plan. Even so, Government examine all the expansion programmes of IDPL through the PIB before investment decisions are taken.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 8-11-74]

Recommendation (Sl. No. 49)

The Committee note that inventory holding of Synthetic Drugs Plant have increased from Rs. 421 lakhs in 1968-69 to Rs. 700 lakhs in 1971-72. These come down to Rs. 642 lakhs in 1972-73. The stocks of raw-materials increased from Rs. 140 lakhs representing eighth months consumption in 1968-69 to Rs. 195 lakhs in 1972-73 representing 3.16 months consumption. Similarly stores and spares increased from Rs. 73.87 lakhs representing 22.8 months consumption

in 1968-69 to Rs. 252.7 lakhs in 1972-73 representing 31 months consumption. The Committee also note that stocks of stores and spares have generally been much in excess of the annual consumption of stores, while consumption of stores and spares ranged from Rs. 36 lakhs in 1968-69 to Rs. 93 lakhs in 1972-73. The actual stocks ranged from Rs. 74 lakhs in 1968-69 to Rs. 250 lakhs in 1972-73.

The Committee also note that the Management have fixed the maximum and minimum levels of stocks and raw materials both for imported raw-materials and indigenous raw-materials, and these stocks levels were subsequently reviewed in August, 1969 and stock margin was added. The Committee are surprised that in spite of the fixation of stock level, the production performance of the unit, is claimed to have been affected, due to shortage of raw material. The Committee would like that this matter should be gone into to find out the critical items of raw materials in respect of which the management have been experiencing difficulties so that advance action may be taken to procure them for purpose of stock. The Committee also recommend that the Management should take immediate action to fix up the maximum and minimum levels in respect of other items of stores after completing A.B.C. analysis.

The Committee find that the slow moving and non moving items of stores and spares constituted a significant proportion of the inventory holdings of these items as on 31st March, 1972. The Committee recommend that a careful review of these holdings should be made and the items no longer required should be disposed of.

(Paras 3.136 & 3.137)

Reply of Government

The plant is authorised to maintain six months' inventory levels of imported raw materials and three months' inventory of indigenous raw materials on an average. As against this, the inventory level of raw materials has come down to 3.16 months' consumption in 1972-73. This is due to the fact that the plant was not been able to procure some of the raw materials from imported as well as indigenous sources in adequate quantities in time in spite of the advance action taken as some of the items were set readily available.

Constant review of the critical items of raw materials in respect of which the management is experiencing difficulties is made by it and efforts to take advance action are made to procure them and avoid stoppage of production.

As regards stores and spares, collaborators had supplied along with the original plant certain quantities of spares and other stores items like stainless steel pipes, valves of special material of construction etc., to be utilised not only during the commissioning of the plant but also during the first few years after the commissioning of the main plant. Almost simultaneously with the commissioning of the main plant, the first phase of expansion of the plant was taken up and procurement action required for completion of the first phase of expansion was initiated. The Management considered it uneconomical and impracticable to have a separate stores for operation of the plant and for carrying out capital expansion schemes and such items which were procured for capital needs of the plant were also added to our original inventories. Hence the recorded rise in the level of inventories.

As regards A.B.C. analysis and maximum and minimum levels for stores and spares, it may be noted that immediately after the first phase of expansion of the plant, the plant has already undertaken the second phase of expansion due to which the consumption patterns are not steady. Moreover, the items of stores and spares are common both to operation and maintenance as well as capital expansion of the plant and as such it was difficult to fix up maximum and minimum levels of most of the items. However the company has been asked to have an A.B.C. analysis done and to fix the maximum and minimum limits.

The list of slow-moving and non-moving items of the stocks held by the plant are prepared at the end of annual stock verification and all such lists are sent to the concerned indenting departments for careful review and their proper utilisation on the various expansion jobs. The items which are considered as surplus to the requirements are disposed of at the best available prices.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 10-2-75]

Recommendation (Sl. No. 50)

The Committee note that physical verification of all stores, raw materials, spares, tools etc. is conducted on the basis of perpetual inventory system. The Committee also note that stores and spare parts to the extent of 24, 21 and 15 per cent have not been verified during 1969-70, 1970-71 and 1971-72 respectively. During 1972-73, however, the percentage has come down to 4.6 per cent. The Committee note that the result of stock verification of raw materials, stores and spares including finished goods for the last 7 years (1966-67 to 1972-73) revealed that Rs. 24.6 lakhs of raw material

and spares were in excess and Rs. 34.75 lakhs were found to be short. Similarly more than Rs. 3 lakhs worth of finished stocks were found to be in excess and more than Rs. 7.7 lakhs worth of finished stocks were found to be short. The Committee were informed that as decided by the Board of Directors in September, 1970 investigation of shortage etc. was undertaken and shortages to the tune of about Rs. 12 lakhs have already been written off. The Committee recommend that responsibility for all cases of losses and shortages should be fixed after a thorough investigation of the remaining cases.

(Para 3.141)

Reply of Government

Physical verification of all stores including raw materials spares, etc. is conducted on the basis of perpetual inventory system. There has been progressive improvement in this regard and the items which were not verified constituted only 4.6 per cent in 1972-73, as against 24 per cent in 1969-70. The plant authorities are trying to improve the position.

As regards shortages, which are estimated at Rs. 20.3 lakhs*, it may be mentioned that these accrued right from the inception of the plant i.e. 1967-68 to 1972-73. The percentage of such losses as compared to the total volume of stores handled works out to roughly below 1 per cent. The items which account for shortage vary from small items like bolts and nuts to corrosive and hazardous chemicals. Investigations are being made by the Plant authorities to find out the reasons leading to such shortages. The progress of investigation has been however delayed due to non-availability of certain old records. Efforts are being made to trace them and expedite the investigation.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 10-2-1975]

Further information asked for by the Committee

The result of investigation may be communicated.

[LSS O.M. No. 26-PU/74 dated 21-5-75]

Further Reply of Government

Some of the reasons for shortages of raw materials which had to be written off are like leakages and breakdown of the pipelines

*The Principal Audit officer has reported that the details of shortages are not available with the Plant.

†Not vetted by Audit.

of stockages, undetectable leakage of the receiver valves, emptying the line material into receiver valves, which were being opened frequently due to faulty operation, etc. Remedial measurs to avoid shortages have been taken and every effort is made to keep the shortages at minimum.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 10-8-1975]

Recommendation (Sl. No. 52)

The Committee note that as on 31st March, 1973 the Company was carrying a stock of 33 tonnes of value over Rs. 10 lakhs of Hydrazine Hydrate as against stock of 1.3 tonnes of value Rs. 43 thousands as on 31st March, 1972. It has been reported by the General Manager of the Plant that the sale of this item had been adversely affected on account of imported material being offered by a Bombay firm at price lower than that of plant. It was also stated that import of this item was banned in 1971-72. The Committee would like to be informed about the disposal of the huge stocks of Hydrazine Hydrate. The Committee have made their recommendation about the expansion of the capacity of this intermediate elsewhere in this Chapter.

(Para 3.149)

Reply of Government

The stock of Hydrazine hydrate (80 per cent concentration) at the end of September, 1974 was 23.33 tonnes (approx.). Thus about 10 tonnes have been disposed of since April, 1973.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 30-10-1974]

Further information asked for by the Committee

What efforts are being made to dispose of the pending stock of 23.33 tonnes (approx.) of Hydrazine Hydrate? Please state in detail indicating the stock in balance of this product at present.

[LSS O.M. No. 26-PU/74 dated 21-5-75]

Further Reply of Government*

The stock position of Hydrazine Hydrate as on the 31st March, 1975 is given below:—

Hydrazine hydrate 100 per cent 1800 kgs

Hydrazine hydrate 88 per cent 600 kgs

*Not vetted by Audit.

It would be observed that the stock of Hydrazine Hydrate is gradually getting liquidated. In order to accelerate the sale of this product and other chemicals, a special cell is being created in the company's Marketing Division.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III dated 10-8-1975]

Recommendation (Sl. No. 54)

The Committee on Public Undertakings in their 46th Report (4th Lok Sabha) had mentioned that staff requirement as estimated by the Unit was 5522 and recommended that the staff requirement should be carefully considered and reduction brought about wherever essential. In response to this recommendation a study of the manpower requirement was undertaken by the Industrial Engineering Department of the unit. According to their recommendation the total manpower was fixed at 3275 in 1970, and 3309 in 1971 and 4053 for the expanded capacity. It has been stated that the strength at the end of November, 1973 is 3143.

The Committee find that though a total strength was recommended by the Industrial Engineering Department, no details are available category-wise with the result that excesses under any category cannot be ascertained.

The Committee also find that the percentage of total establishment expenditure to the total product cost was of the order of 14.5 per cent in 1970-71, 11.15 per cent in 1971-72 and 12.41 per cent in 1972-73. The Committee recommend that Undertaking would make realistic assessment of the staff requirements and regulate the staff strength with reference to production levels obtained from year to year and deploy staff found surplus for other useful and productive purposes.

(Paras 3.165 to 3.167)

Reply of Government

Since 1968, the requirement of manpower is assessed using various industrial engineering techniques. The work load is assessed by well qualified and experienced Industrial Engineers. The details

of year-wise manpower of position and the production of bulk drugs in tonnes are indicated below:

Year	Manpower as on 31st March	Production of bulk drugs in tonnes*	Remarks
1969-70	2869	433*	Production tonnage is less due to gestation period in the case of some of the drugs.
1970-71	3061	640*	
1971-72	3094	1050	
1972-73	3038	1166	
1973-74	3208	1280	

The category-wise manpower employed from time to time indicating the number of posts provided as per Industrial Engineering studies and the number of persons working is attached. It will be seen that except in the case of a few categories, the employment position is quite satisfactory and within limits.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III dated 22-11-74]

Recommendation (Sl. No. 55)

The Committee note that capacity for production of intermediates has been increased from 4932 tonnes to 5346 tonnes per annum on the basis of 330 working days. The Committee find that the production of intermediates fell short of the targets in all the years from 1968-69 to 1971-72. The Committee also note that the targets were generally less than the capacities except in three cases in 1971-72. The Committee were informed that to a great extent the capacity of the intermediates was increased to meet the captive consumption.

The Committee also find that a decision was taken to expand the capacity of intermediates like Hydrazine Hydrate taking into account the market demand for the product. The Committee, target

*At the time of factual verification Audit had pointed out that the production figures are as follows :—

1969-70	329 tonnes
1970-71	506 tonnes.
1971-72	855 tonnes.
1972-73	1164 tonnes.

to note that, as indicated in the Chapter on Inventory Control, there was a heavy accumulation of stock of this material to the extent of 33 tonnes of the value exceeding Rs. 10 lakhs, as on 31st of March, 1973. The Committee also find that the sale of this item has been adversely affected on account of the imported material being offered by a private firm of Bombay at a price lower than the price of the IDPL. The Committee do not see any justification for the expansion of the capacity of this intermediate in the face of the existing conditions. The Committee find that import of this item has since been banned. The Committee, therefore, recommend that the Undertaking should ensure that the cost of this product is competitive compared to the imported item, already available in the market.

The Committee also recommend that the management should take action for the clearance of the huge stock of this material to avoid unnecessary locking up of capital to the extent of Rs. 10 lakhs.

(Paras 3.171 to 3.173)

Reply of Government

Please see reply to Recommendation No 52.

In view of the balance of stocks lying unsold, the production of Hydrazine Hydrate was kept at a low level, during the years 1970-71, 1971-72 and 1972-73, the plant was selling the material which was produced with the plant working in full capacity before expansion. Even then, it was found that they were not able to meet the full requirement of the market. Hence taking into consideration the demand existing in the market and after consultation with the DGTD, it was decided to go in for expansion. But for the existence of imported goods in the Indian Market, the accumulation with SDP would not have developed. When the stock of imported goods gets exhausted, the demand for this product will go up.

Expansion of capacity for production of this intermediate will be only if and when justified by the actual demand in the country. To reduce costs of production is the constant effort of the undertaking, but in this connection the increase in the prices of inputs have to be taken note of.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 8-11-74]

Further information asked for by the Committee

(a) When is the stock of imported goods Hydrazine Hydrate likely to get exhausted?

(b) Have the Government banned further imports of this product?

(c) What specific steps have been taken to reduce the cost of production?

[LSS O.M. No. 26-PU/74 dated 21-5-75]

Further Reply of Government*

(a) to (c): Import of Hydrazine Hydrate is banned for actual users. Imports of Hydrazine hydrate are allowed against only against export of INH and Thiacetazone the import replenishment entitlement being 15 per cent only. In order that the indigenous requirements of INH are fully met, cash assistance normally available has been withdrawn from the year 1975-76. It is expected that by this step, the stocks of hydrazine hydrate which are not considerable now (please see reply to Recommendation No. 52) will be fully disposed of and the company commence full production.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 10-8-1975]

Recommendation (Sl. No. 65)

The Committee note that, in order to avoid complete dependence on exports and to build up image of the plant in the home market as a supplier of quality instruments, the surgical Instruments Plant had formulated a three years perspective plan beginning 1972-73 to 1974-75, both for marketing and production. The Plan envisaged raising of the production of surgical instruments, detachable scalpable blades, some items like scissors and forceps and job orders amounting to Rs. 52.44 lakhs in 1972-73 to Rs. 125.68 lakhs in 1974-75. The value of the export orders is expected to increase from Rs. 47.75 lakhs in 1972-73 to Rs. 39 80 lakhs in 1974-75. The strategy adopted by the plant to achieve the targets included, sustained drive to increase productivity, judicious planning for off-loading of instruments, rationalisation of equipment and facilities, in the tool room, improvement in the planning and control set up of the plant, and appointment of dealers to consolidate the requirements of individual consumers, etc.

The overall performance against the perspective plan for 1972-73 and 1973-74 was as follows:—

	1972-73			1973-74		
	Plan	Actual	%age	Plan	Actual	%age
No. of Instruments (No. in lakhs)	8·08	6·59	82%	9·01	2·76	28%
Value including Job Orders (Rs. in lakhs)	100·19	63·85	68·7%	138·06	27·97	20%

*Not vetted by Audit.

It was explained that but for the serious power cut in Tamil Nadu, the plant would have been able to achieve the targets in full.

The Committee find that it was not lack of order which were responsible for non-fulfilment of the perspective plan.

(Paras 4.88 and 4.89)

Reply of Government*

The implementation of perspective plan was not possible due to market constraints. Production for the year 1974-75 is being undertaken in the light of demand survey and sales projection for the year.

In order to rationalise the tool room, equipment worth Rs. 2.57 lakhs has been purchased during 1973-74 and 1974-75. Provision amounting to Rs. 13.03 lakhs have been made in the budgets of 1974-75 and 1975-76.

During the year 1973-74, 3.63 lakhs of instruments valued at Rs. 33.16 lakhs were produced and job orders worth Rs. 4.36 lakhs were executed. During 1974-75 (upto July, 1974) 121,163 instruments valued at Rs. 13.06 lakhs were produced and job orders worth Rs. 3.11 lakhs were executed.

[Min. of P&C OM No. 8(25)/74-Ch. III, dated 8-11-1974].

Further information asked for by the Committee

It has been stated that during 1974-75 (upto July, 1974) 121,163 instruments valued at Rs. 13.06 lakhs were produced—What is the utilisation of capacity and has it improved or deteriorated? Please state giving details.

(LSS O.M. No. 26-PU|74, dated 21-5-75).

Further Reply of Government*

During the year 1974-75, the total instruments production and job orders was of the value of Rs. 50.24 lakhs as compared to Rs. 37.5 lakhs during 1973-74.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dt. 10-8-1975]

Recommendation (Sl. No. 66)

The Committee are surprised to find that as on 31-12-73 indigenous order to the extent of Rs. 24.57 lakhs, export orders to the

*Not vetted by Audit.

extent of Rs. 47.40 lakhs and job orders for Rs. 10.50 lakhs were stated to be pending with the plant. It was admitted by Government "that the position of execution of orders in Surgical Instruments Plant is far from satisfactory". The Management sought to justify non-execution of these orders on the ground that there was power cut by the State Government to the extent of 40 per cent from September, 1972 and 75 per cent from February, 1973. The Committee are not impressed by this plea as they find that orders were pending in each of the earlier years starting from 1968 to 1972. The Management have also attributed the shortfall to non-development of requisite skills and sectional imbalances between grinding and forging sections and other mechanised sections.

The Committee were informed that the Management of IDPL are already conducting an investigation into the affairs of the Surgical Instruments Plant and that after this investigation was completed Government would decide about the future steps to be taken in this regard. The Committee recommend that this investigation may be conducted with expedition so that the working of the Plant can be put on sound footing. The Committee hope that with the steps proposed to be taken to improve the working of the plant in the light of the investigations currently being conducted by the management, it will be possible to see that the plant is able to execute whatever orders are received by the plant either to meet the internal demand or the export commitments. Committee would like to be informed of the result of investigations.

(Paras 4.90 & 4.91)

Reply of Government*

Though the production commenced in September 1965 based on the original product mix, production of these types were discontinued from the production line in the beginning of 1967. During the year 1967, orders for a large number of types of instruments but with small quantities of each types from a number of parties were received. Simultaneously, the plant was engaged in the development of tooling and process technology for development of new types of instruments against the requirement of family planning authorities. These items were given priority for development and production in 1967-68, 1968-69 and part of 1969-70. The orders received in the latter part of 1968-69 because of their numbers being small were not taken up for production. These orders were carried forward from year to year. In 1969, bulk orders for items from Modexport were received and in export orders also, the items

*Not vetted by Audit.

varied each year. Box Joint forceps had to be developed specially both for diversification programme for indigenous market and to meet the Modexport orders.

Action has been taken by the plant to contact individual parties to ascertain the position regarding the orders pending in the books of the plant and depending upon the replies, such orders will be taken up for production or deleted from the order books. Major lines of production will, however, be confined to the demand as assessed.

Investigations undertaken by the Management referred to examination of the costing procedure of the plant. As a result of the study, prices of different surgical instruments were revised upwards w.e.f. May 1974. Further, the Plant has been directed to recover its costs on most economic basis which must take into account not only the market conditions, but also the fixed and variable costs incurred by the undertaking.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dated 22-11-74].

Further information asked for by the Committee

What steps have been taken for improvement in the working of the plant and what measures have been taken as a result of investigation?

(LSS O.M. No. 26-PU|74, dated 21-5-75).

Further Reply of Government*

A report has been submitted by Surgical Instruments plant which is being examined by the Bureau of Public Enterprises. The salient features of the report submitted to BPE include detailed examination of the pattern of off-take of surgical instruments in the country and the development plans of Health Services, export potential for surgical instruments and recommendations for developing the demand for surgical instruments, indigenous and on export.

[Ministry of P&C O.M. No. 8(25)/74-Ch. III, dated 10-8-75].

Recommendation (Sl. No. 69)

The Committee find that the prices of Surgical Instruments were fixed in 1966 on the basis of estimated cost for 1966-67 when only a

*Not vetted by Audit.

fraction of the capacity of the Plant could be utilised. The prices were consequently were very high compared to the corresponding instruments manufactured in the private sector. It has been claimed by the Company that Instruments of this plant were superior in quality. The Committee regret to note that inspite of the revision of the prices of instruments substantially in July, 1967, taking into account changes in product-mix, current cost of market prices, the selling prices continue to be lower than the cost of production in all items except one and the extent of difference in the case of individual instruments valid from Rs. 2.24 to 206.20. The Committee recommend that the management should critically go into the cost aspects and fix the selling prices at realistic level.

(Para 4.107).

Reply of Government*

As already mentioned in reply to rec. no. 67, prices of instruments for the indigenous market have been revised with effect from 1-5-1974 keeping in view their cost of production during 1973-74, etc., and the sale price of similar instruments marketed by others.

Revised sale prices of 11 instruments cover full costs, including depreciation and interest. Overhead charges are partially recovered in respect of 76 other instruments. Selling price of only one instrument does not cover its prime cost during 1973-74. However, it may be mentioned that only one number of that type of instrument had been manufactured during 1973-74 and its cost of production of 1973-74 is therefore not representative.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dated 27-1-75].

Recommendation (Sl. No. 72)

It has been admitted by the Management that the real problem at the S.I.P. is low productivity of workers which does not enable the Plant to achieve production of even the reduced capacity. The Committee recommend that concerted efforts may be made to raise the level of productivity and achieve the capacity targets.

(Para 4.127)

Reply of Government*

The recommendation has been noted by the Plant Management for guidance and will take necessary action. This aspect will also

*Not vetted by Audit.

be examined by the Committee proposed to be appointed by Government.

[Min. of P&C OM No. 8(25)/74-Ch. III, dated 8-11-1974].

Further information asked for by the Committee

Has the Committee been appointed? If so, when, and what are its terms of reference and when is it likely to submit its report?

(LSS O.M. No. 26-PU/74, dated 21-5-75).

Further Reply of Government

Please see reply to Sl. No. 67.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dated 10-8-75].

Recommendation (Sl. No. 75)

The Committee note that in regard to formulations, Drugs (Prices Control) Order, 1970 had envisaged the fixation of retail prices of formulations by Government of India should be on the basis of formula contained therein. In June, 1970, Government decided that wherever the application of the formula for fixation of prices of formulations in the case of Antibiotics Plants and Synthetic Drugs Plant allowed a higher price than the existing selling price, the latter should be retained but if there were any cases where the formula resulted in reduction of the price, the lower price should be allowed. Consequently IDPL was unable to raise the prices of its formulations instead, it had to effect reduction in some cases.

Consequent upon the continuation of the existing prices of formulations, the Committee are informed that IDPL was put to an estimated loss of 1.98 crores during 1970-71.

The Committee also note that Government have in February, 1974 constituted a Committee to enquire into various aspects of the Drugs and Pharmaceuticals Industry with a view to ensuring that all essential drugs are made available to the consumers at reasonable prices. The terms of reference *inter alia* stipulate an examination of the measures taken so far to reduce the prices of drugs for the consumers and to recommend such further measures as may be necessary to rationalise the prices of drugs and formulations. They hope that the Hathi Committee would give their recommendation by the scheduled date and that Government would take expeditious decision on these recommendation in the interest of making available medicines to public at most competitive rates.

(Paras 5.26, 5.27 and 5.28).

Reply of Government*

At the request of the Chairman of the Committee on Drugs and Pharmaceuticals Industry, Government have extended the date for the submission of the final report by the Committee by a period of six months. The Committee is expected to submit its report by the 7th February, 1975. However, on one of its terms of reference, *viz.*, that relating to quality control of drugs, the Committee has already submitted a report.

(Min. of P&C O.M. No. 8(25)|74-Ch. III, dated 30-10-74).

Further information asked for by the Committee

Has the Committee submitted its report? If so, what are the findings of the Committee and the reactions of the Government thereon?

(LSS O.M. No. 26-PU|74, dated 21-5-75).

Further Reply of Government*

The Committee on Drugs and Pharmaceutical Industry submitted its report to Government on the 6th April 1975. It has made extensive recommendations on various facets of the industry and they are under consideration of Government. The report was laid on the Tables of the two Houses of Parliament on 8-5-75. Copies of the report have also been circulated to the members of the Committee on Public Undertakings.

[Min. of P&C O.M. No. 8(25)|74-Ch. III, dated 10-8-75].

Recommendation (Sl. No. 77)

The Committee find that the turn-over of drugs and pharmaceuticals by IDPL amounted to Rs. 10.2 crores in 1970-71. Rs. 15.55 crores in 1971-72 and Rs. 19.90 crores in 1972-73. This constituted 4.1 per cent, 5.2 per cent and 6.6 per cent of the countries turn-over for these three years. The committee also note that though sales of the company increased from Rs. 101.22 lakhs in 1968-69 to Rs. 2058 lakhs in 1972-73, the company failed to attain even the revised targets of sales in any of the years. The main reasons for non-achievement of sales targets were stated to be lower production in all the years and availability of cheaper imported drugs in the market (for 1968-69 only). The Committee recommend that IDPL should evolve better sales strategies to push up the sales.

The Committee note that as a result of the recommendations made by the Committee in their 40th Report, Government had

*Not vetted by Audit.

issued instructions in June 1971|May, 1972 that Government Departments and Public Sector enterprises should obtain their requirements of drugs from the IDPL|Hindustan Antibiotics Limited to the maximum extent possible and a price preference upto 10 per cent be allowed to them. The Committee have been informed that these instructions are not being followed by some of the State Governments and Director General of supplies and Disposal, who also enter into paralleled rate contracts with private firms.

The Committee also understand that Government medical stores depots under the Ministry of Health and Family Planning have not given effect to the Government instructions issued in June, 1971 and May, 1972 to accord 10 per cent preference to IDPL State Governments contend that they do not come within the perview of the circular issued by the Government of India since health is a state subject. The Committee recommended that Government should once again draw attention of the Government Departments| public sector enterprises to the instructions issued in June, 1971| May, 1972 and impress upon them the need to meet their requirements from the IDPL|Hindustan Antibiotics Limited to the maximum extent possible. Government should also ensure that DGS&D place all orders for the products within the range of production of IDPL|HAL on these undertakings within the ceiling of price preference indicated above.

(Para 6.14).

Reply of Government*

The question of purchase of drugs and medicines by Government exclusively from the Public Sector units has been under consideration for several years in consultation with the Ministries of supply and Health. To arrive at a solution in the light of the Committees recommendation this problem was also discussed on 30-9-1974, in a meeting of the High Level Group for inter ministerial co-ordination in the field of drugs and pharmaceuticals constituted by this Ministry under the Chairmanship of the Secretary (Fertilizers and Chemicals) and having as its members representatives of the Ministry of Health, Ministry of Finance, Ministry of Commerce, BICP, DGTD, and DGHS. A representative from DGS&D also attended the meeting. In the meeting, it was noted that there are two angles to the problem and both affected the public sector. The Government Departments|Hospitals are interested in how to obtain the drugs at the cheaper price within the limited budget allowed to them while the public sector units are interested in how to sell the

*Not vetted by Audit.

drugs at prices which will be economic to them. In the view of the existence of parallel rate contracts which are necessary to have an alternate source of supply in case of failures by one source fixing higher prices for IDPL products does not help the company as the indentors preferably place orders with those having lower prices. It was therefore felt that a practical solution to this problem should be found out by identifying the drugs required in large quantities. It was decided that the DGS&D should study the problem on the above lines and bring up the matter for consideration at the next meeting of the High Level Group.

[Min. of P&C O.M. No. 8(25)|74-Ch. III,dated 30-9-74].

Recommendation (Sl. No. 80)

The Committee have been informed that State Governments mostly go by the price factor in the matter of purchases and give preference to units located in their States. The Director General of Supply and Disposal enters into parallel rate contracts with other companies because of its declared policy of having more than one sources of supply so that in the event of failure of supply of one source, they can fall back on the second sources of supply and also because of the fact that private firms quote rates lower than that of IDPL. The Committee feel that DGS&D should be directed to give preference to IDPL/HAL and only if IDPL, HAL fail to supply drugs of requisite quality that DGS&D should fall back upon other sources with whom DGS&D could, if necessary, enter into reserve rate contract. In the opinion of the Committee, this will ensure adequate business to IDPL and at the same time provide a second source of supply to the DGS&D. The Committee apprehend that if DGS&D continues to go by the system of lowest tender, the possibility of private manufacturers securing the contract by tendering the lowest price and supplying sub-standard or spurious drugs cannot be ruled out. The Committee, therefore, recommend that Government should consider all aspects of the problem and see in what way the present system can be improved upon to ensure availability of genuine drugs to the people at reasonable prices.

(Para 6.47)

Reply of Government

Please see reply to Recommendation No. 77.

[Min. of P&C O.M. No. 8(25)/74—Ch. III dated 4-12-74]

Further information asked for by the Committee

Has the next meeting of the High Level Group been held? If so, when and what is the outcome? Please state the latest position.

[LSS O.M. No. 26—PU/74 dated—21-5-75]

Further Reply of Government*

The matter was discussed in the meeting of the High Level Group on the 30th September, 1974 and it was decided that the DGS&D shall study the problem in all aspects taking into consideration the recommendations of the Committee on Public Undertakings. The DGS&D accordingly submitted the following note:—

"During 1973-74, DGS&D purchased drugs from IDPL worth Rs. 2.47 crores. During 1974-75, so far *ad-hoc* contracts for Rs. 1.39 crores and rate contracts with an approximate drawal of Rs. 6.66 crores have been placed on them. While placing orders during the current financial year, the following guide lines have been observed by DGS&D:—

(a) A price preference up to 10 per cent over the prices quoted by the private sector is allowed to M/s. IDPL.

(b) For items for which bulk drugs are manufactured by IDPL, rate contracts are placed on them on a preferential basis to ensure continuity of supplies.

(c) As far as possible exclusive contracts are placed on IDPL for these items. Paralleled rate contracts if at all are few. In case the competing firm is a small scale unit, price agreements are entered into, which are operated by DGS&D on receipt of formal indents from the users.

Although the figures of rate contracts drawals for the current year are only estimates (and in some cases for a period of two years) yet it indicates a considerable improvement over the purchases in the previous year.

IDPL being a large drug producing concern, its quotations against the tenders of DGS&D help in stabilising the prices of drugs. It provides a check on the prices of those quoted by private sector. Since IDPL is required to quote against each tender, whether *ad-hoc* or rate contract, it prevents forming of rings amongst the private sector firms. It helps in keeping competition alive in the drug industry which in turn is beneficial to the interest of Government purchasers.

DGS&D has so far been effecting purchases of drugs and medicines through rate contracts which are operated mostly by the Direct Demanding Officer, *i.e.* various units of DGHS, CGHS, Railway etc. It has now been decided that in respect of indents from the organisations under the control of Ministry of Health, formal indents will be raised on

*Not vetted by Audit.

DGS&D fixed quantity contracts on short and long term basis would be entered into. Such fixed quantity contracts provide a secure basis to the drug manufacturers for planning their production or distribution. It is likely that such fixed quantity contracts would in the long rup help IDPL to secure larger orders from DGS&D.

DGS&D also provides not only the facility of a Central contracting Organisation but a Central Paying Agency as well. In the absence of such facility, IDPL will find difficulty in the present set up to enter into separate contracts for the supply of drugs with a large variety of Central and State Organisation and to arrange to collect its bills from them".

This was further considered in this Ministry by the Minister of STATE in a meeting. In this connection it was noted that price preference of 10 per cent in respect of public sector firms were given in the context of unfair competition from private sector units and which results in under utilisation of capacity of public sector units and that it referred to the organised sector only. In the case of small scale units, price preference of 15 per cent *vis-a-vis* organised sector is allowed. In the circumstances, it was decided that IDPL should give specific examples as case studies so that the exact nature of the problem and what if anything should be done in this regard should be considered. The information is awaited from the IDPL and Government will examine the matter further.

[Min. of P&C O.M. No. 8(25)/74—Ch. III, dated 10-8-75]

CHAPTER IV

RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Recommendation (Sl. No. 6)

The Committee note that it has not been possible for the company to persuade the medical profession to use Chlorotetracycline Hydro-Chloride for human treatment nor it has been possible to use it as animal feed supplement. Subsequently, the Company has deleted Chlorotetracyclin from the plant's product-mix and have diverted equipment of the value of Rs. 36.72 lakhs (out of Rs. 65.55 lakhs) for meeting the deficiencies in other Sections and equipments valuing Rs. 9.11 lakhs is likely to be used for the production of Griseofulvin. The Committee find that even after such decision, plant and equipment of the value of Rs. 19.17 lakhs will still be lying unutilised. The Management claim that the major portion of the equipment will be utilised in the expansion programme to be finalised. The Committee are sorry to observe that determination of product-mix-without adequate demand survey had resulted in equipment value about Rs. 19 lakhs remaining idle. The Committee expect that the expansion programme would be finalised after a detailed market survey of the products and the surplus plant and machinery would be put to best use.

(Para 2.41)

Reply of Government

The recommendation of the Committee has been noted. Efforts to utilise/divert the equipments for the manufacture of other products are continuing. Equipments to be diverted at the end of 1973-74 are valued at Rs. 10.07 lakhs*

The expansion programme of the plant will be finalised by the company and Government after taking into account the demand of

*According to the Principal Audit Officer, equipment to be diverted at the end of 1973-74 was of the value of Rs. 17·50 lakhs. Out of these, equipments worth Rs. 6·82 lakhs have been earmarked for gresofulvin, leaving a balance of Rs. 10·67 lakhs still to be diverted.

each product as assessed by the Task Force on Drugs and Pharmaceuticals, current market demand of drugs, the expected growth potential and international trends in new product development.

[Min. of P&C O.M. No. 8(25) 74-Ch. III, dated 30-10-74]

Comments of the Committee

Please see para 28 of Chapter I of the Report.

Recommendation (S. No. 26)

The Committee find that the profitability Report drawn up in March, 1970 had provided for handling losses of packing materials to the extent of 15 per cent in glass vials and 5 per cent for capsules While in the case of vials the handling losses were within the norms, in the case of capsules, however, these were quite high in 1970-71, and 1971-72. The excess over norm of 5 per cent being 15,48,701 numbers in 1970-71 and 49,94,642 numbers in 1971-72. The Committee recommend that the abnormal high handling losses incurred in the case of capsules may be investigated and concrete measures taken to bring such losses within the norm fixed by the Management themselves.

(Para 2.298)

Reply of Government

Consumption norms have been formulated by IDPL based on that types of capsules and type of machine used for filling. Loss during filling with indigenous and imported capsules on automatic GKF machine has been fixed at 6 per cent and 3 per cent respectively. In addition, there is further loss of 2 per cent at the stage of strip packing and post strip packing inspection. Figures relating to handling losses are:

Year	Capsules filled	Capsules used	Percentage of excess
1971-72	7,75,67,960	8,64,41,000	11·44
1972-73	3,66,95,140	3,94,30,000	7·45
1973-74	9,13,43,200	10,18,33,400	11·48
1974-75 (1st quarter)	2,98,72,000	3,34,03,000	11·84

The percentage of rejections continue to be high and IDPL have been asked to make a thorough investigation.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dated 8-11-74]

Comments of the Committee

Please see paras 61 and 62 of Chapter I of the Report.

Recommendation (Sl. No. 34)

The Committee find that though the stock of raw materials with the Antibiotics Plant in terms of month's consumption has come down year after year, it is still more than the prescribed limit of the buffer stock, that is two months for indigenous and six months for imported material in certain cases. The management have stated that the build up of the inventory in these cases has been due to frequent changes in the production plans, low off take, transportation in bigger lots, failure of the supplier to strictly adhere to delivery schedule, changes due to technological requirements etc. The Committee also find that according to the review conducted by the Management in 1971-72 stores of the value of 22.10 lakhs were declared surplus. Out of these stores and spares of the value of Rs. 10.59 lakhs are awaiting disposal for more than one year. The Management have also fixed minimum, maximum and reordering levels for 545,546 items in February, 1973 out of 10,484 store items. The norms of the maximum and minimum limits were reviewed by the Management in 1972-73. The Committee have been assured that this work will be over within a period of next two years in respect of all items except some spare parts which are basically stocked as insurance items. The Committee recommend that the Management should expedite this work and ensure that in no case, the stock of raw materials in terms of months' consumption exceeds the prescribed limit.

(Para 2.348)

Reply of Government

The recommendation has been noted and so far a total of 340 items have been included under the automatic procurement system after fixing their maxima, minima and reordering levels. Further work is in progress.

The following raw materials were held in excess over the norms and action has been taken by the Antibiotics plant to transfer some of these raw materials to the Synthetic Drugs Plant, Hyderabad.

S. No.	Description of raw material	Unit	Monthly consumption.	Block position as on 16-10-74
1	2	3	4	5
	Indigenous:			
1.	Ammonium Nitrate	MT	11·58	122·75
2.	Sodium Bromide	MT		All stock transferred to SDP, Hyderabad.

1	2	3	4	5
3.	Sodium Tripoly Phosphate . . .	MT	9·54	114·30
4.	Magnesium Sulphate . . .	MT	0·53	1·785
	Imported :			
1.	Lactose	MT	62·86	347·604
2.	Ammonium Thio Cyanate .	MT	Nil.	All stock transferred to SDP, Hyderabad
3.	Ion-exchange resins			
	(i) KU-2-20	MT		5·892
	(ii) KB-4P-2 . .	MT		13·995
	(iii) KDEP-10P . . .	MT	..	7·269
	(iv) SBS-3 . .	MT		0·324
	(v) KU-2 . . .	MT		0·985
	(vi) KB-2	MT	..	12·920

Ion-exchange resins are not consumed every month and are used either for making up the loss or for complete replacing in the columns. However this stock will last for about 1 to 2 years.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dated 22-11-74]

Comments of the Committee

Please see para 80 of Chapter I of the Report.

Recommendation (Sl. No. 38)

The Committee note that the estimates of Synthetic Drugs Plant were revised on a number of occasions prior to the sanction, by the Government in 1966 for Rs. 2135 lakhs. As admitted by the Government no provision was made in the estimates towards interest on capital and commissioning expenses. The estimates were again revised by the undertaking in 1968 for Rs. 2293 lakhs and approved by the Government in 1971. The actual expenditure upto 31st March, 1972 is of the order of Rs. 157 lakhs was further to be incurred on the project bulk of which related to Plant and Machinery (Rs. 110 lakhs).

The Committee also note that the actual expenditure up to 31st March, 1972 included an amount of Rs. 83.14 lakhs incurred upto September, 1968 and during the period April, 1969 to March, 1972 on carrying out a number of modifications in the course of the erec-

tion and also with a view to assessing installed capacity and production practices.

The Committee regret to note that no details were, however, available about the expenditure incurred on the modifications during the period of October, 1968 to March, 1969 with the result that the responsibility of the collaborators, if any, could not be assessed and the expenditure got automatically charged to the Project estimates. Although, a procedure for estimating the effect of modifications was prescribed in October, 1967, the Committee note that this procedure was not implemented with the result that the effect of this modification could not be evaluated.

The Committee also note that the estimates of 1971 included new works costing Rs. 48.57 lakhs. The Committee regret that even though these new items constituted material modification of the original estimate of the Project, these were not got approved by the Government nor were these brought to the notice of the Parliament as recommended by the Committee in paragraph 2.20 of their 39th Report (1972-73 5th Lok Sabha). The Committee expect that Management/Government will bring these facts to the notice of the Parliament without delay.

(Paras 3.22—3.25)

Reply of Government

It was only in September, 1967 that the main boiler was commissioned and steam could be made available for exploiting the processes in production blocks on a commercial scale, wherever they were completed and were ready for commissioning. Processes in a drug manufacturing plant, where the production is to commence from basic raw materials, the stabilisation of the processes required time dring which cuhanges|modifications to equipments, pipelines etc., would be required before the final product is taken out. The changes are due to various reasons *viz.*, for achieving better yield, quality product, better safety in operation and maintenance etc. Upto April 1969, therefore requisitions for carrying out modifications of this nature, which are initiated by the production department and discussed in various meetings, were entertained and works carried out. Modifications carried out during the stabilization stages were not treated as separate works of capital nature for, the collaborators themselves had given in accordance with the supply contract certain quantum of reserve equipments and pipelines (spares) to be used during the commissioning stages (for changes as and when they become necessary).

The collaborators could carry out, according to the agreement modifications from time to time in the light of technological developments taking place in their country. Hence the expenditure on such modification during the period of erection and commissioning were to be borne by the Company by charging it to the project estimates.

However, as the number of such modifications and their value appeared to be on the increase, it was felt that a procedure should be laid down for keeping a separate account for such modifications carried out and this could be achieved only after detailed examination of the various aspects of the problem. After such a procedure was prescribed in April, 1969, a detailed codified account of all modifications carried out has been maintained.

The procedure for estimating the effect of modifications prescribed in October, 1967, was in respect of capital replacements and capital modifications, which were to be taken up after the commissioning of the Plant. Since the modifications were initially carried out during the course of the erection, no separate study of the impact of the modification in the manner laid down by the procedure prescribed in October, 1967 was possible.

The inclusion of new items of equipments etc., in the Project had the approval of Government. However, the question of bringing this to the notice of the Parliament is under consideration in consultation with the Ministry of Finance.

[Min. of P. & C. O.M. No. 8(25)|74-Ch. III dt. 19-6-75]

Comments of the Committee

Please see para 92 of Chapter I of the Report.

Recommendation (Sl. No. 42)

The Committee also note that there had been shortfall in production in Vitamin B1 and Bitamin B2, Folic Acid, Amidopyrine Piperazine salts and D.C. Citrate etc. on account of which the country had to import these drugs to the extent of Rs. 269.83, Rs. 366.81 and Rs. 219.98 lakhs in 1969-70, 1970-71 and 1971-72 respectively. The Committee need hardly stress that any shortfall in production and non-utilisation of the capacity will only increase the import of the drugs with greater out go of foreign exchange.

The Committee recommend that IDPL should ensure the full utilisation of the capacity in all products and thus avoid the necessity of importing them to save valuable foreign exchange.

(Paras 3.50 & 3.51)

Reply of Government

The item referred to in the above recommendation their installed capacity and production during 1973-74 and 1974-75 (six months) are indicated below:*

S. No.	Item	Installed capacity	Production	
			1973-74	1974-75 (six months)
1.	Vitamin B1	30	30·31	7·52
2.	Vitamin B2	5	1·81	2·18
3.	Folic Acid	1	2·37	1·40
4.	Amidopyrine	10	2·66	0·61
5.	Piperazine Salts	50	67·41	32·52

It will be seen therefrom that there is an improvement in the production of Vitamin B2, Folic Acid and Piperazine salts. The main constraints in increasing the production are the non-availability of raw-materials and the steps as indicated in reply to recommendation No. 41 are being taken by Government.

[Min. of P&C No. 8(25)/74-Ch. III, dt. 10-2-1975]

Comments of the Committee

Please see para 97 of Chapter I of the Report.

Recommendation (Sl. No. 61)

The Committee note that the percentage of rejections in SIP to the total production ranged from 18.95 per cent in 1971-72 to 27.37 per cent in 1970-71. The Committee also find that the percentage of rejections was the highest in the Grinding and Assembly Shops where the rejections showed an increase from 27,538 number of instruments in 1968-69 to 1,06,160 in 1972-73. The Committee were in-

*According to the Principal Audit Officer, the installed capacity in respect of Folic Acid is 2·5 tonnes and not 1 tonne and there is no separate installed capacity for Amidopyrine Moreover, as against the total intalled capacity of 200 tonnes for Analgin and Amidopyrine, the production thereof during 1973-74 was 1959·5 tonnes.

formed that the Management had taken a number of steps to reduce the rejections by more rigid check on the raw materials, stricter inspection of forging tools, improvement in tooling and machinery, promoting facilities for cleaning of stainless steel instruments etc. The Committee were also informed that the rejections in the Grinding and Assembly Shops were high due to inexperienced workmen being frequently put on more and more skilled operations. The Committee are surprised that in spite of the plant having been in operation for more than eight years and the necessary skill for operating the plant could not be developed. The Committee would like that in the interest of attaining high standards in production and minimising the rejections, the Undertaking should consider feasibility of introducing a time bound programme for training the workers in specified skills and deploy them suitably with a view to achieve quality production.

The Committee recommend that norms for rejections may be finalised without any further delay.

(Para 4.46)

Reply of Government*

The rejections that occur in the manufacture of surgical instruments are mainly due to (i) material defect (ii) non-flow of material during forging (iii) Breakage or damage to instruments during fitting and (iv) under-size in grinding. The material defects are now analysed with more specified processes and defects are removed at an early stage. However such rejections at an early stage are also included for computation of percentage of rejections. It may be mentioned that the defects in the raw materials are not assessable in visible inspection before taking up production. The defect of undersize is also due partly to defects in the raw material. The training of workmen was not possible due to the change in the product mix year to year from the inception. This has resulted in lack of high adequate skill amongst the workmen though the general technical know how and skill is not lacking. While trying to achieve an increase in productivity at the initial stage of processing in instruments, higher percentage of rejection occur. Even if there had been a gap of month or two when the workmen are put again on the same time for a few days, the rejections will be more and the productivity will also be less.

Taking into account the high standard of production required for meeting surgical instruments, the minimum rejection during the process has been worked out by the plant authorities on the basis of

*Not vetted by Audit.

their experience and is under consideration of the Board of Directors. A statement showing the rejections for the year 1972-73 and 1973-74 is attached at Appendix XII. The average of rejection of these two years is of the order of 20 per cent. It is hoped to improve the performance reduce rejections to the minimum and this will be feasible with a permanent pattern of production which is now being evolved through market survey and sale projection. The training to the extent a corrective action is required to reduce the rejections will be imparted.

[Min. of P&C O.M. No. 8(25)/74-Ch. III, dated 10-2-1975]

Further information asked for by the Committee

Please state:

(a) what steps have been taken to reduce rejections which have not come down substantially?

(b) Has the feasibility of introducing a time bound programme for training the workers in specified skills and deploy them suitably with a view to achieving quality production as recommended by the Committee, been considered and if so, with what results?

(c) Have the norms for rejections been finalised? Is so, the details thereof may be given.

[LSS O.M. No. 26-PU/74, dt. 21-5-75]

Further Reply of Government

(a) and (b) After the new product mix has been evolved, the production has been very limited due to power shortage and all efforts are being made to minimise the rejections.

(c) The norms for rejections have been finalised.

[Min. of P&C O.M. No. 8(24)/74-Ch. III dt. 10-8-75]

Comments of the Committee

Please see para 133 of Chapter I of the Report.

NAWAL KISHORE SHARMA,
Chairman,
Committee on Public Undertakings.

NEW DELHI;
September 29, 1975
Asvina 7, 1897 (S).

*Not vetted by Audit.

APPENDIX I*

(*Vide* Reply to Recommendation at S. No. 3)

Check List in connection with foreign collaboration agreements

1. *Parties to the Contract.*

(a) The principal party to the agreement should have the necessary expertise and proven experience in the field forming the subject matter of the contract and should not be dependent on other parties for its successful performance.

(b) In most cases the foreign collaborator will simultaneously have the role of the consultant as well as supplier, but at times there would be separate agencies for consultancy and supply. In such cases their role should be distinctly specified.

2. *Appointment of Consultants/Suppliers.*

(a) The foreign collaborator should be chosen on the basis of proven process technology and on the basis of his reliability to complete the work within the stipulated period.

(b) Inter-connected or subsidiary contracts should also be finalised at the same time as the main contract.

3. *Purpose and scope of the contract.*—should be defined clearly. If a project requires any change due to unforeseen circumstanes after the consultancy agreement is signed, necessary enabling provision should be available for such changes, with a clause similar to the one as under:

> "In the course of designing, both the supplier and the customer shall have the right to make alterations and additions in designs with due regard for latest achievements in engineering, design and technology, having intimated the other party and giving due justification thereof. However, all alterations and additions entailing major changes in technical and economic charateristis and in the cost of the project shall be mutually agreed upon by both the parties."

4. *Supply of Know-how.*

(a) The project may be broken into sub-elements to ensure that designs and processes are obtained from the most suitable manufacturers in the world.

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*Not vetted by Audit.

(b) The improvements effected by collaborators to the designs/ processes/equipments supplied by them under the agreement would be made available to the contracting Indian party.

(c) The collaborators would undertake to train Indian personnel and facilitate the transfer of technical know-how to them.

(d) In turn-key agreements the standing of the collaborators would be checked to ensure that effective coordination through them is possible.

5. *Detailed working drawings and Specifications.*

(a) Supply of information and data on design and development including detailed drawings, design sheets, specifications and calculations by the consultants on a regular and continuous basis for a clearly specified period should be ensured.

(b) It has been experienced that supply of mere documentation by the collaborators has been an implement in transference and assimilation of the technical know-how.

Proposals for majority foreign participation in new enterprises should be considered only when one or more of the following main criteria are satisfied:—

(a) the main contribution of the project is in a field of technology where India has made little progress and where great deal of initial or additional development is necessary.

(b) the amount of foreign exchange needed for the project is such that unless the foreigner is allowed to have majority share holding we shall ourselves have to find a substantial amount of the foreign exchange for the project, no alternative methods of long term finance being practicable; and

(c) an essentially export oriented scheme.

(v) There should generally be no provision for payment of a stipulated minimum amount of royalty related to turnover.

(vi) In the case of payment of royalties to overseas concerns by fully-foreign-owned or majority-foreign-owned Indian companies, the following procedure should be followed:—

(a) *Collaboration between a wholly-owned subsidiary of a foreign company in India and the parent company.*

Ordinarily no royalty payments to the parent company will be agreed to but payments towards technical services and fees for contribution towards research expenditure may be considered on merits in individual cases.

(b) *Collaboration between a wholly-owned foreign subsidiary in India and a foreign company other than the parent company.*

As a general policy collaboration between wholly-owned subsidiaries in India and a foreign party other than the parent company should be discouraged.

(c) *Payment of royalty in joint ventures in which the foreign collaborator has a majority holding.*

In cases of companies with majority foreign equity participation it will not be practicable to take the stand that there should be no royalty payments at all. The existing policy of allowing a substantially lower rate of royalty than would otherwise have been agreed to will continue to be followed.

(vii) Royalty payments should normally be restricted to a period of 5 years from the date of agreement or 5 years from the date of commencement of production provided production is not delayed beyond 2 years of signing of agreement (*i.e.* a maximum period of seven years from signing of agreement).

(viii) In all cases of Government approval to foreign collaboration proposals it should be specifically stipulated that the royalty terms were being approved for a particular quantum of production (*viz.* upto the capacity licensed or proposed to be set up, and 25 per cent in excess thereof) and that in case of production in excess of that quantum the prior approval of Government would have to be obtained regarding the terms of payment of royalty in respect of this extra production.

(ix) The fact that foreign investment is allowed should not be a ground for allowing import of capital goods which would otherwise not have been allowed. There should be appropriate scrutiny from the indigenous availability angle to ensure that the maximum possible fabrication of indigenous machinery is insisted upon. It is,

in general, desirable for investment to be in the form of cash, with purchase of equipment from the cheapest source. Where the investment is in the form of equipment, care should be taken to see that the prices charged are reasonable. Where the capital participation exceeds the value of imported machinery, the balance should be brought in cash.

(x) There should be no stipulation that raw materials, components etc. will be obtained only from the foreign collaborator. The Indian parties should have freedom of choice in this regard.

(xi) With a view to promote exports of non-traditional products the following points should be kept in view:

(a) When existing collaboration agreements which limit export franchise, come up for renewal, the restrictions should be totally eliminated or substantially removed. In the event of the foreign collaborator not agreeing to this course of action, renewal of agreements should not be permitted;

(b) Further agreements should be stringently scrutinised to eliminate export restrictions, the approach being that the agreement should allow free export to all countries except perhaps the country of the foreign collaborator or the countries where the foreign collaborator is having joint ventures in the same field of production;

of sub-assemblies and components are as close to the price of the main equipment as possible.

13. *Variations in the conditions for supply of equipments, components, spares and stores.*

(a) Break-up of the prices should be indicated in regard to the payment of freight, siding charges, handling charges, sales tax, terminal taxes, etc.

(b) Include 'weight variation' clause in the agreements so that the tenderers may exaggerate the quantities of materials with a view to making their offers more attractive.

(c) Cash discount, if any, received by the suppliers/collaborators should be taken into account while computing the reimbursements due to them.

(d) For the total quantity of steel or other materials required for the work, certificates from the Engineers of the undertaking should be necessary.

14. *Inspection in the foreign country before despatch.*

Provide for pre-shipment inspection/testing clause by independent Inspection Agencies covering the inspection of materials before despatch.

15. *Shipping Documents.*

In the event of delays in despatch of shipping documents or discrepancies therein the suppliers should be responsible to compensate the customers for losses/extra expenses, if any.

16. *Excess Supply of items|spares.*

Collaborators should agree to take back the items|components| spares etc. supplied|arranged by them if they are found to be in excess of requirements within a period of say 3 to 5 years.

17. *Remuneration for Consultancy service.*

(a) Payment of Licence fee may be split up into 2 parts—first half being payable for the grant of right to set up the plant including supply of drawings, design, data etc. and the second half after commissioning of the plant.

(b) Some agreements provide that the last instalment of the licence fee would become payable within a specified period from the effective date of the agreement. In such cases if the completion of the project is delayed, the last instalment of fee becomes payable before the guarantee test runs are held, with the result the licensor has no financial liability for non-fulfilment of guarantees, if the guarantee test runs are held beyond the period mentioned to the agreement. To overcome this difficulty the licensor may be asked to (i) to extend the specific period as far as possible of (ii) to be responsible for the process guarantees even after the last instalment of the licence fee has been paid.

(c) In case of delay in execution or unsatisfactory performance, in addition to the clause of liquidated damages etc. a right to postpone the payment of instalment could be secured.

(d) Fixation of remuneration as a percentage of the total cost of the project or as a percentage of the cost of plant and machinery, is open to objection as the incentive for economy in designing is lost thereby. Secondly, it would be difficult to know in advance what the commitments on account of the consultants' fees would be. Thirdly, it might result in unintended benefit on account of the increase in cost of work due to extraneous reasons like contractors' delays and failures. In order to avoid these difficulties, the fee as far as possible, when based on a percentage, should be calculated on

the basis of the estimated cost and expressed in the consultancy agreement as a definite figure. If necessary, provision may be made for varying the figure by negotiation if the scope of the project is changed and as a result, a substantial change occurs in the nature of the work to be performed by the consultants.

(e) Where a fixed fee payable either in lump sum or in instalments is agreed to and where the consultants require a portion of the fee within a few days of the agreement being signed, it would be necessary to limit the payment to as small an amount as practicable. The payment of the remaining amounts may be made in instalments at different stages *e.g.* on the submission of the drawings and designs, during erection period and when the plant has gone into production and given satisfactory performance. It would be necessary that the stage for the last instalment is such that in case of a serious defect or failure, it would be possible to withold the last instalment. The quantum of the instalments, as far as practicable, should be related to the amount of work done.

(f) Certain facilities may have to be made available to the consultants in regard to residential and office accommodation, travelling allowances both from the parent country to India and within India, provision of vehicles equipment, medical facilities etc. When assessing the remuneration, the incidence of such facilities should be clearly borne in mind.

(g) Some of the items of work may have to be done in the country, while others may have to be done outside. It is necessary, therefore, that a clear indication in regard to both should be available so as to determine the quantum of remuneration. It would also be useful to include in the agreement a list of staff that would be posted within the country so that no confusion or dispute arises at a later stage. A part of the fee corresponding to the portion of the work to be done in India should be paid for in non-convertible Indian Rupees.

(h) The taxation aspects in respect of the remuneration, salaries etc. to be paid should be kept in mind and not left open.

(j) If materials are supplied to the collaborators|contractors for completion of the works, the "issue rates" covering storage and departmental charges should be agreed upon in advance. This aspect should be finalised even at the time of conclusion of the agreement. Tenders may be invited on the basis of the project supplying such materials and also on the basis of contractor furnishing all the materials.

18. *Posting of technical specialists and provision of free supplies and services.*

(a) As regards technical specialists, interpreters and other supporting staff, the total remuneration should take into account all the benefits like salary and allowances, medical facilities, housing, leave travel facilities and free conveyance.

(b) Provision of free supplies and services to project contractors should be avoided as far as possible.

(c) Public enterprises should not normally agree to construction of any special type of quarters for technical specialists from the suppliers|contractors.

(d) For technical specialists, minimum number of family quarters may be agreed to. Most of the foreigners should be housed in hostel type accommodation or any residential houses converted into hostel accommodation.

(e) As far as possible foreigners should be persuaded to use the officers' clubs constructed for the officers of the undertaking. If a separate club is insisted upon, it would be desirable to convert one of the houses into a club or add one or two rooms to the dining hall of the hostel.

(f) In the cases where the stay of foreign Experts is prolonged because of extension in completion of the project owing to limitation in the Plant and equipments, a clear provision should be made for sharing of expenditure on Experts by foreign collaborators under such circumstances.

19. *Travel by Air.*

Provision for Air travel of foreign experts and their families should be such that the journeys are arranged through Indian National Air Carriers.

20. *Payment in Indian currency.*

(a) In cases where contracts provide for the setting up of revolving fund for payment of the contractual obligations, the maximum amount to be placed in the revolving fund should be specified.

(b) The clause for financing charges, if any incorporated in the agreement, should be clear and specific.

21. *Payment in Foreign currency.*

(a) Foreign exchange aspects should be kept in view and as far as possible the consultants should be required to work with the help of local personnel in India so as to reduce payments in foreign currency.

(b) When payments are to be made in foreign currency it would be better to deposit the rupee equivalent in a bank in India nominated by the Consultants and remittance facility allowed.

22. *Time schedule from Trial run to full production.*

Time schedule for the various important events and progressive targets should be laid down clearly. It would be desirable to watch these time schedules and targets by net work analysis. Constant reviews would be necessary after every important event or delays due to any reason whatsoever to determine the ultimate time schedule in the completion of the project.

A clause for recovery of liquidated damages for delays should be provided. Likewise payment of incentive bonus for improving upon the completion date may be considered where necessary.

23. *Guarantee on performance and maintenance of quality.*

(a) Performance guarantee bond should clearly indicate the liability of the Collaborator/Consultant for satisfactory performance and due fulfilment of the contract in respect of quality, faultless operation, and level of production etc.

(b) Guarantee clauses relating to the professional competence of technicians deputed as also for the accuracy of documents supplied should provide the right of claiming damages and replacement of the defective supplies.

(c) In all contracts for supply of equipments, the Indian party should reserve the right to decide finally whether the non-shipment of minor items would be taken into account for determining the date of last shipment as also the effect of the non-shipment of such items on the erection schedule of the project, the guarantee period for the workmanship guarantee period for the workmanship guarantees etc.

24. *Penalty Clause.*

(a) A clause for recovery of liquidated damages should be included (in addition to the right to terminate the agreement in case of delay in execution or unsatisfactory performance) and also a right to postpone the payment of every instalment in such a situation should be secured. It may also be desirable in many cases to

have a performance guarantee bond being directly enforceable by the enterprise, with regard to the functioning of the equipment and the like. In cases of delay in execution, it would be necessary for the enterprise to make a genuine pre-estimate of the damages likely to be suffered by reason of delay and the like, and to make a provision for liquidated damages on that basis.

(b) Where possible penalty clauses for non-adherence to the committed delivery schedules of equipments, components, materials, designs, specifications, know-how etc. should be provided.

25. *Price Escalation clause.*

Escalation should preferably be admissible only where the rates of labour and material have increased due to fresh Government orders like imposition of new duties, taxes, levies etc. If any price escalation clause is incorporated it may be clearly defined as to what extent and on what basis escalation will be admissible.

26. *Royalty Payments.*

In the case of certain consultancy agreements, utilisation of some patent rights may be involved, which may require payment of royalty or fees for several years to come. As far as practicable, such perpetual payments should be avoided unless justified on financial grounds. It should be considered whether it would be advantageous to buy such rights outright or to make payments on yearly basis.

27. *Indemnities.*

The consultancy agreement should provide a safeguard to the public enterprises in the contingency of any infringement of patent rights and other claims by third parties.

28. *Power of Transfer.*

The Government|Public Enterprises should have the right to transfer all rights and liabilities under the agreement to any other company or organisation provided that the Government/Public enterprises have and maintain a controlling interest in such company or organisation.

29. *Property rights in respect of drawings, tools, fixtures, temporary buildings and left over Materials etc. after the completion of the work.*

The question regarding the title to the plant machinery etc. supplied by the contractor should be adequately covered and spelt out

in the agreement, so that there is no ambiguity regarding the ownership of the materials left after the completion of the project.

30. *Arbitration.*

It may be indicated, whether the Arbitration Act, 1940 shall apply. The number of arbitrators, Umpires, their nationality and the venue of the proceedings may be indicated.

31. *Law of the country and venue for settlement of disputes.*

The contracts, particularly those with foreign parties, should contain an express provision as to the law by which they are to be governed. It would be desirable wherever possible to state that the contracts would be governed by Indian Law.

32. *Force majeure Clause.*

If the execution of the contract is delayed for any period because of hostilities, embargo, blockades or for any other reason beyond either party's control, the parties shall not be held to the date of execution of the contract and the representatives of the parties to the contract shall immediately consult each other and agree upon the necessary measures to be taken.

The existence of such circumstances within the territory of the countries of the parties to the contract shall be confirmed by certificates to be issued by the appropriate authorities in the countries concerned.

33. *Giving notices for Termination of Agreement.*

There should be a clause for premature termination of a consultancy agreement in case the work is found to be unsatisfactory or not suitable. There should also be an indication regarding the manner of settling the account in case such contingency arises. As far as possible, the quantum of remuneration should approximate the quantum of work actually done and legitimate expenses incurred by the consultants. It should also be clearly laid down that whatever work has been done by the consultants shall be the property of the employer and all papers, drawings and designs etc. should be secured in suitable form before final payments are made.

34. *Project estimates.*

Project estimates should be drawn up realistically and provision made for all essential items, so that these estimates are not revised frequently.

Enclosure

Extracts from O.M. No. ID&PC-5(26)/68-II, dated 25-1-1969 regarding foreign collaboration policies and procedure—Guide lines.

* * * *

The following are some of the general principles to be borne in mind while dealing with foreign investment/collaboration cases:—

(i) Even when the principle of foreign investment in a particular industry is accepted, it is important to ensure that, to the maximum extent possible, effective control in a joint venture rests in Indian hands. That is why foreign equity participation beyond 49 per cent is accepted in only exception cases. It is probable that in view of the Indian shareholding being divided, the foreign collaborator may be in a position to exercise effective control on the basis of a holding of less than 49 per cent. In view of this, all cases with foreign holding in excess of 40 per cent should be looked at carefully and, where approved, such steps as may be practicable (such as insistence on majority Indian Directors) should be taken to ensure that effective control remains in Indian hands. In Judging the relevance of foreign equity holding to effective control, it would also be pertinent to distinguish between cases where the foreign equity holding belongs to a single group of management (or closely related groups of management) and those where it is shared, particularly with foreign financial institution including International Institutions.

While our policy is to encourage foreign private investments in the industries which we desire to develop, one of the criteria for judging such proposals would be related to the profitability of a particular industry. While considering proposals for foreign equity participation in industries where the profit margin is substantially high, Ministries should take into account the quantum of dividends which will have to be remitted abroad in a relatively short period and relate this to the likely earning or saving of foreign exchange.

(ii) Normally royalty is expressed as a percentage of the ex-factory selling price of the product, minus the landed cost of the imported components including ocean freight, insurance, customs duties payable thereon etc.

In appropriate cases the alternative of expressing royalty as a fixed amount per unit of production may be considered. This may be particularly appropriate in cases where the Indian price of a commodity is expected to be very high as compared to the International price.

In respect of the engineering industries, a provision should be made in all collaboration agreements to the effect, that if a readily indentifiable component is made by the same Indian party in collaboration with another foreign party, on a royalty basis, the cost of such a component should be deducted from the *ex*-factory price of the final product for the purpose of computation of royalty. Similarly, if the same foreign collaborator is associated with the manufacture of the final product and also any of the identifiable components, even if the Indian partners are different, the cost of such components should also be off set from the value of the final product for the purpose of the computation of royalty.

(iii) For the purpose of these guidelines royalty has been grouped into two ranges, a low range upto 3 per cent and the other upto 5 per cent. All royalties are subject to Indian taxes. The Ministries and the Department of the Government of India should not as a rule negotiate on the basis of payment of fees to foreign collaborators free of Indian taxes but should insist on such payments being fixed subject to applicable Indian taxes.

The question has been considered whether in cases where minority foreign investment is allowed, the rate of royalty applicable should be something less than what would be admissible if there is no equity participation. A view has been expressed that in so far as the foreign investor gets a share in the profits of the company, there is a justification for a reduction in the royalty rate. On the other hand, the foreign investors have often taken the stand that their participation in the equity risk should not be ground for denying payments which would otherwise have been made. Government have accepted this position. It is felt that we should not take a rigid stand that there should be an appreciable reduction in the percentage of royalties on account of equity participation particularly as this may act as a disincentive to investment. In the interest of quick decisions, it does not seem desirable to have too much of a refinement to regulate the rate of royalty according to the quantum of minority investment.

(iv) In the very limited number of cases where majority foreign participation is agreed to the royalty payments to the foreign collaborators should be on a substantially reduced basis of production processes. Therefore, supply of detailed design sheets, specifications and design calculations should be insisted upon.

(c) Relevant clauses should contain such details as quality of raw materials, specifications for substitute materials and alternative suitable process etc.

6. *Payment of know-how fees.*

Where the agreement provides for payment of know-how fees in instalments, sufficient interval may be allowed between instalments to permit completion of all formalities and procedural requirements.

7. *Limitation of the duties of consultants/suppliers.*

The consultants' recommendation shall not be mandatory in nature. The final decision in any matter, technical or economic, shall rest with the Undertaking/Indian Government. The responsibility of the consultants *vis-a-vis* that of the management should be clearly laid down. The consultant should not have a free hand to commit the management of the undertaking without prior consultation.

8. *Specifications, Rate schedules, Quantities etc.*

Should be set out in detail and with precision, considering special conditions of contracts, if any, such as free supply of electricity, accommodation, taxes, duties etc.

9. *Schedule of equipments/components and stores to be used.*

(a) Provide for the posting of an officer at the collaborator's works to advise and guide with regard to the indigenous availability of materials, implementation of Indian standards, safety and other requirements etc. while the designs are under preparation.

(b) Names of equipments|components|spares should be clearly specified to avoid vague expressions like standard equipments etc. since disputes may later on arise over the interpretation of such expressions.

(c) No commitment for import clearance for any item should be made without prior consultation with DGTD.

10. *Item-wise price schedule where possible for the foreign equipments/components and stores.*

(a) Item-wise list of supplies with prices would be useful to check whether the rates allowed to the contractor are reasonable. Pricing of the equipment by average weight should be avoided.

(b) Supply of components/equipments at cost plus a specified percentage of profit over the cost should be avoided as some of the companies do not agree to the detailed scrutiny of their costs or estimates by others.

11. *Methods and sources for obtaining the foreign equipments/components and stores.*

Provide for the right to procure components/equipments directly from the concerned suppliers in case the prices quoted by such suppliers are lower than those quoted by the collaborators.

12. *Schedule of indigenous equipments/components and supplies.*

(a) Ensure maximum indigenous participation in design and manufacture.

(b) Break-up of sub-assemblies and component prices may be indicated in the contract itself.

(c) It might be advisable to first settle the prices of the main equipment on a competitive commercial basis and then to see that the total of itemised prices.

(c) in low-priority or non-essential fields of production where foreign collaboration is not generally allowed, a relaxation be made where the foreign collaborators agree to undertake a major share of the production for exports; and

(d) the existing policy of not allowing foreign collaboration in trading activities may be relaxed where such collaboration is *exclusively* aimed at augmenting our export sales.

The Ministries should ensure that the export clause in the collaboration agreements gives correct and definite information regarding the countries to which exports will be specifically permitted or disallowed and this information should be clearly indicated in the Notes| Summaries prepared for consideration of the Foreign Investment Board or its Sub-committee.

In considering applications for foreign investment/collaboration in low priority and non-essential fields, no specific percentage can be rigidly enforced in regard to the quantum of production to be underwritten by the foreign collaborator for export; this will have to be considered on the basis of the export potential of each product. Before putting up such cases to Foreign Investment Board, Ministry of Commerce should be consulted and their views obtained in each case.

(xii) Where an indigenous "know-how" capable of commercial exploitation is available, importation of know-how is not normally permissible.

(xiii) The important of avoiding repetitive *import of know-how* for the same or similar product or process should be kept in view.

Also to the extent practicable fresh entrants should be asked to obtain the know-how imported by those already in the field.

In fields of manufacture where a number of collaborations have already been approved and a new application is received for approval of foreign collaboration in the same field, step should be taken to explore whether it is possible for the new applicant to obtain the know-how from one of the parties who are already in possession of it. In the many of the existing agreements there is secrecy clause. In future agreements the Ministries should ensure that there is a provision to the effect that the technical know-how|product design|engineering design can be passed on to another Indian party, should it become necessary, on terms as mutually agreed to by all the parties concerned, including the foreign collaborators, and subject to the approval of Government.

In fields where there is likelihood of 3 or 4 units of the same industry, being set up at about the same time and all of them are likely to require foreign collaboration, it should be ensured that negotiations for acquisition of know-how for these units are conducted in a co-ordinated manner, with selected foreign parties, rather than permit each Indian party to negotiate individually and independently of each other. Economics of scale would make themselves felt in such a case of negotiation on a multi-plant basis and result in lowering or royalty rate and lump-sum fees for the first as well as every subsequent unit.

(xiv) In appropriate cases, and to the maximum extent practicable, there should be provision for *Indian scientific, technological and engineering institutions* being associated with the foreign collaboration, so that the foreign 'know-how' is absorbed in our economy as quickly as possible and further developments could take place with the country. While approving a case of foreign collaboration, stress should be laid on the development of indigenous "know-how" as early as possible, so that it may be possible to discontinue the collaboration after the period of validity of the agreement.

(xv) With a view to ensuring maximum possible utilisation of Indian Consultancy services, wherever Indian consultancy is available it should be utilised exclusively and if foreign consultancy is also required, Indian consultancy should also be associate and, as a rule, be the primary agency employed for consultancy. From amongst the Indian consultancies, preference should be given to agencies in which the predominent interest is Indian.

Clearance of the Foreign Investment Board should be obtained by the concerned Ministry|Department before consultancy services involving payment in foreign exchange of Rs. 50 lakhs or more are agreed to.

(xvi) Suitable provision should be made for the training of Indians in the field of production and management.

(xvii) The question of use of foreign brand names/trade marks should be examined from the view points (i) whether any additional payments is envisaged for the use of such foreign brand names; and (ii) whether the use of such names would adversely affect the small scale sector or the indigenous industry. In such cases the use of foreign brand names should not be allowed for products manufactures under foreign collaboration and meant for the Indian market. There should, however, be no objection to the use of foreign brand names on the products meant for export.

(xviii) A predominantly foreign owned company with agency functions operating in India should be called upon to redifine its functions, wherever it proposes to associate Indian capital or, in other words, reduces foreign equity.

(xix) Cases of 100 per cent foreign owned Indian companies or predominantly foreign owned companies seeking to take over another predominantly foreign owned Indian company or any other category of Indian company (a) by complete merger or (b) by making inter-corporate investments, within the ambit of Section 372 of the Companies Act, should be brought before the Foreign Invest Board/Sub-Committee. All cases of merger of two Indian companies which will result in the merged company having a direct cum beneficial non-resident shareholding in excess of 40 per cent of the equity capital should also be brought before the Foreign Investment Board.

APPENDIX II*

(*Vide* reply to Recommendation at S. No. 7)

Recommendations of Technical Committee on the working of Antibiotic Plant, Rishikesh and the Progress on Implementation of those recommendations

Recommendations of Technical Committee	Progress of implementation
I. ORGANISATION SET-UP :	
Technical Committee has recommended a radical re-structuring in the organisational set-up for proper coordination and management of operations.	Based on the recommendation of the Technical Committee, necessary changes have been made in the organisational set-up, keeping in view the problem of coordination and management of operations, which are unique to this plant because of constraints of process technology and layout. In order to integrate more effectively the activities of Fermentation and Recovery & Purification blocks a post of Chief, Bulk Production was constituted with the responsibility of managing operations of both the blocks. This post has been subsequently filled up by a senior technologist. A separate "Department of Technical Development" has been created. The combined responsibility of operations planning and evaluation of technological problems and suggesting remedial measures to the operating staff and the pilot plant has now been placed under the exclusive control of Chief, Technical Development who is responsible for scaling up the process developed in the research labs. The Chief, Technical Development, who has been assigned this function, carries out almost the same functions as are outlined by the Technical Committee for the post of Chief, Fermentation Development. Certain re-organisation has also been carried out in the R &D section with a view to intensifying the Research & Development activities. As regards the groupings of other functions certain clarifications have been sought by the Company from the Ministry of Petroleum and Chemicals to consider their implementation.
2. TECHNOLOGICAL TALENT :	
The Committee has pointed out that talent in the organisation is low and the placement of such talent as	In pursuance of the recommendations of the Technical Committee to up-grade the technological skill of the work force, the training department has been placed under the direct

*Not Vetted by Audit.

Recommendations of Technical Committee	Progress of implementation
is available has been inappropriate in most key-positions, while conceding the fact that the plant had to operate under limited availability of talent.	charges of an Asstt. Supdt. (Trg.), who reports to the Personnel Manager. there has been a qualitative change in the type of training programmes offered during the last one year in so far as the emphasis has been placed more on the development of awareness of the modern management techniques as applicable to our situation. A team of Indian Statistical Institute has carried out programmes on the application of 'Statistical quality Control' techniques, so as to improve the ability of technologist to resolve problems on a more rational basis rather than adopting "Shoot by hunch" method.
The committee has recommended for the recruitment of fresh talent from outside and to initiate appropriate training programmes for personnel at all levels. To the extent that training programmes may be expected to advance skills, they contribute (i) to greater efficiency in work (ii) in opportunity for the organisation to locate talent and fill positions from within by promotions when such occasion arises either due to migration of the incumbents or due to expansion programmes within the plant.	Other functional areas have also been adequately covered by this team. Although it is difficult to evaluate quantitatively the impact of those training programmes on the improvement of technological skill, an analysis of the responses of participants collected after the training programmes indicates that these programmes have been well received and have achieved the objective for which they were designed. The systematic approach in resolving technological problems has resulted in significant improvement both in the quality and quantity of output.
3. The Committee has pointed out that profitability at the full capacity utilisation of the plant are not very encouraging as even the slight variation in yields and upward movement of the cost of raw materials and wages may turn the profitability into a loss.	As already stated in our comments on the report sent to the ministry *vide* our letter No. IDP/MD/73 dated 20th November, 1973 the Antibiotics plant is over staffed with highly qualified personnel which include 19 Ph. Ds, 68 Engineering Graduates, 96 Engineering Diploma holders, 24 Agricultural graduates, 100 post-graduates in science and 410 ordinary graduates in science. In fact, more than 25 per cent. of the persons employed in the plant are Degree/Diploma holders. It is conceded, however, that there is overall low talent in the Antibiotics field in the country and that is true for the plant as well. The plant is making best possible use of talent available to it.
In this content, committee has recommended :	(i) Results of research work carried out during the year 1973-74
(i) Accelerating the development of such technology in the plant itself.	(a) *Panicillin Fermentation.* A high yielding penicillin isolate with the productivity of 15000 to 16000 units/ml. in the shake flask was stabilised and made available for trial use in the main plant. (b) *Penicillin recovery.* A modified method of crystallizing penicillin in the form of K-salt from 2nd butyl acetate extract avoiding carbon treatment has been worked out in the Pilot Plant. This method has shown that the recovery of K-salt from the second butyl acetate extract would be 88-90 per cent as compared to 73-74 per cent obtained now.

(ii) If time is critical important as it should, to introduce such technology from wherever it is available.

(iii) Formulating capacity of the plant both for capsules and vials should be further increased to improve the ratio of sale of formulations to bulk.

(iv) The product -mix of the formulations should be modified include newer formulations with better profitability. A beginning has already been made in this direction.

(v) More emphasis should be given on the sales of those products where profit margin is higher.

(vi) In consideration of the fact that modern trends showing increasing use of semi-synthetic penicillin, the question of converting surplus potassium penicillin into ampicillin and other semi-synthetic penicillins should be given a serious thought.

in the plant. This would give an overall increase of 12-15 per cent more of K-salt from the native solution (*i. e.* 75-78% as compared to 6-62 % of the present trend). The method was recommended for trials in the main plant.

(c) *Tetracycline and Oxy tetracycline recoveries*:

As a result of R & D efforts the recovery processes both for tetracyline as well as oxy tetracycline have been modified from ion-exchange resin to precipitation methods which have not only improved recovery efficiencies significantly but have also helped to enhance the capacity of the Plant for these antibiotics. The average recovery efficiencies achieved during the last 3 months (Sept. to Nov. 74) for tetracycline and oxy Tetracycline are 57. 43% and 47.57% against 35·0% & 38·0% respectively during 1972-73.

(d) *Penicillin*. As a result of modifications carried out in sodium penicillin section during 1973-74 the stability of sodium salt which was a very serious problems before modification as shown definite improvement during 1974-75.

Ion-exchange method for preparing sodium penicillin from potassium Penicillin has been worked out in the laboratory. It has been tried successfully in the Pilot Plant and trial runs are being taken up in the main plant. This should improve the efficiency by about 15%.

A Technical Development Department as stated earlier has been created at the plant to intensify the development and improvement in technology so that yields and efficiencies of different antibiotics can be brought up to improve the profitability. The Plant has also introduced new strains as a part of up-grading the technology in case of streptomycin, tetracycline and oxytetracycline. This has resulted in progressive improvement in fermentation activities. The average activity achieved during the last 3 months (Sept. to Nov. 74) for different antibiotics is given below :

Product	Av.act.(U/ml) (Sept. Nov. 74)	Av.act. during the year 72-73
Penicillin	7926	7687
Streptomycin	6874	4438
Tetracycline	6858	3400
Oxytetracycline	9885	7071

Recommendation of Technical Committee	Progress of implementation

(ii) In order to gain time for bringing in radical changes in the technology, the company is in the process of seeking collaborations in adtibiotics field from Western Countries. Recently a memorandum of understanding has been signed with M/s. Rachelle Laboratory, California, U.S.A. for Doxycycline and other antibiotics. A drug delegation led by Managing Director of IDPL had visited various countries for this purpose. Offers for the transfer of technology for 6APA and semi-synthetic penicillin, from western Countries are under examination for expeditious implementation of these Projects.

(iii) In consistence with the recommendations of the Technical Committee to improve the ratio of sale of formulation to bulk scheme to expand capsulation capacity of the Plant to nearly two times of the existing capacity has already been finalised and the modification work as also procurement of some equipment is in hand. Since the achievement of rated capacity in vialing is dependent upon the availability of vials and rubber stoppers, etc. efforts have been made to develop parties for the same. A unit of J. G. Glass has already been commissioned in the vicinity of the plant as its ancillary which is now able to supply about 6·7 million vials/per month. In addition, the plant has also entered into a contract for the supply of glass vials with Alembic, Baroda (2 million/month) during the current year till the time the local J. G. Glass achieves its rated capacity of 200 million vials per annum. After having achieved the rated capacity the question of further expansion can be considered.

(iv) The product-mix of formulation is being modified and formulations like chloramphenicol, chlorostrep, griseolfulvin tablets, OTCIM, Ampicillin, Doxycycline, are in the process of manufacture/introdution to improve the profitability of the plant.

(v) In addition to IV above the company is progressively increasing the production of tetracycline and oxytetracycline which have better returns. The production of the two bulk antibiotics in milliards has been as under :—

Year	Tetracycline	Oxytetracycline
1973-74	14,652·80	12,152·24
1974-75 (up to Nov. 1974)	12,738·80	15,613·65

(vi) The company has taken up development of technological know-how for production of semi-synthetic penicillin using 6-A PA as the intermediate compound. In this connection, work has already started in the research laboratories at ABP and it has been going on for the last 10 months. It has been tackled as separate problem and involves.

(a) Isolation of micro-organisms capable of hydrolysing potassium Penicillin to 6-APA.

(b) Isolation and purification of 6-APA.

(c) Preparation and resolution of D-phenylglycine.

(d) Synthesis of Ampicillin.

The (a) and (b) steps when worked out will help the utilisation of the potassium penicillin available in the Plant. To this extent some success has been seen and an organism capable of hydrelysing potassium penicillin has been isolated. Further work is going on and a defined technology for production of 6-APA from potassium Penicillin is likely to be finalised by first quarter of 1975.

Steps (c) and (d) are also being tackled and some progress has been made regarding preparation of DI-phenylglycine and resolution of D-phenylglycine from this mixture. Synthetic work of ampicillin using 6-APA and D-phenylglycine is also being taken up. We expect a laboratory technology for ampicillin synthesis to be completed by June 1975. Laboratory trials for synthesising methycycline and oxy-cycline have been successfully completed using commercially available 6-APA.

4. (i) Certain modifications have been implemented or are in the process of implementation for different departments to improve upon the working and to have better control on operations. Some of them are listed below:—

(*a*) The chilled water temperature in the Fermentation Block has been modified from 14oC to 8oC for better temperature control (date of expansion—Nov. 1973).

(*b*) The main air heater has been diverted product-wise for effective control on sterility (Date of completion—30-6-74).

4. The Committee has suggested :

(*i*) The list of specific and characteristic physical needs of the individual departments. The plant management should be enabled to acquire those to facilitate greater control of operations.

(*ii*) There is a real need for careful technical analysis of all suggested or intended changes by appropriate agencies with the plant supplemented, if necessary by available outside cooperation before embarking on the implementation of major changes of the plant. It is the adoption of such rational methods, which are supplemented with keen time and cost consciousness, that is the prime need of the plant. The adoption of shoot by hunch, methods may or may not

Recommendation of Technical Committee	Progress of implementation
yield expected results, the probability of the latter being vastly greater.	(*c*) Additional primary air filters have been provided in the Fermentation Block to meet requirement on individual products. (Date of completion of job—30-6-74). (*d*) Individual air filters have been modified where necessary to overcome the deficiency in their design. (Date of completion—May ' 74). (*e*) Entrainment separators in the air supply system have been modified to provide better dehumidified air to the Fermentation Block. (Date of completion—July 1974). (*f*) Non return valves are being provided to avoid back flow from the fermentor during the power failures/power fluctuations. (Job is in progress). (*g*) Arrangement for additional air compressors are being made to overcome the problem of air starvation after power failure (Order placed, not yet received). (*h*) Work on provision of automatic foam control at experimental basis is in hand. (*i*) The scheme for expansion of Animal House has already been finalised. (*ii*) In order to scrutinise, evaluate and scale up the technical changes from research laboratory and Department or from other sources, a Technical Development Department has been created so that these technological changes can be properly implemented in the plant. The Pilot Plant is being strengthened so that each change can be suitably evaluated before implementing in the main plant.
5. The Committee has suggested that in order to develop pervasive attitude of healthier appreciation of the real economic needs of the organisation among plant personnel it is imperative that the organisation drops the standard of protocol levels in all its discussions and book keeping and replaces, in its place standards of economic performance expected of the plant and its constituent units every year which are arrived at with the involvement of the concerned unit. Capacity considerations should be reserved by	We have already introduced new strains in the Plant so that the concept of protocol capacity which is based on the expected yield of old strains is no more valid. The profitability of the plant has also been re-worked recently in the light of the yields of new strains, revised recovery efficiencies and latest cost of raw materials and other inputs. Based on the above factors, the break-even point of the plant has been shifted upward and efforts are being made to revise the targets so that the profitability can be achieved within the shortest possible period.

the top management as a convenient reference point for purposes of review and not to imply that as the units approached the pre-determined capacities their performance would be considered adequate. Only a 'Moving boundary' approach of this kind will keep the constituent units tensed and motivated to higher levels of achievement where self urge of the right kind is missing for whatever reasons.	Production plans are being framed on the basis of attainable production and all the limitations that are likely to create bottleneck in this plant are duly discussed and advance actions are being taken.
6. The Committee has recommended that the management at the centre would do well to give complete autonomy to plant both in technical and administrative matters after making the changes recommended here without involving itself directly in minor exercises at Surveillance of individual Technical operations on the Plant, however, important and tempting they may appear at the moment of pressure.	Necessary delegation of power has already been made to the Plant. However, the Company is reviewing delegation of power to modify the same wherever authority is not commensurate with the responsibility.
7. The Committee has recommended that the life in a remotely located place like Virbhadra is difficult, in part due to the isolation it makes for, but mainly due to the fact that basic amenities like housing, medical aid, education, shopping and recreational facilities are so inadequate as to make living both for them and their families extremely unpleasant.	Realising the difficult conditions of living in Rishikesh as pointed out by the Technical Committee, the company has introduced revised scales as per the recommendations of the Third Pay Commission. This has benefited each employee to the extent of 30% of their total emoluments in the pre-revised scales. The benefit of house rent allowance to the extent of 7% has also been introduced from June 3, 1974 for those employees who are not allotted the Company's accommodation. The liberalised facilities of leave travel concession as recommended by III Pay Commission has also been introduced to improve the working condition of employees. Active support of the local management is available to all cultural and social organisations/ institutions in the township to organise recreational/social functions designed to provide diversion to the workmen from the routine.
8. *Promotion Policies* :	
The Committee has recommended that personnel promotion policies must not only be fair but must also appear to be fair. It suggested that formation of departmental promotion committees as being more	The Plant has drawn up a draft promotion policy for workmen which has been handed over to the recognised unions, for comments. The seniority list of various categories of staff has also been prepared and circulted. Each promotion is effected only after a duly constituted departmental promotion committee has considered all eligible candidates with

Recommendation of Technical Committee	Progress of implementatin
suited to achieve this end than the practice of leaving the discretion to individuals.	reference to their seniority and performance in the job as revealed through Annual Confidential Reports and Merit Rating Cards. Special training Programmes have been organised to upgrade skill of those people who have been stagnating in the Present post due to lack of education/technical qualification required for higher posts. As a step to recognise merit, a scheme has also been implemented to award to meritorious employees grant of advance increments or other suitable rewards. A suggestion scheme has also been introduced to ensure participation of employees in their areas of operation.
9. The Committee has recommended a larger measure of involvement of working in many routine non-technical matters affecting production and in measures intended to provide welfare measures.	In line with the recommendations of the Technical Committee, employees representatives have been appointed on Advisory Committee, Grievance Committee, Resident Welfare Committee, Canteen Committee and Contributory Welfare Fund Committee. The participation of employees on these committees ensures their involvement in matters affecting their welfare. The Personnel Department keeps in constant touch with aspiration and grievances of workmen on various issues through various formal and informal channels. An analysis of views expressed by employees in informal seminars arrangned by the Training department revealed that many of the grievances of workmen arise out of lack of adequate knowledge about the company's policies on matters affecting them. In order to plug this communication gap, the Personnel Department has undertaken to draw up a comprehensive manual on personnel policies. The manual is proposed to be widely circulated so as to improve the general awareness of employees in respect of company's policies governing their welfare and work.
10. *Setting up a national Centre for the study of applied Microbial Sciences and Technology* The Committee has recommeded to set up a National Centre for the study of applied microbial sciences and Technology which will help ensure a sound technical base for the country in a field of antibiotics and is likely to yield newer kinds of microbial products in medicines and other fields. A centre like this would also provide for advanced training in applied microbial sciences and technology.	Setting up a National Centre for study of applied Microbial sciences and Technology will be useful and action in this regard may be initiated by the Government.

APPENDIX III

(*Vide* reply to Recommendation at S.No. 9)

Statement showing the various antibiotics, their approved capacities (licences and letters of intent) Fifth Plan Target, gap at present proposals of the public sector, production and imports during the years 1972-73 and 1973-74

S. No.	Item	Unit	Name of parties	Capacity Licensed	Letters of intent	Total	Target 1978-79	Cap. Further proposals of public Sector IDPL	HAL	TOTAL	PRODUCTION 1972	PRODUCTION 1973	IMPORTS 72-73	IMPORTS 73-74
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	Penicillin	MMU	IDPL	140											
			HAL	84											
			Alembic	100											
			Standard	40											
				364	Nil	364	780	416	Nil	216	216	239	200	99·90	5·18
2	Streptomycin	T	IDPL	85											
			Synbiotics	62											
			Alembic	20											
			HAL	90	80										
				257	80	337	325	468	35	80	115	199·1	181·99	90·21	51·94
3	Tetracycline	T	IDPL	25											
			HAL	1·5											
			Synbiotics	3·0											
			Gyanamid	10·0											
			Pfizer	5·0											
				44·5	—	44·5	200	155·5	70	—	70	28·17	28·505	20·125	54·025

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
4	Oxytetracycline	T	IDPL Pfizer	25 9	—	34	80	46	—	—	—	46·72	56·21	1·52	Nil
				34											
5	Dimethyl-Chlorote-tracycline	T	Not separately indi-cated												
6	Chloramphenicol	T	Parke Davis Boehringer Knoll Dey So Chem Eso Lab. Themis	20 30 53 0·8											
				103·8	5	108·3	390	281·2	—	—	—	41·65	57.50	102·5	64·99
7	Amphotericin	T	Synbiotics	1·0	—	1·0	3	2	—	—	—	0·55	0·39	—	—
8	Ampicillin and Other Synthetic Penicillin	T	Rambaxy Cipla HAL Alembic	5·0 0·75 — —	 5 5										
				5·75	10	15·78	35	19·25	10	30	40	—	—	0·415	—
9	Nacitracin	BU	—	—	—	—	23	23	—	—	—	—	—	18·26	12·924
10	Cycloserine	T					6	8				—	—	0·69	0·641
11	Erythromycin	T	Alembic Themis HAL Abbott. Lab.	6 4	 6 4										
				10	10	20	30	10	—	13	13	1·06		14·421	9·00

12	Griseofulvin	T	IDPL	6	—	6	20	40	—	—	—			8·515	4·816	
13	Hamycin	Kgs.	HAL	250	—	250	150	—	—	—	—	—		—	—	
14	Kenamycin	T	Alembic	1	—	1	0·8	—	—	10	10			0·110	0·131	
15	Neomycin	T	HAL	2												
			Synbiotics	0·3												
				2·3	—	2·3	10	7·7	—	3	3			2616	4458	
16	Nystatin	T	IDPL	10	—	10	3	—						—	—	
17	Oleandomycin	Kgs.					1500	1500						—	—	
18	Polymyxin	Kgs.	—	—	—	—	130	130						102·05	128·56	
19	Cephaloridine	—	—	—	—	—	—							—	—	
20	Centamycin	—	—	—	—					5	5			—	—	
21	Rifampicin	—	—											—	—	
22	Framycetin	Kgs.	—	—	—	—								291	694	
23	Lincomycin	—	—	—	—	—								—	—	
24	Doxycycline	T	IDPL	—	5											
			Ranbaxy	—	2·5											
					7·5	7·5	—	—	—	—	—	—	—	—	—	

APPENDIX IV*

(*Vide* reply to Recommendation at S. No. 18)

ANTIBIOTICS PLANT, RISHIKESH

Statement Showing the Consumption Co-ffiecient Kg./Mlrd. of some major Raw Materials for various Antibiotics

Serial No.	Particulars	Protocol	July '74	Aug. '74	Sept. '74	Oct. '74	Average Apr. to October, 1974	Average for the year 1973-74
1	2	3	4	5	6	7	8	9
	PENICILLIN							
	I. Fermentation							
1	Corn Steep Liquor	10·08	24·53	16·25	9·48	6·96	12·18	13·84
2	Groundnut Oil	1·96	4·25	5·25	2·91	2·33	3·18	4·34
3	Hydrol (42%)	7·86	4·84	3·36	1·43	4·13	2·65	7·62
4	Lactose + Sugar	10·00	23·75	15·90	10·62	7·35	13·37	17·51
5	Phenyl Acetamide	0·63	0·55	0·46	0·36	0·39	0·40	0·79
	II. Recovery & Purification Block							
1	Butyl Acetate	5·60	10·53	7·46	14·07	12·92	10·13	11·82
2	Butanol	2·70	5·46	2·49	2·39	2·82	3·06	2·25
	III. Sodium Penicillin							
	Butyl Acetate	2·59	2·52	2·77	2·55		2·22	2·79

Butanol	5·73	4·52	5·43	5·53		5·26	8·81	
IV. Procaine Pencillin : ¶								
1 Butanol	0·22	0·18	0·20	0·22		0·20	0·25	
STREPTOMYCIN								
I. *Fermentation*								
1 Glucose (91%)	12·85	11·61	10·54	7·62	8.54	10·15	19·28	
2 Groundnut oil	3·55	1·49	0·97	1·10	1·37	1·93	7·26	
3 Hydrol (42%)	10·50	16·10	15·88	11·56	12·46	13·90	21·59	
4 Oxalic Acid	4·35	3·85	3·56	2·49	2·57	3·28	6·27	
5 Soya been flour	12·60	14.05	12·43	9·38	10·35	11·55	17·61	
II. Recovery & Purification								
1 Hydrochloric Acid (Tech.)	10·00	6·19	10·37	9·36	9·70	10·82	21·82	
TETRACYCLINE								
I. *Fermentation*								
1 Corn Steep Liquor	6·20	13·34	23·33	5·69	4·31	9·49	15·18	
2 Calcium Carbonate	3·70	4·44	7·94	2·65	1·89	3·56	6·16	
3 Ground nut oil	7·00	13·51	20·20	7·52	3·28	9·39	12·17	
4 Soya been flour	..	5·75	8·92	3·26	2·32	4·74	5·08	

*Not vetted by Audit.

1	2	3	4	5	6	7	8	9
	OXYTETRACYCLINE							
	I. Fermentation							
1	Corn Steep Liquor	4·40	7·17	6·06	3·94	3·10	4·02	5·32
2	Groundnut oil	8·20	6·13	3·33	3·41	2·83	3·49	8·52
3	Oxalic Acid	5·00	3·34	3·90	3·26	2·35	2·91	5·51
4	Maize Starch	17·02	14·32	14·72	12·65	9·95	11·49	21·09
5	Soya been flour	5·40	..	..	..	..	1·83	6·29
	II. R & P Block							
1	Oxalic Acid	..	1·46	2·23	2·13	1·45	1·87	2·55

APPENDIX V

(*vide* reply to Recommendation at S. No. 22)

No. 8(25)/74-Ch. III (DC)

Government of India

(Bharat Sarkar)

Ministry of Petroleum and Chemicals

(Petroleum Aur Rasayan Mantralaya)

Shastri Bhavan

—0O0—

New Delhi, the 9th August 75.

To

The Managing Director,

Indian Drugs and Pharmaceuticals Limited,

N—12, South Extension, Part—I,

New Delhi—110049.

Subject:—Recommendation of the Committee on Public Enterprises on improvement of steam condensate return.

—0O0—

Sir,

In am directed to refer to Recommendation No. 22 of the Committee on Public Undertakings in their 56th Report on the IDPL, in regard to improvement of steam condensate return.

It is noted that as indicated in the discussions, the IDPL have initiated action to study the problem in consultation with Indian and foreign experts. As the improvement of steam condensation return would result in the reduction in the cost of production, you are requested to expedite the study as suggested by us and inform Government of the results thereof.

Yours faithfully.

(V. Rajagopalan)

Under Secretary to the Government of India.

APPENDIX VI*

(*Vide* Reply to Recommendation at S. No. 28).

Statement showing details of Sales return and loss due to their reprocessing

Products	1971-72			1972-73			1973-74		
	Qty.	Value	Loss due to reprocessing	Qty.	Value	Loss due to reprocessing	Qty.	Value	Loss due to reprocessing
1	2	3	4	5	6	7	8	9	10
		Rs.	Rs.		Rs.	Rs.		Rs.	Rs.
BULK									
1. Sodium Pen., IP. BU	290181	145090	38393	274975	137488	86878	514385	825719	376654
2. Procaine Pen. I. P. BU. .	404918	202459	92231	37791	16395	8767	..		..
3. Procaine Pen. NSBU .	324257	164331	71237			..	..	..	..
4. Tetracycline HCl IP Kgs. .	35515	35347	12349	..	..	..	..	..	..
5. Streptomycin Sulphate IP Kgs. .	..	..	..	197731	8331	13248	131768	3624	1021
6. Chlorotetracycline Kgs. .	0988	642	Not assessed	..	..	..	..	..	..
7. Oxytetracycline Kgs. . . .	..			22000	187000	46640	50	42500	..
8. Nystatin milliards . . .	..	..	..	48053	26439	Not assessed	..	..	..
		548369	214710		425643	155533		303317	77675

*Not vetted by Audit.

1	2	3	4	5	6	7	8	9	10
B. FORMULATION									
1. Fortified P. Pen. 4 lacs units.	11002	5105	4220	771925	351226	269689	..	..	..
2. Sodium Pen. 5 lacs units. . .	9497	5318	3794			..	..	..	..
3. Streptomycin 1gm. .	212	121	97	..		..	..	..	..
4. Streptomycin Pen. 1 gm. . .	101	91	91	..	..	..	..	..	..
		10645	8202		351226	269689	..	..	..

APPENDIX VII

(*Vide* reply to Recommendation at S. No. 32)

SYSTEM OF PREPARATION OF COST STATEMENTS IN ANTIBIOTICS PLANT

The cost statements are prepared monthly for each bulk drug, formulation and services separately. For the purpose of cost collection the plant is divided into:

(a) Production departments

(b) Service departments

(c) Maintenance department

(d) Factory overheads

(e) General administration and

(f) Township

The departments are further divided into cost centres for identifying the expenditure interms of product/service and in terms of operation/maintenance. All primary documents *viz.*, requisition for expenditure, issue indents etc. bear reference to the relevant cost centre number. Expenditure is booked by the accounts department to the cost Centre indicated in the primary documents. Actual cost of products/services are collected under the following elements.

(a) Raw materials

(b) Packing and filling materials

(c) Operating labour

(d) Operating supplies

(e) Services

(f) Maintenance cost

(g) Factory overheads

(h) Depreciation and

(i) Interest.

RAW MATERIAL AND PACKING & FILLING MATERIAL CONSUMPTION

Raw materials and packing & filling materials are taken in the cost statements from the productwise consumption statements furnished by the production blocks, after verifying the issues with the PSL maintained in accounts department.

OPERATING LABOUR AND SUPPLIES

Expenses of operating labour and supplies are taken from the cost ledger which gives cost centrewise details of expenses.

Services Cost:

Services cost for each service, for example electricity, steam etc. is calculated separately every month from the cost ledger. The expenditure of each service is then distributed to products and other services, overhead departments on allocation basis furnished by Production, Planning and Control department.

Maintenance Cost:

Expenses of maintenance are compiled from the cost ledger and distributed to products/services/overhead departments on capital cost of the respective departments.

Overhead Expenses:

This comprises of works and administration overheads Research and Development, share of Central Office expenses township and other misc. expenses. These are allocated to products on conversion cost ratio.

Depreciation and Interest:

Depreciation and Interest are allocated to products/services/overhead departments on book value of assets relating to each. The appointment of depreciation and Interest charges pertaining to services and overhead departments on products is done like other expenses of these departments i.e. in the case of services departments, allocation of services and overhead departments conversion cost ratio.

Besides preparation of monthly cost statements, critical cost reviews are prepared and sent to Chief of Bulk Production and Sr. Superintendent (F&P) for Bulk drugs/formulations. Productwise analysis and critical comments are also prepared separately and sent to Head of Production blocks for their information and necessary action. These comments are sometimes discussed in meetings convened for this purpose.

APPENDIX VIII

(*Vide* reply to Recommendation at S. No. 45)

Statement showing the Bulk Drugs/Intermediates manufactured by IDPL and the present import policy

S. No.	Item	Import policy	Import plan for 1975-76 in respect of canalised items
1	Para phenetidine	Restricted	
2	Phenacetin	Banned	
3	Sulphanilamide	Banned	
4	Sulphaguanidine	Canalised	Nil
5	Sulphadimidine	Canalised	Nil
6	Sulphacetamide/Sodium	Banned	
7	Vitamin B_1 Inj. grade (MN)	Canalised Canalised	Nil 5T
8	Vitamin B_6.	Canalised	Nil
9	Folic Acid	Canalised	Nil
10	Sodium PAS	Banned	
11	Analgin	Canalised	100T
12	Amidopyrine	Canalised	27T
13	Pip hydrate	Canalised	
14	Pip Adipate	Canalised	
15	Pip Citrate	Canalised	
16	Pip Phosphate Sulphamethizole	Canalised Restricted	
17	Nicotinamide	Banned	
18	Thiacetazone	Banned	
19	Phenobarbitone/Sodium	Canalised	11T
19A	Diethyl Carbamonium Citrate	Banned	
20	Solium Ascorbate	Banned	
21	Acetazoloamide	Banned	
22	Malonic ester	Banned	

S. No.	Item	Import policy	Import plan for 1975-76 in respect of canalised items
23	Nethyl ester	Not in any list	
24	Tip Hexahydrate	Canalised	100T
25	Sod Bisulphite	Banned	
26	Ethyl acetate	Banned	
27	Acetyl acetone	Restricted	
28	Aceto butyro acetone	Not in any list	
29	Trichloroacetone	Not in any list	
30	Hydrazine hydrate	Banned	
31	Penicillin	Banned	
32	Streptomycin	Canalised	10T
33	Tetracycline Hcl	Canalised	60T
34	Oxyetracycline	Banned	

APPENDIX IX

(*Vide* reply to Recommendation at S. No. 48)

Statement showing the dates from which the Selling Prices of Bulk Drugs have been Increased

Name of the drug	Date from which selling price is revised	Revised Price
		Rs. P.
Phenacetin	19/4/1974	49·90
	10/2/1975	64·57
Sulphanilamide	12/8/1974	58·32
Sulphanilamide (Fine powder)		61·28
Sulphaguanidine	22/8/1974	115·61
	19/4/1974	99·50
Sulphadimidine	22/8/1974	161·41
	19/4/1974	131·70
Sulphacetamide	19/4/1974	87·69
	22/8/1974	102·25
Paracetamol	19/4/1974	78·08
Vitamin B-1	19/4/1974	592·48
	10/2/1975	592·48
Vitamin B-2	8/5/1974	935·48
Folic Acid	1/4/1974	1527·02
Sodium PAS	8/8/1974	53·29
Analgin	19/4/1974	174·53
	22/8/1974	175·02
Amidopyrine	8/5/1974	132·43
D.C. Citrate	19/4/1974	257·88
	10/2/1975	281·19
Thiacetazone	19/4/1974	150·52
Pip. Adipate	8/5/1974	76·05
Pip. Citrate	8/5/1974	71·04
Pip. Phosphate	8/5/1974	69·64
Pip. Hexahydrate	8/5/1974	61·00
Nicotinamide	19/4/1974	226·69
Phenobarbitone	19/4/1974	273·68
	22/8/1974	276·11

APPENDIX X

(*Vide* reply to Recommendation at S. No. 70)

Statement showing the inventory of imported stainless steel and alloy steel lying unutilised

Value in Lakhs

Sl. No.	Description	As on 31-3-72	As on 31-3-73	As on 31-3-74	As on 31-8-74
1	H.R. Stainless Steel . . .	8·10	6·64	6·09	5·70
2	C.R. Sheet	3·15	3·06	3·01	3·00
3	Alloy Tool Steel	13·17	12·70	11·49	11·47
4	Silver Steel	16·50	15·32	14·60	14·27
		40·92	37·72	35·19	34·44

APPENDIX XI

(*Vide* reply to Recommendation at S. No. 74)

Statement indicating the selling prices of drugs in the range of IDPL

	Original Rs./kg.	Present Rs./kg.	
Streptomycin	295	343	
PAS (Sodium Salt)	31·28	53·29	
PAS	41·83	64·09	
Sulphacetamide	62·50	102·25	
Sulphaguanidine	44·00	89·74	
Sulphadimidine	77·00	161·41	
Diethyl Carbamazine Citrate	190·00	267·88	
Phenacetin	44·00	49·90	
Paracetamol	50·00	70·08	(from imported para-nitrochlorobenzene)
		78·08	(from phenol)
Analgin	140·00	178·96	
Phenobarbitone	186·57	260·92	
Vitamin Bl	487·00	620·67	

APPENDIX XII

(*Vide* reply to Recommendation at S. No. 61)

UNIT : SURGICAL INSTRUMENTS PLANT, MADRAS

Statement Showing the Incidence of Process Rejections for 1973-74 and 1972-73.

Sl. No.	GROUPS	Production (Nos.)		REJECTION						Total Rejection 73-74	Total Prod.+ Rej. 73-74	%on total 73-74	Total Rejection 73-74	Total Prod.+ Rej. 72-73	%on total 72-73
				Forge Shop Qty./ No.	%	Machine-shop Qty./ No.	%	G & A Qty./ No.	%						
1.	KNIVES	1973-74	1,32,146	4,651	2·98	—	—	19,192	12·31	23,843	1,55,989	15·29	—	—	—
		1972-73	1,19,521	4,468	3·29	—	—	11,940	8·73	—	—	—	16,408	1,35,929	12·07
2.	SPOT WELDED	1973-74	45,922	1,782	2·82	901	1·43	14,508	22·99	17,191	63,113	27·24	—	—	—
		1972-73	80,302	3,935	4·52	682	0·78	2·052	2·37	—	—	—	6,669	86,971	7·67
3.	SCISSORS	1973-74	55,413	2,578	3·95	754	1·16	6,479	9·93	9,811	65,224	15·04	—	—	—
		1972-73	31,769	3,064	7·08	219	0·51	8,201	18·96	—	—	—	11,484	43,253	26·55
4.	BOX JOINTS	1973-74	78,832	10,223	8·44	7723	6·38	24,334	20·09	42,280	1,21,112	34·91	—	—	—
		1972-73	1,92,659	13,808	5·07	9961	3·66	66,012	20·56	—	—	—	79,781	2,72,440	29·28
5.	CURETTS	1973-74	35,518	2,408	5·39	506	1·13	6,208	13·90	9,122	44,640	20·42	—	—	—
		1972-73	1,25,453	9,355	6·22	737	0·49	14,906	9·91	—	—	—	24,998	1,50,451	16·62
6.	MISCELLANEOUS	1973-74	14,991	147	0·73	1165	5·82	3,723	18·59	5,035	20,026	25·14	—	—	—
		1972-73	1,19,543	2,082	1·54	650	0·48	13,049	9·64	—	—	—	15,781	1,35,324	11·66
	TOTAL :—	1973-74	3,62,882	21,789	4·63	11049	2·35	74,444	15·84	1,07,282	4,70,104	22·82	—	—	—
		1972-73	6,69,247	36,712	4·45	12249	1·49	1,06,160	12·88	—	—	—	1,55,121	8,24,368	18·82