

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 1456
TO BE ANSWERED ON THE 11th February, 2020

Central Drugs Standard Control Organisation

**1456. SHRI KIRTI VARDHAN SINGH:
SHRI MANOJ KOTAK:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the Government is aware of the fact that the Central Drugs Standard Control Organisation (CDSCO) has flagged 37 batches of medicines including crucial ones for failing quality test in the month of November, 2019;
- (b) if so, the details of the medicines and their manufacturers;
- (c) the action taken by the said authority so far;
- (d) whether public sector enterprises manufacturing medicines are also among the defaulters and if so, the details thereof;
- (e) the steps likely to be taken by the Government to prevent such incidents in future so as to maintain the quality of the medicines; and
- (f) the action taken by the Government on fake/ imitation of a genuine medicine during the last five years?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)**

(a),(b),(c)&(d): Yes sir, details of drugs declared as spurious/substandard/adulterated/misbranded by Central Drug Testing Laboratories are regularly uploaded on CDSCO website (www.cdsc.nic.in) under the heading "Alert". Details of such cases of Not of Standard Quality for month of November, 2019 is enclosed as **Annexure-A**.

Licence for manufacturing, sale & distribution of drugs are granted by the State Licensing Authorities appointed by respective State Governments. State Governments are empowered to take action on violations of any of the provisions of Drugs & Cosmetics Act, 1940 and Rules made thereunder. All above cases have been forwarded to the State Drugs Controllers of the concerned State where the drug was manufactured for taking necessary action.

(e) & (f): Government have taken various regulatory measures to ensure the quality of medicines in the country.

Details are as under;

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts for trial of cases related to spurious and sub-standard drugs.

The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 (in April, 2008) to 511 (in June, 2019).

The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

On 3.4.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority. Draft Rules have been published vide GSR 999 (E), dated 5th 10.2018 to amend the Schedule M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines.

The Government has approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs.1750 crores. Out of this, Rs. 900 crore is for strengthening the central drug regulatory structures and Rs.850 crore is for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore was released under the Central component whereas Rs. 87.90 crore was allocated during 2018-19 under this component. Rs. 82.90 crore was allocated during the year 2019-20. Under the State component, Rs. 81.36 crore was released during 2016-17 and 17-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

Further, as per the information received from various State/U.T. Drugs Controllers the No. of drugs samples tested, No. of drugs samples declared sub-standard quality, spurious/ adulterated drugs, its percentage and action taken during last five years is enclosed as **Annexure B**.

Such information received from various Zonal/Sub-zonal offices of CDSCO is enclosed as **Annexure C**.

List of Drugs declared as Not of Standard, for the Month of November, 2019

S. No.	Name of Drugs/medical device/cosmetics	Batch No./Date of Manufacture/Date of Expiry/Manufactured By
1	Pantoprazole Gastro Resistant Tablets I.P.	B. No.: T-7172 Mfg dt: 10/2018 Exp dt: 09/2020 Mfd by: M/s Kwality Pharmaceuticals Ltd. Nag Kalan, Majitha Road, Amritsar.
2	Ibuprofen Tablets I.P. 400 mg.	B. No.: 01019-BJA36 Mfg dt: 01/2019 Exp dt: 12/2020 Mfd by: M/s Biogenetic Drugs Pvt. Ltd. Vill-Jharmajri, Baddi, Dist-Solan H.P-174103
3	Pantoprazole Enteric Coated Tablets 40 mg.	B. No.: T-7224 Mfg dt: 11/2018 Exp dt: 10/2020 Mfd by: M/s Kwality Pharmaceuticals Ltd. Nag Kalan, Majitha Road, Amritsar
4	Telmisartan Tablets I.P. 40mg. (Telziver-40)	B. No.: LVT-28800 Mfg dt: 04/2018 Exp dt: 03/2020 Mfd by: M/s Life Vision Healthcare, Plot No. 140-141, E.P.I.P, Phase-I, Jharmajri, Baddi, Dist- Solan, H.P.-174103
5	Levocetirizine Dihydrochloride Tablets I.P. 5mg.	B. No.: LC18004 Mfg dt: 04/2018 Exp dt: 03/2020 Mfd by: M/s Life Max Cancer Laboratories, Plot No. 106 & 106A, Sector-6A, I.I.E., SIDCUL, Haridwar, Uttarakhand-249403
6	Albendazole Tablets I.P. (C-Bend)	B. No.: G002/2561 Mfg dt: 04/2019 Exp dt: 03/2021 Mfd by: M/s Elfin Drugs Pvt. Ltd. Vill-Berson, Nalagarh (H.P)-174101
7	Albendazole Tablets I.P. 400 mg.	B. No.: 8605318, Mfg dt: 10/2018 Exp dt: 09/2021 Mfd by: M/s Karnataka Antibiotics & Pharmaceuticals Ltd., Plot No. 14, II Phase, Peenya, Bangalore-560058
8	Pantoprazole Tablets I.P. (PAD-40)	B. No.: T03PA11-18 Mfg dt: 11/2018 Exp dt: 10/2020 Mfd by: M/s Adsila Organics Pvt. Ltd. Liwaspur Road, Vill-Bahalgarh-131021, Haryana
9	Cedoxil 500mg Tablets	B. No.: T-16549 Mfg dt: 03/2018 Exp dt: 02/2020 Mfd by: M/s Jackson Laboratories Pvt. Ltd., Bye Pass, Majitha Road, Amritsar-143004

10	Amlodipine Tablets IP 5mg	B. No.: CHT-9124 Mfg dt: 03/2019 Exp dt: 02/2021 Mfd by: M/s. Bengal Chemicals & Pharmaceuticals Ltd., NH-No.74 Roorkee-Dehradun Highway, Kisanpur, Roorkee-247667, Uttarakhand.
11	Carbamazepine Extended Release Tablets IP (ACETOL CR-200 TABLETS)	B. No.: AAB8B007 Mfg dt: 03/2018 Exp dt: 02/2020 Mfd by: Psychotropics India Limited, Plot No.- 46 & 49, Sector-6A, IIE, SIDCUL, Industrial Area, Ranipur, Haridwar-249 403 (Uttarakhand)
12	Albendazole Vet. Oral Suspension (FLUKGON)	B. No.: 205 Mfg dt: 11/2018 Exp dt: 10/2020 Mfd by: Albro Pharmaceuticals Pvt. Ltd. GMP Certified Company Muktsar 152026, Punjab.
13	Prebiotic and Probitic Capsules (REPURE CAPSULES)	B. No.: HC-1805016 Mfg dt: 05/2018 Exp dt: 04/2020 Mfd by: Helax Health Care Private Limited, Khasra No. 410, Village- Karondi, Roorkee- 247667, District- Haridwar
14	Suspension of Calcium, Vitamin B12 and Vitamin D3 (CALCI-D)	B. No.: SL-398 Mfg dt: 05/2019 Exp dt: 04/2021 Mfd by: Sridhara Life sciences Pvt. Ltd. Khasra No. 285,290, Village- Sisona, Bhagwanpur, Roorkee, Haridwar (Uttarakhand)-247661
15	Ferrous Ascorbate, Folic, Zinc and Cynocobalamin Syrup (FEROFOL-BZ)	B. No.: MSL-091 Mfg dt: 03/2019 Exp dt: 02/2021 Mfd by: Maskon Life Sciences Pvt. Ltd. Kh. No. 69& 70 Khatakeri, Bhagwanpur, Roorkee (U.K.) INDIA
16	MDZIME – DT (Cetirizine Dihydrochloride Tablets)	B. No.: ZT-8313 Mfg dt: 01/2019 Exp dt: 12/2021 Mfd by: M/s. Zenith Healthcare Ltd., 388/34, Chandogar Ind. Estate, Sarkhej Bavla Highway, Changodar -382210
17	Ramizim - 2.5 (Ramipril Tablets I.P. 2.5 mg)	B. No.: EH97M801 Mfg dt: 12/2018 Exp dt: 11/2020, Mfd by: M/s. ZIM Laboratories Limited (Unit-II), A-8/14, MIDC, Area, Kalmeshwar 441501, Dist Nagpur, Maharashtra
18	Trypsin Chymotrypsin Tablets	B. No.: T 53903 Mfg dt: 05/2018 Exp dt: 04/2021 Mfd by: M/s. Vardhman Exports, A-188, T. T.C., MIDC, Khairne, Navi Mumbai – 400 710.
19	Ramipril Tablets I.P. 2.5 mg	B. No.: RAPT18004 Mfg dt: 12/2018 Exp dt: 11/2020 Mfd by: M/s. Ravian Life Sciences Pvt. Ltd., Plot No. 34,

		Sec. 8A, IIE, SIDCUL, Haridwar -249 403, UK.
20	Cadpril 5 (Ramipril Tablets I.P)	B. No.: ZPR0037 Mfg dt: 08/2018 Exp dt: 07/2020 Mfd by: M/s. Preet Remedies Ltd., 183-186, HPSIDC, Industrial Area, Baddi, Distt. Solan – (H.P.) – 173205
21	Vitamin B-Complex Tablets NFI	B. No.: KA19001 Mfg dt: 01/2019 Exp dt: 06/2020 Mfd by: M/s. Ortin Laboratories Ltd., 275 & 278 (Part) I.D.A. Pashamylaram -502307, Medak, AP.
22	Medtoin (Phenytoin Sodium Tablets I.P.)	B. No.: SPT190048A, Mfg dt: 01/2019 Exp dt: 12/2020 Mfd by: M/s. Salus Pharmaceuticals, 480/211, Harraipur, P.O. Gurumajra, Teh. Baddi, Distt. Solan, (H.P.) – 173 205
23	DOXYGUARD (Doxycycline & Lactic Acid Bacillus Capsules)	B. No.: SOC-615F Mfg dt: 01/2018 Exp dt: 12/2019 Mfd by: M/s. Symbiosis Pharmaceuticals Pvt. Ltd., (Unit-III), Trilokpur Road, Kala Amb-173030 (H.P)
24	OMEPR (Omeprazole Capsule I.P. 20mg)	B. No.: UOME 1803 Mfg dt: 02/2018 Exp dt: 01/2020 Mfd by: M/s. Bal Pharma Limited, Plot No. 1, 2, 3 & 69, Sector 4 IIE, SIDCUL, Pantnagar, Rudrapur Distt-Udham Singh Nagar, Uttarakhand, India
25	CREPE BANDAGE (10 CMS X 4 MTRS)	B. No.: 37 Mfg dt: 10/2017 Exp dt: 3 Yrs from Mfg. Date Mfd by: M/s. Hindustan Surgical Appliances, 29, Huzuri Mull Lane, Kolkata - 700 014.
26	Metronidazole Tablets I.P. 400 mg	B. No.: 7596027 Mfg dt: 08/2017 Exp dt: 07/2020 Mfd by: M/s. Bengal Chemical & Pharmaceuticals Ltd., 164, Maniktala Main, Road, Kolkata – 700054
27	Ramizim 5 (Ramipril Tablets I.P. 5 mg)	B. No.: EO82M801 Mfg dt: 12/2018 Exp dt: 11/2020 Mfd by: M/s. Zim Laboratories Limited (Unit-II), A-8/14, MIDC Area, Kalmeshwar 441501, Dist Nagpur, Maharashtra
28	Zinc Sulphate Tablets IP 20 mg	B. No.: 05069 Mfg dt: 06/2019 Exp dt: 05/2021 Mfd by: M/s. Healthy Life Pharma Pvt. Ltd., N-31/1, M.I.D.C., Tarapur, Dist. Palghar, Boisar-401506, Maharashtra
29	Bacitracin Zinc	B. No.: B190304 Mfg dt: 03/2019 Exp dt: 03/2023 Mfd by: M/s. Yancheng Youhua Pharmaceutical &

		Chemical Technology, Co. Ltd., China
30	Ciprofloxacin Tablets IP 250 mg	B. No.: (10)CITW-31 Mfg dt: 04/2019 Exp dt: 03/2021 Mfd by: M/s. Nestor Pharmaceuticals Limited, 11, Western Extension Area, Faridabad-121001
31	Cycloserine Capsules USP 250 mg	B. No.: ECB5836A Mfg dt: 07/2018 Exp dt: 06/2021 Mfd by: M/s. Macleods Pharmaceuticals Ltd., Plot No. 25-27, Survey No.366, Premier Industrial Estate, Kachigam, Daman 396210 (U.T)
32	Rabiun-DSR (Enteric coated Rabeprazole Sodium and Domperidon SR Capsules)	B. No.: NY1180 Mfg dt: 05/2019 Exp dt: 04/2021 Mfd by: M/s. Intas Pharmaceuticals Limited, Samardung Road, Kabrey Block, Namthang Elaka, South Sikkim- 737 132
33	Eptoin 300 ER (Phenytoin Sodium Extended Release Tablets 300 mg)	B. No.: SDE0020 Mfg dt: 03/2019 Exp dt: 02/2021 Mfd by: M/s. Sidmak Laboratories (India) Pvt. Ltd., Plot No.20, Pharma City, Selaqui Industrial Area, Dehradun- 248197, Uttarakhand
34	Cefpirome Injection (Azzicef),	B. No.: GS1547G, Mfg. dt: 08/2018, Exp. dt: 07/2020, Mfd by: Not mentioned
35	"Purport to contain Amoxicillin & Potassium Clavulanate equivalent to Amoxicillin 500 mg, Potassium Clavulanate Diluted IP equivalent to Clavulanic Acid 125 mg	B. No.: Not Specified, Mfg. dt: Not Specified, Exp. dt: Not Specified, Mfd by: Not Specified

Number of samples tested and enforcement actions taken by States/UTs Drugs Controller during last five years

Year	No. of drug samples tested	No. of drugs samples declared not of standard quality	% No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx. value of drug seized (in INR)	No. of Raids Conducted
2014-15	74199	3702	4.98	83	0.11	152	10	85	58251111	14042
2015-16	74,586	3703	4.96	234	0.31	289	2	59	55313470.5 + Govt. Supply	3648
2016-17	76,721	2,780	3.6	123	0.16	186	17	106	7,72,68,717.5	10,921
2017-18	82,599	2783	3.36	236	0.28	131	16	163	17,86,08,008	7067
2018-19	76,101	2,549	3.35	205	0.27	484	77	153	80389057 (Approx.)	33,492

Number of samples tested and enforcement actions taken by Zonal/Sub-zonal offices of CDSCO during last five years

Year	No. of drug samples tested	No. of drugs samples declared not of standard quality	% No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx. value of drug seized (in INR)	No. of Raids Conducted
2014-15	3605	121	3.36	0	0	Nil	Nil	Nil	Nil	48
2015-16	2897	115	3.96	5	0.17	38	Nil	4	21052298	42
2016-17	5207	146	2.80	Nil	0.0	21	4	Nil	3911850	56
2017-18	7088	381	5.37	2	0.028	17	1	6	8820385	8
2018-19	10382	310	2.98	5	0.048	31	9	4	38218920	52