

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

LOK SABHA  
UNSTARRED QUESTION NO. †395  
TO BE ANSWERED ON 15<sup>th</sup> September, 2020

**Norms for Drug Manufacturing**

**†395. SHRI NARANBHAI KACHHADIYA:  
SHRI PRADEEP KUMAR SINGH:  
SHRI JOHN BARLA:  
SHRIMATI RATHVA GITABEN VAJESINGBHAI:  
SHRI PARBATBHAI SAVABHAI PATEL:  
SHRI SHANTANU THAKUR:**

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

- (a) whether the Government has laid down any norms for drug manufacturers;
- (b) if so, the details thereof;
- (c) whether any notice has been issued to such drug manufacturers who are not adhering to the said norms;
- (d) if so, the details thereof during the last three years and the till date; and
- (e) the details of the action taken by the Government so far against the said drug manufacturers?

**ANSWER**

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

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(a) to (e): The details of requirement for manufacturing of drugs are prescribed under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. License for manufacture of drugs is granted through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under.

The manufacturer is required to comply with the conditions of license including the requirement of compliance of Good Manufacturing Practices which are prescribed under Schedule-M of Drugs and Cosmetics Rules, 1945.

Details of the enforcement actions taken by various SLAs based on the drugs samples tested, drugs samples declared sub-standard quality, spurious/adulterated drugs and percentage of thereof during 2016-17 to 2018-19 is at Annexure-A. Such information received from various Zonal/Sub-zonal offices of the Central Drugs Standard Control Organisation (CDSCO) is at Annexure-B.

Annexure-A

Enforcement actions taken by States/UTs Drugs Controller during last three years

Year	No. of drugs 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
2016-17	76,721	2780	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	2549	3.35	205	0.27	484	77	153	8,03,89,057 (Approx.)	33,492

**Annexure-B**

**Enforcement actions taken by Zonal/Sub-zonal offices of CDSCO during last three years**

<b>Year</b>	<b>No. of drugs samples tested</b>	<b>No. of drugs samples declared not of standard quality</b>	<b>% No. of drugs samples declared not of standard quality</b>	<b>No. of drugs samples declared spurious/adulterated</b>	<b>% No. of drugs samples declared spurious/adulterated</b>	<b>No. of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs</b>	<b>No. of cases (as mentioned in the earlier column) decided</b>	<b>No. of persons arrested</b>	<b>Approx. value of drug seized (in INR)</b>	<b>No. of Raids Conducted</b>
2016-17	5207	146	2.80	Nil	0.0	21	4	Nil	39,11,850	56
2017-18	7088	381	5.37	2	0.028	17	1	6	88,20,385	8
2018-19	10382	310	2.98	5	0.048	31	9	4	3,82,18,920	52