

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. †1325
TO BE ANSWERED ON 06TH FEBRUARY, 2026**

QUALITY OF DRUGS

†1325. SHRI PATEL UMESHBHAI BABUBHAI:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details regarding the quality of drugs categorized as "Not of Standard Quality (NSQ)", the cancellation of licenses and compliance with Good Manufacturing Practices (GMP) by pharmaceutical companies during the period 2020-2025;
- (b) the number of pharmaceutical companies in India whose drugs were found to be "Not of Standard Quality (NSQ)" during the period from 2020-2025;
- (c) the list of such companies along with the details of penal actions taken against them, year-wise;
- (d) the number of companies whose manufacturing licenses were suspended or cancelled during the period 2020-2025 along with the details of the grounds on which such actions were taken;
- (e) whether any serious violations of Good Manufacturing Practices (GMP) were found during inspections conducted by the Central Drugs Standard Control Organisation (CDSCO) at any pharmaceutical factory during the aforementioned period; and
- (f) if so, the specific parameters of such violations and the actions taken against the concerned entities?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SHRI PRATAP RAO JADHAV)**

- (a) to (f): As per information received from States/UTs Drugs Controllers, the number of drug samples tested in last five years by various States/U.Ts and status regarding number of drug samples declared Not of Standard Quality/spurious/ adulterated including enforcement actions taken is as under:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	Number of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2020-21	84,874	2,652	263	236
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961

List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Adulterated by the Central Drugs Testing Laboratories is uploaded and available on the website of CDSCO under the heading of Drug Alert (www.cdsco.gov.in) and actions initiated as per provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder.

In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.
