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

LOK SABHA STARRED QUESTION NO. 199 TO BE ANSWERED ON THE 12TH DECEMBER, 2025

TESTING AND MONITORING OF DRUGS BY CDSCO

*199. DR. MOHAMMAD JAWED:

Will the **MINISTER OF HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details of samples of cough syrups, medicines, Oral Rehydration Salts (ORS), protein powders and other nutritional supplements tested by the Central Drugs Standard Control Organisation (CDSCO) during the last five years, State/UT-wise;
- (b) the number of samples found to be sub-standard or adulterated, along with the action taken against the concerned manufacturers or distributors;
- (c) whether the Government has launched any special drives to track and prevent counterfeit health and nutritional products, if so, the details thereof and if not, the reasons therefor; and
- (d) the steps taken/proposed to be taken by the Government to strengthen drug testing infrastructure and laboratory capacity in the country, States/UT-wise?

ANSWER THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (d) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 199 FOR 12TH DECEMBER, 2025

(a) & (b) The manufacture, sale and distribution of drugs are regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection.

As per information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last five years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/Adulterated
2020-21	84,874	2,652	263
2021-22	88,844	2,545	379
2022-23	96,713	3,053	424
2023-24	1,06,150	2,988	282
2024-25	1,16,323	3,104	245

Further, Food Safety Standard Authority of India (FSSAI) and its regional offices through the State/UT Food Safety Departments, carry out regular surveillance, monitoring, inspections, and random sampling of food to ensure compliance with the quality & safety standards established under the Food Safety and Standards Act (FSS), 2006, and the Rules and Regulations made thereunder.

(c) As a part of quality monitoring and in order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. Firms have

been identified based on risk criteria like number of drugs declared as not of standard quality, complaints, criticality of the products etc. As of now, CDSCO along with 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 States/UTs as per the provisions of the Drugs Rules 1945.

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.

(d) Further, for strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 17 New Drug Testing Labs have been constructed and 24 existing labs have been up-graded in various States/UTs.
