

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 2028
TO BE ANSWERED ON 10TH MARCH, 2026**

TESTING AND SURVEILLANCE OF DRUGS BY CDSCO

**2028. SHRI ASHOKRAO SHANKARRAO CHAVAN:
DR. MEDHA VISHRAM KULKARNI:
SHRI BRIJ LAL:
SHRI NARAYANA KORAGAPPA:
SMT. KIRAN CHOUDHRY:
SHRI UJJWAL DEORAO NIKAM:
SHRI BABURAM NISHAD:**

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

- (a) the details of testing carried out by the Central Drugs Standard Control Organisation (CDSCO) during the last five years, State/UT-wise;
- (b) the number of samples declared sub-standard, misbranded or adulterated, and;
- (c) the enforcement action initiated against the respective manufacturers or distributors;
- (d) whether any special enforcement or monitoring drives have been undertaken to detect and curb the circulation of counterfeit health and nutritional products;
- (e) if so, the details thereof and if not, the reasons therefor; and
- (f) the steps taken or proposed to be taken by the Ministry to augment drug testing infrastructure and enhance laboratory capacity across the country, State/UT-wise?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (c): 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

(d) & (e): 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.

Also, more than 1100 cough syrup manufacturers and 380 blood centres have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

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.

(f): To strengthen the drug testing infrastructure and enhance laboratory capacity across 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 19 New Drug Testing Labs have been constructed and 28 existing labs have been up-graded in various States/UTs.
