GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 2725
TO BE ANSWERED ON 17TH MARCH, 2026

Quality control of Ayush drugs

2725 **Shri Raghav Chadha:**

Will the Minister of ***Ayush*** be pleased to state :

(a) the details of AYUSH drug manufacturing units inspected in the last five years, State-wise and year-wise;
(b) the number and percentage of samples found sub-standard or misbranded, year-wise and State-wise;
(c) whether repeated non-compliance by licensed manufacturers has been observed and, if so, the details thereof; and
(d) the measures taken by Government to strengthen vigilance and enforcement systems?

ANSWER
THE MINISTER OF STATE (IC) OF MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) As per the information received from State/UT Licensing Authorities, the details of Ayush drug manufacturing units inspected in the last five years is placed at **Annexure-I**.

(b) As per the information received from State/UT Licensing Authorities, the number of samples found sub-standard or misbranded is placed at **Annexure-II**.

(c) As prescribed in the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Sowa-rigpa, Unani and Homoeopathy drugs, is vested with the State Drugs Controllers/ State Licensing Authorities appointed by the concerned State/ UT Government.

As per the information received from State/UT Licensing Authorities, no instances of repeated non-compliance by licensed manufacturers have been observed.

(d) The Government of India has taken following measures to strengthen vigilance and enforcement systems for Ayush drug manufacturing units in order to ensure the quality, safety and regulatory compliance of Ayurveda, Siddha, Sowa-rigpa, Unani and Homoeopathy (ASSU&H) medicines.

i. Enforcement of the Drugs and Cosmetics Act, 1940:

Manufacturing, sale and distribution of Ayush drugs are regulated under the Drugs and Cosmetics Act, 1940 and Rules, 1945, which mandate licensing, inspection and compliance with prescribed standards. Manufacturing without a valid license is prohibited, and State Licensing Authorities conduct inspections and enforcement through drug inspectors.

ii. Mandatory Good Manufacturing Practices (GMP):

Ayush drug manufacturing units are required to comply with Good Manufacturing Practices (GMP) for obtaining and retaining manufacturing licenses. GMP ensures proper infrastructure, quality control systems, documentation, and hygiene standards during manufacturing.

iii. Strengthening of Drug Testing Infrastructure:

The Government provides financial assistance to States/UTs for establishing and upgrading State Drug Testing Laboratories (DTLs) and strengthening regulatory mechanisms. These laboratories test Ayush medicines for identity, purity, strength, heavy metals, microbial load and pesticide residues as per pharmacopoeial standards.

iv. Implementation of "Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana (AOGUSY)":

This Central Sector Scheme (2021–2026) aims to improve the quality of Ayush drugs by:

i. Strengthening drug testing laboratories
ii. Upgrading Ayush pharmacies
iii. Improving manufacturing standards and regulatory oversight

v. Creation of Ayush Vertical in Central Drugs Standard Control Organization (CDSCO):

An Ayush vertical has been established in CDSCO to strengthen regulatory coordination between the Centre and States and ensure better monitoring of quality and safety of Ayush medicines.

vi. Pharmacopoeial Standards and Quality Control:

The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) develops pharmacopoeial standards and formulary specifications for Ayush drugs. Compliance with these standards is mandatory for manufacturers.

vii. Pharmacovigilance Programme for Ayush Drugs:

Ministry of Ayush is implementing a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs under its Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY). The program operates through a dedicated three-tier network comprising 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvC) and 97 Peripheral Pharmacovigilance Centres (PPvC) across the country. The All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush serves as the NPvCC for the implementation of the program. All PPvCs/IPvCs routinely report Misleading Advertisements (MLAs)/Objectionable Advertisements (OAs) and suspected Adverse Drug Reactions (ADRs) to the respective State/ UT Licensing Authorities for necessary action.

viii. Quality Certification and Third-Party Evaluation:

Quality Certifications Scheme is implemented by the Quality Council of India (QCI) for grant of Ayush mark to Ayurvedic, Siddha and Unani products on the basis of third-party evaluation of quality in accordance with the status of compliance to domestic and international standards.

ix. Digital and Consumer Vigilance Measures:

Ministry of Ayush has developed an IT enabled online portal “Ayush Suraksha” and launched the portal on 30th May, 2025 to enhance regulatory transparency and accountability in the Ayush sector. The portal features a centralized dashboard for real-time tracking of suspected Adverse Drug Reactions and capturing of Misleading Advertisements/Objectionable Advertisements for prompt regulatory action and in-depth data analysis. The portal allows consumers and Ayush healthcare professionals to report and regulatory authorities to monitor misleading advertisements and adverse drug reactions.

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Annexure-I

As per the information received from State/UT Licensing Authorities, the details of Ayush drug manufacturing units inspected in the last five years are as follows:

S. No.	State/UT	Year	Number of inspections conducted
1.	Himachal Pradesh	2021-22	119
		2022-23	110
		2023-24	91
		2024-25	65
		2025-26	72
2.	Odisha	2021-22	36
		2022-23	29
		2023-24	08
		2024-25	12
		2025-26	08
3.	Tamil Nadu	2021	337
		2022	396
		2023	442
		2024	513
		2025	643
4.	Kerala	2021	241
		2022	432
		2023	372
		2024	314
		2025	342
5.	Maharashtra	2021-22	182
		2022-23	279
		2023-24	371
		2024-25	384
		2025-26	140
6.	Madhya Pradesh	2021	148
		2022	128
		2023	111
		2024	127
		2025	116
7.	Delhi	2021-22	86

		2022-23	105
		2023-24	108
		2024-25	114
		2025-26	110
8.	Jharkhand	-	75
9.	Arunachal Pradesh	2021-22	01
		2022-23	01
		2023-24	01
		2024-25	01
		2025-26	01
10.	Gujarat	2022- to Till date	485
11.	Uttarakhand	Last 5 years	300
12	Puducherry	2024	08
		2025	13
13.	Tripura	-	Nil
14.	Chandigarh	-	Nil
15.	Meghalaya	-	Nil

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Annexure-II

As per the information received from State/UT Licensing Authorities, number/percentage of samples found sub-standard or misbranded in the last five years is as follows:

S. No.	State/UT	Year	Number/percentage of samples found sub-standard or misbranded
1.	Himachal Pradesh	2021-22	31
		2022-23	53
		2023-24	38
		2024-25	108
		2025-Upto 05.03.26	36
2.	Tripura	2021-22	Nil
		2022-23	65
		2023-24	07
		2024-25	36
		2025-Upto 09.03.26	07
3.	Odisha	2021-22	329 / 15.87%
		2022-23	303 / 18.5%
		2023-24	112 / 16.5%
		2024-25	07 / 2.7%
		2025-26	66 / 14.83%
4.	Tamil Nadu	2021	10
		2022	07
		2023	33
		2024	08
		2025	35
5.	Kerala	2021	21
		2022	37
		2023	13
		2024	14
		2025	25
6.	Maharashtra	2021-22	15
		2022-23	15
		2023-24	08
		2024-25	30
		2025-26	14
7.	Madhya Pradesh	2021	06
		2022	24

		2023	04
		2024	04
		2025	61
8.	Delhi	2021-22	14
		2022-23	14
		2023-24	03
		2024-25	03
		2025-26	01
9.	Jharkhand	2021	06
		2022	03
		2023	00
		2024	05
		2025	01
10.	Arunachal Pradesh	-	Nil
11.	Uttarakhand	2021-22	3.6%
		2022-23	6.5%
		2023-24	5.2%
		2024-25	2.7%
		2025-26	2.7%
12.	Gujarat	2023	05
		2024	25
		2025	13
13.	Puducherry	-	Nil
14.	Chandigarh	-	Nil
15.	Meghalaya	-	Nil

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