GOVERNMENT OF INDIA
MINISTRY OF AYUSH
RAJYA SABHA
UNSTARRED QUESTION NO-1767
ANSWERED ON 04/08/2026

METALS IN AYUSH MEDICINES

1767. SHRI KARTIKEYA SHARMA

Will the Minister of AYUSH be pleased to state: -

(a) the quality assurance mechanisms presently in place to monitor permissible limits of heavy metals in AYUSH medicines;

(b) the details of inspections, laboratory testing and enforcement action undertaken during the last three years against manufacturers found violating prescribed quality standards; and

(c) whether Government proposes to further strengthen testing, traceability and quality certification of AYUSH medicines, and the details thereof?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH

(SHRI PRATAPRAO JADHAV)

(a) & (c) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayush drugs. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T and Schedule M-I of the Drugs Rules, 1945 for Ayurvedic, Siddha, Sowa-rigpa, Unani and Homeopathy drugs respectively and to follow the quality standards of drugs as prescribed in the respective pharmacopoeia. Drug Testing Laboratories are approved by the Ministry of Ayush under Rules 160A to 160J of the Drugs Rules, 1945, for carrying out tests relating to the identity, purity, quality and strength of Ayush drugs. As on date, 118 private Drug Testing Laboratories have been approved by the Ministry across States and Union Territories for conducting such tests in accordance with the provisions of the Drugs Rules, 1945.

Drug Inspectors collect medicine samples regularly from manufacturing firms or retail shops within their jurisdiction and send them to Drug Testing Laboratory under Drug Control department for quality testing and if any sample is found to be 'Not of Standard Quality' (NSQ), appropriate action is initiated such as preventing the sale of the medicines from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder. There are 34 Drug Testing Laboratories available in State/UTs for testing of the Legal Samples drawn by the Drug Inspectors of concerned State/UTs.

The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate organization under Ministry of Ayush, develops pharmacopoeial standards and formulary specifications for Ayush drugs, which serve as the official compendia for ascertaining the quality Control (identity, purity, and strength) of the Ayush drugs included therein, as per Drugs and Cosmetics Act, 1940 and the Rules made thereunder. These quality standards of Ayush drugs also prescribe the permissible limits of Heavy Metals as per WHO guidelines. Compliance with these standards is mandatory for production of Ayush drug being manufactured, sell and stocked in India. Implementation of these pharmacopoeial standards ensures that the medicines conform to optimum quality standards in terms of identity, purity and strength.

Further, Ministry of Ayush is implementing a Central Sector Scheme, namely, Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards like WHO-GMP and NABL respectively.

In addition, the Ministry of Ayush has undertaken the following initiatives to promote quality assurance and certification of Ayush products:

i. WHO Certificate of Pharmaceutical Product (WHO-CoPP) to Ayush drugs is issued by Central Drugs Standard Control Organization (CDSCO) after joint inspections of manufacturing units by Drug Inspectors posted in Ayush vertical along with drug inspectors of State/UTs and CDSCO for compliance with WHO Technical Report Series (TRS) guidelines for Herbal Medicines.
ii. Ministry of Ayush has launched Ayush Quality Mark (AQM) initiative through the Ayush Export Promotion Council (AYUSHEXCIL). Under this framework, the Ayush Quality Mark is being granted after scrutiny and verification of valid quality certifications and statutory approvals issued by the competent Government authorities, such as WHO-GMP, Ayush Premium Mark and other recognised certifications, as applicable.
iii. Ayush Standard Mark and Ayush Premium Mark are awarded to Ayush Drugs by Quality Council of India (QCI) based on third-party assessment of compliance with prescribed national and international quality standards.

(b) As per the information received from State/UT Governments, details of inspections conducted, legal samples tested and enforcement action taken during the last three years against manufacturers for violating quality standards are attached at **Annexure-I.**

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Annexure-I

As per information received from State/UT Govts., details of inspections conducted, legal samples tested and enforcement action taken during the last three years against manufacturers for violating quality standards

Sl. No.	State/UT	Year	No. of inspections conducted	No. of legal samples tested	Action Taken
1.	Delhi	2023-24	275	577	3 samples failed and action taken as per the provisions of Drugs & Cosmetic Act, 1940 and Rules made thereunder.
		2024-25	269	694	1 sample failed and action taken as per the provisions of Drugs & Cosmetic Act, 1940 and Rules made thereunder
		2025-26	270	1312	1 sample failed and action taken as per the provisions of Drugs & Cosmetic Act, 1940 and Rules made thereunder
2.	Goa	2023-24	7	114	Nil
		2024-25	5	89	Nil
		2025-26	5	191	Nil
3.	Himachal Pradesh	2023-24	65	576	-
		2024-25	142	738	-
		2025-26	80	353	-
4.	Odisha	2023-24	32	569	-
		2024-25	7	153	-
		2025-26	29	417	-
5.	Tamil Nadu	2023-24	-	-	-
		2024-25	-	1696	-
		2025-26	-	2692	-
6.	Andaman & Nicobar Islands (samples tested by Tamil Nadu based on MoU)	2023-24	-	-	-
		2024-25	-	36	-
		2025-26	-	13	-

7.	Tripura	2023-24	-	-	-
		2024-25	-	145	-
		2025-26	-	55	-
8.	Bihar	-	Total No. of Inspections- 61	Total No. of Samples Collected- 68	-
9.	Gujarat	2024	118	172	-
		2025	90	197	-
		2026	25	91	-
10.	Madhya Pradesh	2023	-	698	Samples declared NSQ- 89
		2024	-	391	Samples declared NSQ- 80
		2025	-	501	Samples declared NSQ- 132
11.	Punjab	2023-24	-	82	All formulations have been cancelled after receiving failed sample reports sent by Drug Testing Laboratory, Patiala.
		2024-25	-	243	
		2025-26 (till date)	-	82	
12.	Jharkhand	-	Total No. of Inspections- 18	Samples declared NSQ- 4	Action has been taken in accordance with Drugs & Cosmetic Act, 1940 and Rules made thereunder
13.	Kerala	-	Total No. of Inspections- 270	-	Following actions have been taken against the firms where inspections were done: 1. Departmental action taken 2. Suspended the production of the product found NSQ for 30 days.
14.	Rajasthan	2023-24 to 2025-26	In the last three years (2023-24 to 2025-26), action was taken to suspend and cancel the manufacturing approvals of 13 medicines of 10 pharmaceutical manufacturing units which violated the prescribed quality standards, as per Drugs & Cosmetics Act, 1940 & Drugs Rules 1945.		

15.	Uttar Pradesh	-	Approx. 1100 Ayush drug manufacturing units (3346 times) were inspected in the last three years. 04 Manufacturing units were found violating prescribed quality standards, therefor legal actions have been taken under the Drugs & Cosmetics Act, 1940 & Drugs Rules 1945.		
16.	Lakshadweep	-	No such cases are reported in this UT.		
17.	Jammu & Kashmir	-	NIL	-	-
18.	Chhattisgarh	-	NIL	-	-
19.	Meghalaya		NA- There are no licensed AYUSH drug manufacturing units in Meghalaya.		
20.	Andhra Pradesh	2023-24	NIL	NIL	-
		2024-25	NIL	NIL	
		2025-26	NIL	NIL	
21.	Nagaland	-	NIL As there is no functional laboratory.	NIL	
22.	Mizoram	-	NIL - As there are no manufacturing units in Mizoram.	NIL	
23.	Sikkim	-	NA - Unavailability of Laboratory Equipment at State Drug Testing Laboratory.		
24.	Haryana	-	-	-	_
25	Manipur	-	NIL - As there are no manufacturing units in Manipur		