GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA

UNSTARRED QUESTION NO - 2155

TO BE ANSWERED ON 01/08/2025

"Standardisation of AYUSH Medicine and Products"

2155. Shri Naveen Jindal and Smt. Pratima Mondal

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

(a) the measures being taken by the Government to ensure the quality and standardisation of AYUSH medicines and products including quality control measures and the implementation of standards like the Ayurvedic Pharmacopoeia of India;

(b) the quantifiable results of such measures towards ensuring standardisation and quality control of AYUSH medicines, State/UT-wise;

(c) the efforts made by the Government to enhance the acceptability of AYUSH medicines globally through quality control and standardisation during last five years;

(d) the corrective measures taken by the Government to prevent the use of adulterated or sub-standard AYUSH medicines during each of the last five years, year-wise, State/UT-wise along with the results thereof;

(e) the details of the initiatives launched by the Government to promote international cooperation and recognition of AYUSH systems, particularly in the context of export promotion and regulatory harmonization with other countries; and

(f) the steps taken by the Government to strengthen evidence-based research and validation of AYUSH treatments and the manner in which Government is collaborating with scientific institutions to enhance clinical credibility of AYUSH treatments in the country?

ANSWER

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

(SH. PRATAPRAO JADHAV)

(a) & (b) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. Rule 158-B and Rule 85 (A to I) of the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy medicines respectively. 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 & Schedule M-I of the Drugs Rules, 1945 for Ayurveda, Siddha, Unani drugs and Homoeopathy drugs respectively and also to follow the quality standards of drugs as prescribed in the respective pharmacopoeia.

2. Drug Inspectors collect medicine samples regularly from manufacturing firms or sale 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', appropriate action is initiated such as preventing the sale of the products from the market and appropriate legal actions as per Drugs and Cosmetics Act 1940 and Rules made thereunder

3. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), subordinate office under Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. Details in this regard are at Annexure-I

4. PCIM&H also acts as the Central Drugs Laboratory for Indian Medicine and Homoeopathy for the purpose of testing or analysis of ASU&H Drugs. Further, it imparts Capacity Building Trainings at regular interval for standardization/quality control/ testing or analysis of ASU&H drugs to Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analyst) and other stakeholders on quality control of ASU&H drugs on laboratory techniques and methods used to maintain the quality of ASU&H drugs.

5. Drug Testing Laboratories are being recognized under Rule 160 A to J of the Drugs Rules, 1945 for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. 34 Drug Testing Laboratories of State/UTs are testing quality of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs and raw materials for legal samples.

6. Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards under one of the components. The total financial allocation to this scheme is Rs. 122.00 crores for five years.

7. Further Ministry of Ayush encourages following certifications of Ayush products as per details below:-

- An Ayush vertical has been created in Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures ensuring safety and quality of Ayush drugs. Further, CDSCO issues WHO Certificate of Pharmaceutical Product (WHO-CoPP) to Ayush drugs having compliance to such standards.

- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH standard and premium 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.

(c), (d) & (e) The Ministry of Ayush, developed the central sector scheme for Promotion of International Cooperation for AYUSH (IC Scheme). Under this scheme the Ministry provides support to Indian AYUSH drug Manufacturers/ Ayush Service providers to give boost to the export of AYUSH products and services; facilitates the International promotion, development and recognition of AYUSH systems of medicine; foster interaction of stakeholders and market development of AYUSH at international level; promote academics and research through the establishment of AYUSH Academic Chairs in foreign countries and holding training workshop/symposiums for promoting and strengthening awareness and interest about AYUSH Systems of Medicine at international level including Ayurveda.

As per the information received from State/UT the details of the corrective measures taken by the Government to prevent the use of adulterated or substandard Ayush medicines during each of the last five years, year-wise, State/UT-wise along with the results thereof are available at Annexure- II.

Under the CSS IC Scheme 25 Country to Country MoUs, 15 Ayush Chair MoUs and 52 Institute to Institute level MoUs have been signed.

(f) Ministry of Ayush undertakes various research initiatives through its various Research Councils and National Institutes which includes pre-clinical & clinical research, drug standardization research, Fundamental Research, literary research, survey etc. Mo Ayush is also collaborating with various scientific institutions such as ICMR, DBT, DST, IITs, AIIMS, NIPER, ICAR etc. through MoUs.

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Annexure-I

Annexure to Part (b) of LSUSQ No.2155 to be answered on 01.08.2025

So far, **2269** quality standards on raw materials (Single Drugs of plant/animal/Mineral/metal/ Chemical origin) used in ASU&H has been published, the details as follows:

Name of Pharmacopoeia	**Published quality standards of single drugs**
Ayurvedic Pharmacopoeia on India (Part I, Vol. I to X)	665
Siddha Pharmacopoeia on India (Part I Vol. I to II)	139
Unani Pharmacopoeia on India (Part I Vol. I to VII)	338
Homoeopathic Pharmacopoeia on India (Vol. I to XI)	1127

426 quality standards of ASU formulations also been published in respective Pharmacopoeias. The details as follows:

Name of Pharmacopoeia	**Published quality standards of formulations**
Ayurvedic Pharmacopoeia on India (Part II, Vol. I to V)	223 and 01 standalone quality standard
Siddha Pharmacopoeia on India (Part II)	01 standalone quality standard
Unani Pharmacopoeia on India (Part II Vol. I to IV)	200 and 01 standalone quality standard

Further, **2799** formulary specifications of ASU drugs also published in Formularies of respective system. The details as follows:

Formulary	**Specifications**
Ayurvedic Formulary of India	1035 (Part I to IV) and 01 standalone formulary specification
Siddha Formulary of India	532 (Part I to II) and 01 standalone formulary specification
National Formulary of Unani Medicine	1229 (Part I to VI) and o1 standalone formulary specification

In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 392 single drugs incorporated in API also published.

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Annexure-II

Annexure to Part (d) of LSUSQ No.2155 to be answered on 01.08.2025

State/ UT-wise details of the corrective measures taken by the Government to prevent the use of adulterated or substandard Ayush medicines during each of the last five years, year-wise, State/UT-wise along with the results thereof are as follows –

<table>
<tr><th>S.No.</th><th>Name of the State/ UT</th><th>Details</th></tr>
<tr><td>1.</td><td>Puducherry</td><td>Directorate of AYUSH is involved in conducting IEC activities and sensitizing the public to prevent the use of adulterated of substandard Ayush medicines.</td></tr>
<tr><td>2.</td><td>Delhi</td><td>Routine inspections by the Drugs Control Officials and lifting of samples of Ayurvedic and Unani medicines for test/analysis from government approved laboratories.</td></tr>
<tr><td>3.</td><td>Lakshadweep</td><td>This U.T does not have any Manufacturing Units and Drugs Testing Laboratories for ASU&H Drugs.</td></tr>
<tr><td>4.</td><td>Tripura (Agartala)</td><td>One State Drug Testing Laboratory (Ayush) has been established for quality testing of Ayush drugs in the state of Tripura.
<table>
<tr><th>Year wise report</th><th>Misbranded Ayush Medicines</th><th>Not of standard Ayush Medicines</th></tr>
<tr><td>2020-2021</td><td>04</td><td>-</td></tr>
<tr><td>2021-2022</td><td>-</td><td>-</td></tr>
<tr><td>2022-2023</td><td>62</td><td>03-</td></tr>
<tr><td>2023-2024</td><td>07</td><td>-</td></tr>
<tr><td>2024-2025</td><td>36</td><td>-</td></tr>
<tr><td>2025-till date</td><td>-</td><td>01</td></tr>
</table>
Recently state government has been notified State Licensing Authority (ASU Drugs) and Inspecting Officers of Drugs (ASU drugs) to enforce and regulate Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 which prohibits misleading advertisements for Ayush drugs.</td></tr>
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5.	Uttarakhand	The Government has taken stringent corrective measures to prevent the use of adulterated or substandard Ayush medicines. Those measures, along with their results, over the last five years include: - Regular Inspections: Regular inspections are being diligently carried out by drug inspectors on a continuous basis to monitor manufacturing units and market products • Systematic Sample Testing: Over the last two years, more than 390 samples of Ayush medicines were rigorously tested in state laboratories to ascertain their quality and compliance with prescribed standards Any instances of non-compliance lead to immediate regulatory action. - Training Programs: Regular training is being conducted for drug inspectors and for Pharmacies, making them aware of the acts' provisions and ensuring compliance.
6.	Manipur	Inspections are conducted at the Ayush retail/wholesale outlets by the Drug Inspectors along with the staffs. Ayush medicines were tested at Government approved Laboratory outside state to check the quality and genuineness. i. 2020-21 - 26 (Twenty Six) samples of Ayush medicines were tested, ii. 2021-22 – 23 (Twenty Three) samples of Ayush medicines were tested. iii. 2022-23 – NIL iv. 2023-24 – NIL v. 2024-25 - NIL
7.	Kerala	Department initiate action, filed FIR against not of standard quality Ayush medicines and suspend the products.
8.	Haryana	NIL
9.	Arunachal Pradesh	NIL

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