GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA
STARRED QUESTION NO. 403
TO BE ANSWERED ON 20th MARCH 2026

Standardisation and Quality Control of AYUSH Drugs

403. Shri Gyaneshwar Patil:
Shri Bhumare Sandipanrao Asaram:

Will the Minister of AYUSH be pleased to state:

(a) whether the Government proposes to establish a mechanism to address the issues of standardisation and quality control of AYUSH drugs and products in the country;
(b) if so, the details thereof along with the various efforts being made to improve the quality of AYUSH drugs/products in the country, State/UT-wise including Madhya Pradesh and Maharashtra;
(c) the additional measures taken or proposed to enhance research and development (R&D) in the field of AYUSH and collaborate with international organizations;
(d) the details of the plan of the Government to promote the wider use of high-quality AYUSH drugs and products among the consumers; and
(e) whether any shortfall has been observed in the manufacturing of various AYUSH drugs and if so, the details thereof?

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

(a) to (e) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 403 for 20th March 2026

(a) and (b) Ministry of Ayush has established adequate mechanisms for standardisation and quality control of Ayush drugs in the country. The details of these mechanisms, along with the various efforts being undertaken to further improve the quality of Ayush drugs across the country, State/UT-wise including Madhya Pradesh and Maharashtra, are as follows:

1. The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha, Sowa-Rigpa and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs Rules, 1945. Further, second schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic 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 & Schedule M-I of Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.
2. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a 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 and compliance to this quality standards are mandatory for the manufacturing for sale of ASU&H drugs across the country. So far, 2325 quality standards on raw materials (single drugs of plant/ animal/ mineral/ metal/ chemical origin) used in ASU&H drugs, 426 quality standards of ASU formulations and 2799 formulary specifications of ASU drugs has been published. In addition to above, supporting documents in the form of Macro, Microscopic & TLC Atlas on 392 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also published. Further, 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.
3. Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. Further, there are 34 Drug Testing Laboratories of State/UTs for testing quality of

Ayurveda, Siddha, Sowa-Rigpa and Unani drugs and raw materials including legal samples.

4. As prescribed in Drugs and Cosmetics Act, 1940 and Rules 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/UT Drug Controllers/ Licensing Authorities appointed by the concerned State/ UT Government.
5. 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 drugs from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder.
6. Ministry of Ayush has established an Ayush vertical in the Central Drugs Standard Control Organisation (CDSCO), which includes the posts of 1 Deputy Drugs Controller, 4 Assistant Drugs Controllers, and 4 Drug Inspectors. Drug Inspectors posted in Ayush vertical, inspect various manufacturing units including risk-based inspections in coordination with the licensing authorities/drug inspectors of the respective States/UTs for ensuring safety and quality of Ayush medicines.

(c) Government of India has established Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central Council for Research in Homoeopathy (CCRH), Central Council for Research in Siddha (CCRS) and Central Council for Research in Yoga & Naturopathy (CCRYN) under the Ministry of Ayush as apex organizations for undertaking, coordinating, formulating, developing and promoting research in Ayush system on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and invitro-propagation technique), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Research activities are carried out through its peripheral Institutes/Units located across the country and also in collaboration with various Universities, Hospitals and Institutes.

Further, Ministry of Ayush is implementing the Central Sector Scheme, namely Ayurgyan Scheme. The Scheme inter-alia has the components of (i) Research & Innovation in Ayush and ii) Ayurveda Biology Integrated Health Research. Under the Research & Innovation in Ayush and Ayurveda Biology Integrated Health Research components, financial assistance has been provided to the Organizations/Institutions for research studies including clinical research in Ayush systems of medicines.

Ministry of Ayush is implementing the central sector scheme for Promotion of International Cooperation for Ayush (IC Scheme). Under this scheme Ministry of Ayush 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. Under this Scheme, 27 Country to Country MoUs, 16 Ayush Chair MoUs and 54 Institute to Institute level MoUs have been signed.

(d) Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) with financial outlay of Rs. 122.00 crores for five years since 2021-2022. The components of AOGUSY scheme are as follows -

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

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.

Further, Ayush Quality Mark for Ayush products and services for Global standards have been launched during WHO Global Summit in December 2025. This certification scheme strengthens consumer trust in Ayush products and services by ensuring internationally accepted standards of quality, safety, and efficacy.

Ministry of Ayush has published the National List of Essential Ayush Medicines (NLEAM) comprising 201 Ayurveda, 200 Siddha, 200 Unani and 200 Homoeopathy drugs in year 2022. Further, under central sponsored scheme namely National Ayush Mission (NAM) scheme, State/UT Governments are provided with Grant-in-Aid for procurement of this NLEAM in the hospitals, dispensaries and co-located facilities.

(e) As per the information received from States/ UTs governments, details of shortfall observed in the manufacturing of various Ayush drugs are available at **Annexure-I.**

Annexure-I

State/ UT-wise details of shortfall observed in the manufacturing of various Ayush drugs are as follows -

S.no.	Name of the State/ UT	Details of shortfall noticed
1	Madhya Pradesh	Yes, non-compliance of Schedule T has been observed in 03 manufacturing unit namely M/s Siddhi Herbal Gwalior, M/s Shivam Pharmacy Gwalior and M/s Rabhiaans Herbals Pvt Ltd Indore. The license of the above three firms has been cancelled.
2	Bihar	Shortfall has been noticed in compliance of Drugs and Cosmetics Act 1940 and Drug Rules 1945 in M/S Radha Homeo Laboratory, Gautam Buddha Road, Gaya ji, Bihar. Legal action has been taken as per Drug & Cosmetic Act 1940 and Drug Rules 1945.
3	Tripura	There is no manufacturing unit in Tripura.
4	Odisha	NIL
5	Maharashtra	NIL
6	Delhi	NIL
7	Gujarat	NIL
8	Puducherry	NIL
9	Uttarakhand	NIL
10	Uttar Pradesh	NIL
11	Haryana	NIL
12	Kerala	NIL
13	Himachal Pradesh	NIL
14	Goa	NIL
15	Punjab	NIL

*****