GOVERNMENT OF INDIA
MINISTRY OF AYUSH
RAJYA SABHA

UNSTARRED QUESTION NO. 2722
TO BE ANSWERED ON 17th MARCH 2026

Standardization and quality control of AYUSH products

2722 Dr. K. Laxman:

Will the Minister of *Ayush* be pleased to state:
(a) the measures taken to strengthen pharmacopoeial standards and quality control for AYUSH drugs and formulations;
(b) the role of the Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) in ensuring safety and efficacy;
(c) the impact of the AYUSH mark and certification schemes in building consumer trust, both domestically and for exports; and
(d) the steps to promote evidence-based validation of traditional AYUSH treatments?

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

(a) and (b) 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. As per Drugs and Cosmetics Act, 1940 and Drugs Rules 1945, compliance to these quality standards are mandatory for the manufacturing of ASU&H drugs. 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, PCIM & H impart training to the Drug Regulatory Authorities, State Drug Analyst etc on laboratory techniques and methods used to maintain quality of ASU & H drugs.

The Drugs & Cosmetics Act, 1940 and Rules made there under 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, 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.

Further, 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.

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 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. 34 Drug Testing Laboratories of State/UTs are testing quality of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs and raw materials for legal samples.

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.

(c) 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.

(d) 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 cultivation), 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.

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