GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 2485
TO BE ANSWERED ON 13th FEBRUARY 2026
Quality of AYUSH Medicines

2485. Smt. Geniben Nagaji Thakor:

Will the Minister of AYUSH

be pleased to state:

(a) whether the Government has issued any guidelines regarding the quality, standardization and safety of AYUSH medicines in the country;

(b) if so, the details thereof;

(c) the steps taken by the Government to curb fake AYUSH medicines; and

(d) the details of penal provisions in case of violations?

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

(a) and (b) The details of guidelines regarding the quality, standardization and safety of Ayush medicines in the country are as follows:

1. The Drugs & Cosmetics Act, 1940 and Rules made thereunder have exclusive regulatory provisions for Ayurvedic, 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. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of Ayush drugs including proof of safety & effectiveness, compliance to Good Manufacturing Practices (GMP) for manufacturing of Ayurveda, Siddha, Sowa-rigpa, Unani (ASSU) drugs and Homeopathy drugs as per Schedule T & Schedule M-I of Drugs Rules, 1945 respectively and to maintain quality standards of drugs as given in the respective pharmacopoeia.

2. 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 Drug Controllers/Licensing Authorities appointed by the concerned State/ Union Territory Government.
3. Drug Inspectors collect drug 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 drugs from the market and initiating legal actions as per Drugs and Cosmetics Act, 1940.
4. 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.
5. PCIM&H also acts as the Central Drugs Laboratory for Indian Medicines 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, Drug Analysts and other stakeholders on quality control of ASU&H drugs on laboratory techniques and methods used to maintain the quality of ASU&H drugs.
6. 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 Ayurvedic, Siddha, Sowa-rigpa and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha, Sowa-rigpa and Unani drugs. As on date, 34 State Drug Testing Laboratories and 108 Private Drug Testing Laboratories are approved for quality testing of Ayurvedic, Siddha, Sowa-rigpa and Unani drugs and raw materials.
7. Further, Ministry of Ayush encourages following certifications of Ayush products as per details below: -
    - The scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines. This scheme is administered by Central Drugs Standard Control Organization (CDSCO) and the certificate is granted on the basis of joint inspection

of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority.

- Quality Certifications Scheme 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.
- Ayush Quality Mark for Ayush products and services for Global standards has been launched during WHO Global Summit in December, 2025.

8. Ministry of Ayush has implemented Central Sector Scheme, Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) with total financial outlay of Rs 122.00 crores for five years from 2021-22 to 2025-26. One of the components of this scheme is to strengthen and up-grade Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
9. Ministry of Ayush has established an Ayush vertical in the Central Drugs Standard Control Organisation (CDSCO) to inspect various manufacturing units in coordination with the licensing authorities/drugs inspectors of respective States/Union Territories for ensuring safety and quality of Ayush medicines.

(c) and (d) The steps taken by the Government to curb fake Ayush medicines and the details of penal provisions in case of violations are as follows: -

1. Sections 33E, 33EE, and 33EEA of the Drugs and Cosmetics Act, 1940 define misbranded, adulterated, and spurious Ayurveda, Siddha and Unani (ASU) drugs, respectively.
2. Further, Section 33EEC prohibits the manufacture of any misbranded, adulterated, or spurious ASU drug.
3. The penalties for manufacturing of misbranded or adulterated or spurious ASU drugs, or for manufacturing ASU drugs without a valid licence, are mentioned under Section 33-I (1) of Drugs and Cosmetics Act, 1940.
4. Section 17, 17A and 17B of Drugs and Cosmetics Act, 1940 provides definition of misbranded, adulterated and spurious Homoeopathic drugs. Section 27 of Drugs and Cosmetics Act, 1940 provides penalties for manufacturing of misbranded, adulterated and spurious Homoeopathic drugs or drugs manufactured, sold, or distributed without a valid licence.

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