

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**LOK SABHA  
UNSTARRED QUESTION NO. 1002  
TO BE ANSWERED ON 05<sup>th</sup> DECEMBER 2025**

Regulatory Compliance for ASU Drug Manufacturers

1002. Dr. T Sumathy *Alias* Thamizhachi Thangapandian:

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government has undertaken any recent review of regulatory compliance issues faced by drug manufacturers and practitioners of Ayurvedic, Siddha and Unani (ASU) in Tamil Nadu and if so, the details thereof;
- (b) whether the Government has assessed the capacity of State drug-testing laboratories and Government Analysts in Tamil Nadu, if so, the details thereof and the steps being taken to strengthen testing, reduce pendency and upgrade lab infrastructure;
- (c) whether the Government proposes to issue simplified guidance or phased compliance support for small Siddha and other ASU practitioners who face challenges in labelling, packaging and documentation and if so, the details thereof; and
- (d) the details of consultations held with State Licensing Authorities in Tamil Nadu on these matters?

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

(a) As per the Drugs & Cosmetics Act, 1940 and Drugs Rules 1945, 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 drug controllers/ State licensing authorities appointed by the concerned State/ Union Territory Government.

Further, as per the information received from State Government of Tamil Nadu, State Drug Inspectors (Indian Medicine) of Govt. of Tamil Nadu regularly undertake inspections of manufacturing premises to ensure Safety and quality of raw materials, compliance of final products with prescribed regulatory standards and adherence to Good Manufacturing Practices (GMP).

(b) In the State of Tamil Nadu, one State Drug Testing Laboratory (Indian Medicine) and one Government Analyst are currently functioning to facilitate the testing of Ayurveda, Siddha,

Sowa-Rigpa, Unani, and Homoeopathy drugs. The State Drug Testing Laboratory has been supported by the Ministry of Ayush with a grant of ₹1.12 crore for its strengthening and upgradation under the Central Sector Scheme Ayush Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY).

Further, 14 private drug testing laboratories are recognized in Tamil Nadu under Rule 160 E of Drugs Rules 1945 for testing of raw materials and drugs. As per the information received from Tamil Nadu state, details of sample tested by state drug testing laboratory, Tamil Nadu are placed at **Annexure**.

(c) Labelling and packing provisions for Ayurveda, Siddha, Sowa-Rigpa and Unani (ASSU) drugs are mentioned under Rule 161 of Drugs Rules 1945. Exemption in labelling and packing provisions for export of Ayurveda (including Siddha) and Unani Drugs are mentioned under Rule 161A of Drugs Rules 1945. Further, the provisions for good manufacturing practices for Ayurveda, Siddha, Sowa-Rigpa and Unani drugs are mentioned under schedule T of Drugs Rules 1945. As per section 33EEC of Drugs and Cosmetics 1940, Vaidyas and Hakims who manufacture Ayurveda, Siddha or Unani drug for the use of their own patients are exempted from the provisions of Drugs and Cosmetics Act and Rules made there under.

Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) is a subordinate office under Ministry of Ayush, conducts quarterly capacity building training (CBT) Programmes for a wide range of stakeholders, including drug regulators/enforcement authorities, quality control and technical personnel associated with ASU&H drugs, ASU&H drug manufacturers, Ayush-accredited State/UT's Drug Testing Laboratories, faculty of ASU&H pharmacy colleges, and technical personnel from other scientific institutions. During the last three financial years, PCIM&H has conducted a total of 11 CBT Programmes, in which 207 participants including 07 participants from Siddha system took part.

(d) Ministry of Ayush consult State/UT's Government including Tamil Nadu Government on various matters of ASSU drugs. As per section 33 D of Drugs and Cosmetics Act 1940, Central Government constitutes Ayurvedic, Siddha and Unani Drugs Consultative Committee with representatives from State/UT Governments including Tamil Nadu government to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of Drugs and Cosmetics Act, 1940 in respect of ASSU drugs.

## Annexure

As per the information received from Tamil Nadu state, details of sample tested by state drug testing laboratory, Tamil Nadu are as follows: -

Samples	Duration	Total No of Samples Tested	Standard Quality	Not of Standard quality
Statutory samples collected in Tamil Nadu	January 2025 to till date	1925	1891	34
Statutory samples received from Andaman & Nicobar as per memorandum of understanding	January 2025 to till date	37	37	-

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