GOVERNMENT OF INDIA

MINISTRY OF AYUSH

LOK SABHA

UNSTARRED QUESTION NO. 4676

TO BE ANSWERED ON 28th March 2025

"AYUSH Drug Standardization and Quality Control"

4676. Dr. Rani Srikumar:

Will the Minister of Ayush be pleased to state:

(a) the total number of AYUSH medicines standardized and certified for quality under Central Government Schemes during the last five years, year-wise;

(b) the details of the funds allocated, released and utilized for establishing drug testing laboratories and ensuring quality control of AYUSH products during the same period;

(c) the measures being taken to prevent the sale of substandard or adulterated AYUSH medicines in the domestic and international markets;

(d) whether there are plans to establish additional testing laboratories and regulatory bodies to strengthen quality assurance in AYUSH systems; and

(e) if so, the details thereof?

ANSWER

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

(SHRI PRATAPRAOJADHAV)

(a) 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 & Homoeopathic (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included therein, as per Drugs & Cosmetics Act, 1940 and Rules made thereunder and compliance to these quality standards are mandatory for the production of ASU&H drug being manufactured, sell and stocked in India. The pharmacopeial and formulary standards of ASU&H drugs published in last five years are at **Annexure-I**.

(b),(d)and(e) In the year 2021, Ministry of Ayush has implemented a Central Sector Scheme-Ayush Oushadhi Gunavatta Evam Uttpadan Samvardhan Yojana (AOGUSY) with total Budget allocation of Rs. 122.00 Crores for five years. The first component of the Scheme is to Strengthen and upgrade Ayush Pharmacies and Drug Testing Laboratories (DTL) to achieve higher standards of World Health Organisation-Good Manufacturing Practices((WHO-GMP) and National Accreditation Board for Testing and Calibration Laboratories(NABL) standards, respectively.

Till date, Rs. 5.31 Crores have been sanctioned to 12 ASU&H drug testing laboratories under the scheme. The details are annexed as **Annexure-II.**

(c) 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, Unani(ASU) 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.

Drug Inspectors collect medicine samples regularly from manufacturing firms or sale shops with in their jurisdiction and sent it to Drug Testing Laboratory under Drug Control department for quality testing and if any sample found to be Not of Standard Quality, appropriate action is initiated as per Drugs and Cosmetics Act 1940 and Rules made thereunder.

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Annexure -I

The pharmacopeial and formulary standards of ASU&H drugs has been published in last five years

Pharmacopoeia:

Publication	Volume & Year	Number of Monographs
Formulary Specification of Ayush Kvätha Cürna	2020	01
Formulary Specification of Ayush Kuṭinir Cüraṇam	2020	01
Formulary Specification of Ayush Safüf-i-Joshända.	2020	01
Ayurvedic Pharmacopoeia of India, Part I (Single Drugs)	Vol. X, 2022 (Minerals & Metals)	20
Ayurvedic Pharmacopoeia of India, Part II (Formulations)	Vol. V, 2025	21
The Unani Pharmacopoeia of India, Part-I (Single Drug)	Vol. VII, 2022	40
The Unani Pharmacopoeia of India, Part II (Formulations)	Vol. IV, 2022 (Improved version)	50
Homoeopathic Pharmacopoeia of India	Vol. XI, 2025	68

Formulary Specifications:

Publication	Part & Year	Number of Formulations
Formulary Specification of Ayush Kvätha Cürna	2020	01
Formulary Specification of Ayush Kuṭinir Cüraṇam	2020	01
Formulary Specification of Ayush Safüf-i-Joshända.	2020	01
Ayurvedic Formulary of India (Veterinary)	Part IV, 2022	50
Siddha Formulary of India	Part III (Tamil), 2024	133
	Part I Revised (Tamil), 2025	248
National Formulary of Unani Medicine	Part IV (Revised), 2022	166
	Part I (Revised), 2025	441

Supporting document:

Publication	Volume & Year	Number of Monographs
Thin Layer Chromatography (TLC) Atlas	API Drugs Pt. I, Vol. II, 2025	42

Annexure -II

Details of Funds Released under AOGUSY Central Sector Scheme under component- Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards

S.No.	F.Y.	State	Pharmacy/DTL	Particulars	Amount released
1	2021-22	Mizoram	DTL	State Govt. of Mizoram	Rs. 1,800,000
2	2022-23	Uttar Pradesh	DTL	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P (DTL)	Rs. 7,767,000
3	2023-24	Tripura	DTL	State Govt. of Tripura	Rs. 7,668,000
4		Jammu & Kashmir	DTL	State Govt. J&K	Rs. 8,629,500
5		Mizoram	DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 6,720,884
6		Tamil Nadu	DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 2,000,000
7		Arunachal Pradesh	DTL	State Drug Testing Laboratory , Arunachal Pradesh	Rs. 1,799,813
8	2024-25	Arunachal Pradesh	DTL	State Drug Testing Laboratory , Arunachal Pradesh	Rs. 1,724,400
9		Tamil Nadu	DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 5,100,000
10		Mizoram	DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 3,940,500
11		Tamil Nadu	DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 4,157,062
12		Mizoram	DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 1,800,000
				Total	**Rs. 53,107,159**