

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**LOK SABHA  
UNSTARRED QUESTION NO.1683  
TO BE ANSWERED ON 16<sup>TH</sup> DECEMBER, 2022**

**QUALITY CONTROL OF AYUSH PRODUCTS/MEDICINES**

**1683. SHRIMATI RANJEETA KOLI:  
DR. MANOJ RAJORIA:  
SHRI BALAK NATH:  
SHRI SUMEDHANAND SARASWATI:**

Will the Minister of **AYUSH** be pleased to state:

- (a) whether the Government has taken any step for Standardization and Quality Control of AYUSH Products/Medicines keeping in view of their increasing demand in the country including Rajasthan;
- (b) if so, the details thereof;
- (c) the details of such specific herbs/medicines of Ayurveda for which quality control standards have been set by the Government;
- (d) the details of the steps taken/being taken by the Government to make adequate availability of the required medicinal components for the production of medicines;
- (e) whether any policy is being formulated to provide required education and provision of licences to the people engaged in production and marketing of such medicines in the country including in Rajasthan; and
- (f) if so, the details thereof ?

**ANSWER  
THE MINISTER OF AYUSH  
(SHRI SARBANANDA SONOWAL)**

(a) to (c): Yes Sir. As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory

guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to D) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic medicines. 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 and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush has taken following steps for Standardization and Quality Control of AYUSH Products/Medicines in the country:

- i. Schemes to support Ayurvedic medicines production: Under National Ayush Mission (NAM) from 2014-2021, apart from other services Grant-in-aid were also provided for Strengthening of State Government ASU&H Pharmacies. At present, Central Sector Scheme for Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. The components of the AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) Scheme are as under;
  - 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.
- ii. Consequent upon decision of Central Government (dated 3<sup>rd</sup> June, 2020), the Government of India has re-established Pharmacopoeia Commission for Indian Medicines and Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging into it, the two central laboratories namely PLIM and HPL (notified vide gazette dated 6<sup>th</sup> July, 2020). PCIM&H lays down Pharmacopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the identity, purity and strength of the drugs included therein. List of publications published till date is enclosed at **Annexure-I**. Further, being an appellate laboratory for testing of ASU&H drugs;

samples received from Government agencies especially from the Hon`ble court. etc. are being tested by PCIM&H to ensure the quality of ASU&H drugs as per the prescribed standards.

iii. In addition to the above, for facilitating exports, Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH 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 international standards.

iv. 27 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. As on date 81 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

v. Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

vi. Central Council for Research in Homoeopathy (CCRH) under Ministry of Ayush, has so far established pharmacognostical standards on 317 drugs, physico-chemical standards on 336 drugs and pharmacological standards on 151 drugs which include plants, chemicals, minerals and animal sources. One hundred forty-nine (149) drugs have been studied in all the three aspects.

vii. Central Council for Research in Unani Medicine (CCRUM) under Ministry of Ayush is conducting Drug Standardization Research Programme to standardize the products of Unani Medicine for its quality and safety.

(d) Ministry of Ayush, Government of India had implemented Centrally Sponsored Scheme of National Ayush Mission (NAM) to promote the cultivation of medicinal plants since 2015-16 to 2020-21. Under 'Medicinal Plants' component of the National Ayush Mission Scheme, market driven cultivation of 140 prioritized medicinal plants in identified clusters/zones was supported and implemented in a mission mode through selected State Implementing agencies throughout the country. As per the scheme guidelines, the support was provided for:

- I. Cultivation of prioritized medicinal plants on farmer's land.
- II. Establishment of nurseries with backward linkages for raising and supply of quality planting material.
- III. Post-harvest management with forwarding linkages.
- IV. Primary processing, marketing infrastructure etc.

Ministry of Ayush has approved / supported 56,305 hectare area, 220 nurseries, 354 post-harvest management units etc. under medicinal plants component of National Ayush Mission (NAM) from the financial year 2015-16 to 2020-21.

Further, at present National Medicinal Plants Board, Ministry of Ayush is implementing a scheme entitled "Central Sector Scheme on Conservation, Development and Sustainable Management of Medicinal Plants" wherein the following activities are supported:

- (i) In-situ conservation / Ex-situ conservation including establishment of herbal garden.
- (ii) Promotional activities including establishment of nurseries for raising the planting material for plantation, marketing and trade of medicinal plants produce.
- (iii) Livelihood linkages with Joint Forest Management Committees (JFMCs) / Panchayats / Van Panchayats / Biodiversity Management Committees (BMCs) / Self Help Groups (SHGs).
- (iv) Information Education and communication (IEC) activities like Training / Workshops / Seminars/ Conferences etc.
- (v) Research & Development activities on various aspects of medicinal plants

Central Council for Research in Homoeopathy (CCRH) under Ministry of Ayush has Central of Medicinal Plant Research Institute (CMPRH) at Emerald, Nilgiris district, is maintaining, cultivating the germplasm of 104 plant species (92 exotic and 12 indigenous) medicinal plants used in homoeopathy. The raw drugs of these medicinal plants are being supplied to manufacturers.

The State Government of Odisha is providing funds for procurement of reaw drugs from various suppliers and utilization of the same in the two Government Ayurvedic Pharmacies located at Bhubaneswar and Bolangir each year.

(e) & (f) Yes Sir. Ministry of Ayush has implemented Central Sector Scheme for Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) for the year 2021-2026. Under the 3<sup>rd</sup> component of AOGUSY Scheme, i.e. “Strengthening of central and state regulatory frameworks including technical human resource & capacity building programs for ayush drugs”, Ministry of Ayush has initiated comprehensive program for development of human resources for the ASU&H industry and regulatory personnel in the states. Details regarding the training conducted for Ayush drug regulators, industry personnel and other stake holders are as follows -

<b>Sl No.</b>	<b>Participating States</b>	<b>Host institute/ Venue</b>
1.	North Zone Jammu& Kashmir; Ladakh, Himachal Pradesh; Punjab; & Chandigarh, Haryana, Uttarakhand, Delhi	Regional Ayurveda Institute, Mandi Himachal Pradesh
2.	West Zone Rajasthan, Haryana, Uttar Pradesh, Gujarat, Goa, Maharashtra, Daman and Diu, Dadar and Nagar Haveli	Regional Ayurveda Research Institute for Skin Disorders, Ahmadabad, Gujarat
3.	Soth Zone Tamil Nadu; Andhra Pradesh; Telangana; Kerala; Karnataka; Puduchery; & Lakhsdweep, Andaman and Nicobar	National Institute of Unani Medicine (NIUM), Bangalore, Karnataka

As per the information received from State/UT government-

- Government of Odisha, technical education is imparted in three Government Ayurvedic Medical Colleges of the State located in Puri, Behrampur and Bolangir.
- Training sessions are being organized by Ayurveda Drugs Control Department, Government of Kerala. In 2022, three sessions of training were provided to manufacturers.

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**SUMMARY OF PHARMACOPOEIAL AND RELATED PUBLICATIONS****I. AYURVEDA PHARMACOPOEIAL PUBLICATION**

<b>Publication</b>	<b>Part</b>	<b>Volume &amp; Year</b>	<b>Number of Monographs</b>
<b>Ayurvedic Pharmacopoeia of India</b>	Part I (Single Drugs)	Vol. I, 1986	80
		Vol. II, 1999	78
		Vol. III, 2001	100
		Vol. IV, 2004	68
		Vol. V, 2006	92
		Vol. VI, 2008	101
		Vol. VII, 2008 (Minerals & Metals)	21
		Vol. VIII, 2011 (Hydro-alcoholic & Water extracts)	60
		Vol. IX, 2016 (Hydro-alcoholic & Water extracts)	45
		Vol. VI, 2022 (Minerals & Metals)	20
	<b>Total</b>		<b>665</b>
	Part II (Formulations)	Vol. I, 2007	50
		Vol. I, 2011 (Hindi Ed.)	
		Vol. II, 2008	51
		Vol. II, 2011 (Hindi Ed.)	
Vol. III, 2010		51	
Vol. IV, 2017		50	
Pharmacopoeial Monograph of Ayush Kvātha Cūrṇa (Stand- alone) 2021		01	
<b>Total</b>		<b>203</b>	
<b>Supporting Pharmacopoeial Publications</b>	Thin Layer Chromatography (TLC) Atlas	API Drugs Pt. I, Vol. I, 2009	80
		API Drugs Pt. I, Vol. III, 2016	99
	Macroscopy and Microscopy Atlas	API Drugs Pt.-I Vol. V, 2009	92
		API Drugs Pt.-I Vol. I, 2011	80

Publication	Part & Year	Number of Formulations
Ayurvedic Formulary of India	Part I, 2003 (2 <sup>nd</sup> Edition)	444
	Part II, 2000	191
	Part III, 2011 (Bilingual)	350
	Formulary specification of Ayush Kvātha Cūrṇa (Stand-alone) 2021	01
	Part IV, 2022 (Veterinary)	50
<b>Total</b>		<b>1036</b>

## II. SIDDHA PHARMACOPOEIAL PUBLICATIONS

Publication	Part	Volume & Year	Number of Monographs
Siddha Pharmacopoeia of India	Part I (Single Drugs)	Vol. I, 2008	73
		Vol. II, 2011	66
		<b>Total</b>	<b>139</b>
	Part II (Formulations)	Pharmacopoeial Monograph of Ayush Kuṭinīr Cūrāṇam (Stand-alone)	01

Publication	Part & Year	Number of Formulations
Siddha Formulary of India	Part I (Tamil), 1984 Part I (English), 1992	248
	Part II (Tamil), 2011	151
	Formulary specification of Ayush Kuṭinīr Cūrāṇam (Stand-alone)	01
	<b>Total</b>	<b>400</b>

## III. UNANI PHARMACOPOEIAL PUBLICATION

Publication	Part	Volume & Year	Number of Monographs
The Unani Pharmacopoeia of India	Part-I (Single Drug)	Vol. I, 2007	45
		Vol. II, 2007	50
		Vol. III, 2007	53
		Vol. IV, 2007	50
		Vol. V, 2008	52
		Vol. VI, 2009	48
		Vol. VII, 2022	40
	<b>Total</b>		<b>338</b>

Publication	Part	Volume & Year	Number of Monographs
<b>The Unani Pharmacopoeia of India</b>	Part II (Formulations)	Vol. I, 2009	50
		Vol. II, 2010	50
		Vol. III, 2016	50
		Vol. IV, 2019	50
		Pharmacopoeial Monograph of Ayush Safūf-i-Joshānda (Stand-alone)	01
<b>Total</b>			<b>201</b>

Publication	Part & Year	Number of Formulations
<b>National Formulary of Unani Medicine</b>	Part I, 1984	441
	Part II, 1994	202
	Part III, 2001	103
	Part IV, 2006	166
	Part V, 2008	178
	Part VI, 2011	139
	Formulary specification of Ayush Safūf-i-Joshānda (Stand-alone)	01
	<b>Total</b>	<b>1230</b>

#### IV. HOMOEOPATHY PHARMACOPOEIAL PUBLICATION

Publication	Volume & Year	Number of Monographs
<b>Homoeopathic Pharmacopoeia of India</b>	Vol. I, 1971	180
	Vol. II, 1974	100
	Vol. III, 1978	105
	Vol. IV, 1984	107
	Vol. V, 1987	114
	Vol. VI, 1990	104
	Vol. VII, 1999	105
	Vol. VIII, 2000	101
	Vol. IX, 2006	100
	Vol. X, 2016	101
	<b>Total</b>	<b>1,117</b>