

Implementation of Ayush Quality Mark

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The **Ayush Quality Mark**, launched on **19th December, 2025** during the **2nd World Health Organization (WHO) Global Summit on Traditional Medicine**, act as a unified quality assurance framework to promote globally accepted standards for Ayush products and services. The implementation of the initiative has been entrusted to AYUSHEXCIL, which is an Ayush Export Promotion Council notified by Directorate General of Foreign Trade (DGFT), Ministry of Commerce and supported by Ministry of Ayush. The Ayush Quality Mark covers Ayush products, Ayush hospitals, day-care centres, clinics, wellness centres, Medical Value Travel Facilitators (MVTs) and Ayush product testing laboratories. The framework is aligned with internationally accepted standards of quality, safety and efficacy and is supported through accredited certification. The initiative is further complemented by ongoing measures under the **Ayush Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY)** for strengthening quality control infrastructure, regulatory capacity, pharmacovigilance and standardisation.

Ministry of Ayush has implemented a Central Sector Scheme, namely Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY), which was approved by Standing Finance Committee (SFC) on 16.03.2021. The total budget allocation to this scheme is Rs.122.00 crores for five years.

During financial year 2025-26, 03 State Drug Testing Laboratories (DTLs) have been supported financially under the AOGUSY scheme. The details of the total amount of funds allocated and released for upgrading drug testing laboratories under AOGUSY during 2025-26 are annexed at **Annexure-I**.

Certificate of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines has been extended to Ayurveda, Siddha and Unani (ASU) medicines to strengthen regulatory measures ensuring safety and quality of Ayush drugs. Under the WHO Certification Scheme on the quality of Pharmaceutical Products moving in International Commerce, the Central Drugs Standard Control Organization (CDSCO) issues CoPP for ASU drugs intended for export. The CoPP is issued for the purpose of product registration in importing countries and is based on a joint inspection conducted by representatives of CDSCO, Ministry of Ayush, and the respective Licensing Authority, in accordance with the applicable guidelines and regulatory requirements as per WHO Technical Report Series (TRS).

Ministry of Ayush is implementing the AYURGYAN Scheme, a Central Sector Scheme, under which the Ayurveda Biology Integrated Health Research (ABIHR) has been introduced as the third component to support collaborative, evidence-based research integrating Ayurveda with modern science. The component aims to promote scientific validation of Ayurvedic principles and interventions through preclinical and clinical research, strengthen research capacity, and foster inter-institutional collaborations across the country. Till date, 11 research projects have been sanctioned under the ABIHR component. The details are annexed at **Annexure-II**.

Ministry of Ayush has not received any proposal for extending these Research and Development (R&D) initiatives or research infrastructure to academic institutions from Odisha including Kandhamal. Therefore, no such proposal is under consideration for setting up specialised Ayush research units in

Ministry of Ayush has taken following steps to strengthen the quality assurance, testing and global acceptance of Ayush drugs/medicines in the country:

1. The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy (ASSU&H) drugs. 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 and Schedule M-I of the Drugs Rules, 1945 for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs respectively and to follow the quality standards of drugs as prescribed in the respective pharmacopoeia.

Drug Inspectors collect medicine samples regularly from manufacturing firms or retail 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 medicines from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder. There are 34 Drug Testing Laboratories available in State/UTs for testing of the Legal Samples drawn by the Drug Inspectors of concerned State/UTs.

2. The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate organization under Ministry of Ayush, develops pharmacopoeial standards and formulary specifications for Ayush drugs, which serve as the official compendia for determining their identity, purity, and strength. Compliance with these standards is mandatory under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. PCIM&H also functions as the Appellate Drug Testing Laboratory for Ayush drugs and conducts regular capacity-building programmes for Drug Regulatory Authorities, Drug Analysts, and other stakeholders on standardization, quality control, and testing methodologies to strengthen the quality assurance system for Ayush drugs.
3. Drug Testing Laboratories are approved by Ministry of Ayush under Rules 160A to 160J of the Drugs Rules, 1945, for carrying out tests relating to the identity, purity, quality and strength of Ayush drugs. As on date, 118 private Drug Testing Laboratories have been approved by Ministry across States and Union Territories for conducting such tests in accordance with the provisions of the Drugs Rules, 1945.
4. Further, Ministry of Ayush is implementing a Central Sector Scheme, namely, Ayush Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards like WHO-GMP and National Accreditation Board for Testing and Calibration Laboratories (NABL) respectively.
5. In addition, Ministry of Ayush has undertaken the following initiatives to promote quality assurance and certification of Ayush products:

- To strengthen regulatory oversight, Ayush Vertical in CDSCO facilitates the issuance of the World Health Organization Certificate of Pharmaceutical Product (WHOCOPP) for eligible Ayush drugs through joint inspections with State/UT Licensing Authorities.
- Ayush Standard Mark and Ayush Premium Mark are awarded to Ayush Drugs by Quality Council of India (QCI) based on thirdparty assessment of compliance with prescribed national and international quality standards.
- Ayush Quality Mark Programme was launched by the Ministry of Ayush to strengthen quality assurance, enhance consumer confidence, and improve the Global recognition and competitiveness of Ayush products and services.
- Ayurveda and Yoga has been included under Sectional Committee 2 of ISO/TC249 to focus on International Standards of Ayurveda and Yoga, terminology, quality and safety of ingredients, extracts,

finished products, Ayurveda based dietary supplements, Yoga accessories etc.

Annexure-I

The details of total amount of funds allocated and released for upgrading drug testing laboratories (DTLs) under AOGUSY during 2025-26 are as follows:

- Amount allocated under Grant-in-aid (GIA) head of the AOGUSY (for upgrading DTLs and Pharmacies) during 2025-26 is Rs.17.50 crores.
- Amount of funds allocated and released for upgrading State DTLs is as mentioned below-

(Amount in Rs.)

S. No.	State	Component	Govt./Pvt./PSU	Particulars	Total amount Sanctioned/ Allocated	Amount Released in previous years	Amount Release in 2025-26
1.	Arunachal Pradesh	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Govt.	State Govt. DTL	53,24,026	2023-24: 17,99,813 2024-25: 17,24,400	17,99,813
2.	Mizoram		Govt.	State Govt. DTL	1,60,61,384	2021-22: 18,00,000 2023-24: 67,20,884 2024-25: 57,40,500	18,00,000
3.	Madhya Pradesh		Govt.	State Govt. DTL	75,83,262	-	75,83,262

Annexure-II

State-wise details of ongoing research projects under ABIHR component, Ayurgyan Scheme, Ministry of Ayush:

State	Project Title
Andhra Pradesh	Development of drug master file and technical dossiers on selected single botanicals used in Ayurveda
	Development of Technical dossier of Trigonella Foenum graecum - Stage I (preclinical studies- oral toxicity, genotoxicity, efficacy, Pharmacokinetic studies and safety pharmacology in rodents)
Gujarat	Development of Technical dossier of Zingiber Officinale- Stage I (preclinical studies- oral toxicity, genotoxicity, efficacy, Pharmacokinetic studies and safety pharmacology in rodents)
Karnataka	Development of Technical dossier of Bacopa monnieri- Stage I (preclinical studies- oral toxicity, genotoxicity, efficacy, Pharmacokinetic studies and safety pharmacology in rodents)
Karnataka	Investigation of potential leads from Ayurveda therapeutics for management of Antimicrobial Resistance (AMR)
Madhya Pradesh	Preclinical Toxicological Evaluation and Safety Pharmacology of Selected Ayurvedic Formulations Triphala churna, Lashunadi vati, and Brihat Vata Chintamani Rasa
Maharashtra	Development of Technical dossier of Boswellia serrata- Stage I (preclinical studies- oral toxicity, genotoxicity, efficacy, Pharmacokinetic studies and safety pharmacology in rodents)
Maharashtra	Preclinical Toxicological Evaluation and Safety Pharmacology of Selected Ayurvedic Formulations - Laksha Guggulu, Dadimadi Ghrita and Ekangaveera Rasa
Uttar Pradesh	Development of Technical dossier of Withania somnifera - Stage I (preclinical studies- oral toxicity, genotoxicity, efficacy, Pharmacokinetic studies and safety pharmacology in rodents)
West Bengal	Preclinical Toxicological Evaluation and Safety Pharmacology of Rajah Pravartini Vati, Phala Ghrita and Drakshavaleha
	Toxicological Evaluation, Safety Assessment, and Metabolomic Profiling of Selected Ayurvedic drugs and Formulations

This information was given by Union Minister of State (I/C) for Ayush, Shri Prataprao Jadhav, in a written reply in Lok Sabha today.

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