

GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 964
TO BE ANSWERED ON 9th DECEMBER 2025

Standardisation and validation of Ayush drugs

964 Dr. Syed Naseer Hussain:

Will the Minister of Ayush be pleased to state:

- (a) the processes in place under the AYURGYAN Scheme to ensure the rigorous standardisation and validation of Ayush drugs especially under efficiency and safety parameters;
- (b) the data on the number of Ayush drugs successfully validated with any notable improvements in quality standards;
- (c) whether there are any collaborations with external regulatory agencies or research bodies to meet global standards of validation and certification for Ayush drugs; and
- (d) if so, the details thereof?

ANSWER

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

(a) & (b) Under Ayurveda Biology Integrated Health Research (ABIHR) component of Ayurgyan Scheme, financial assistance is provided to the eligible organizations including scientific institutions for high end Research activities. The ABIHR component is focused on generation of evidence on safety and efficacy of Ayurveda interventions and drug development & standardization through pharmacological studies, safety & toxicity evaluation, pharmacokinetics & pharmacodynamics studies and high-end clinical trials. These processes collectively ensure rigorous standardization and validation of Ayush drugs on efficiency and safety parameters. With the objective of drug development based on

single botanicals in Ayurveda for positioning in the global market, Ministry of Ayush has prioritized 05 single botanicals in project mode through pro-active approval with Central Council of Research in Ayurvedic Science (CCRAS) for the development of comprehensive quality and safety dossier by outsourcing GLP-compliant laboratories.

A total of 11 projects (i.e. 02 in FY 2023-24, 04 in FY 2024-25 and 05 in FY 2025-26) have been supported under ABIHR component for drug development in Ayurveda and validation of Ayurveda drugs under efficiency and safety parameters.

(c) & (d) Under Central Sector Scheme of Ministry of Ayush namely Ayush Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana (AOGUSY), there is a provision to provide 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.

Ministry of Ayush also 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 based on 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 premium mark to Ayurvedic, Siddha and Unani products based on third party evaluation of quality in accordance with the status of compliance to international standards.
