GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA

UNSTARRED QUESTION NO. 5544
TO BE ANSWERED ON 27th MARCH 2026

Licence of AYUSH Products

5544. Dr. Anand Kumar:

Will the Minister of AYUSH be pleased to state:

(a) whether it is a fact that formal clinical studies have been published for only approximately 72 Ayurvedic and 27 Siddha medicines, whereas thousands of AYUSH products have been licensed in the Country during the last three years;
(b) if so, the details thereof along with the reasons for the lack of adequate scientific evidence and research on AYUSH medicines;
(c) whether the Government is aware that due to the lack of scientific evidence, Indian traditional medicines face difficulties in gaining acceptance in stringent regulatory markets such as Europe and the United States, if so, the details thereof;
(d) the steps being taken by the Government to strengthen scientific testing, standardisation and treatment protocols for AYUSH medicines; and
(e) whether the Government is formulating any time-bound action plan to develop research-based evidence to make AYUSH medicines globally acceptable and if so, the details thereof?

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

(a) to (e) For issue of license to manufacture for sale of the Ayurveda, Siddha, Sowa-Rigpa and Unani medicines, the conditions relating to safety study and experience or evidence of effectiveness has been provided under Rule 158B of Drugs Rules, 1945. As per Rule 168 of Drugs Rules 1945, manufacturer has to comply standards for manufacturing of Ayurveda, Siddha and Unani drugs. Further Rule 85 (A to I) of the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines, wherein for license to new homoeopathy medicines, the manufacturer shall produce such documentary and other evidence as may be required by licensing authority for accessing the therapeutic efficacy of the medicines including minimum proving carried out with it. Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides for quality standards of Homoeopathic drugs.

Clinical trials are carried out by adopting prevalent guidelines such as Good Clinical Practice Guidelines for ASU drugs (GCP-ASU), Ethical guidelines for Bio-Medical Research (ICMR), and WHO guidelines for traditional medicines, etc., as per requirement. Further an addendum to ICMR National Ethical Guidelines for Biomedical and Health Research

Involving Human Participants, 2017 for research in integrative medicine has also been published in year 2025.

Ministry of Ayush is implementing the Central Sector Scheme, namely Ayurgyan Scheme. The Scheme inter-alia has the components of (i) Research & Innovation in Ayush and ii) Ayurveda Biology Integrated Health Research. Under the Research & Innovation in Ayush and Ayurveda Biology Integrated Health Research components, financial assistance has been provided to the Organizations/Institutions for research studies including clinical research in Ayush systems of medicines. Number of Publications of the Research Activities conducted on Ayush formulations under the component of Research & Innovation in Ayush of Ayurgyan Scheme during the period from FY 2022-23 to 2025-26 are available at **Annexure I.**

Further, Government of India has established Central Council for Research in Ayurvedic Sciences, Central Council for Research in Unani Medicine, Central Council for Research in Homoeopathy, Central Council for Research in Siddha and Central Council for Research in Yoga & Naturopathy under the Ministry of Ayush as apex organizations for undertaking, coordinating, formulating, developing and promoting research in Ayush system on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and cultivation), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Research activities are carried out through its peripheral Institutes/Units located across the country and also in collaboration with various Universities, Hospitals and Institutes. The details of clinical evidence on Ayush formulations published by research councils under Ministry of Ayush, during the last three years are available at **Annexure II.**

The Central Council for Research in Ayurvedic Sciences has generated scientific evidence of clinical efficacy and safety of 182 classical Ayurveda formulations for 40 disease conditions through clinical trials. The research outcomes of studies have been published in indexed medical journals for wider dissemination. CCRAS is also conducting scientific validation of new combinations (coded drugs) through systematic process of drug development viz. drug standardization and quality control, preclinical safety/toxicity studies and biological activity studies (as appropriate) and clinical trials as per requirement. CCRAS has developed three guidelines for validation/research of the Ayush approach and drugs namely:

1. General guidelines for drug development of Ayurvedic formulations.
2. General guidelines for safety/toxicity evaluation of Ayurvedic formulations.
3. General guidelines of clinical evaluation of Ayurvedic interventions.

In addition, the Ayush Research Portal which is a repository of Evidence Based Research Data of Ayush Systems at Global Level has a data of 7243 Clinical trials conducted.

Standard Treatment Guidelines (STGs) for Ayurveda, Unani, Siddha, and Homeopathy with Yoga integration have been published for the following diseases:

A. Standard Treatment Guidelines on Management of Common Musculoskeletal Disorders, published in year 2024 includes STGs on Osteoarthritis, Rheumatoid arthritis, Cervical spondylosis, Lumbar spondylosis, Fibromyalgia, Adhesive capsulitis
B. Standard Treatment Guidelines on Management of Metabolic disorders, published in year 2025 includes STGs on Diabetes Mellitus, Dyslipidemia, Gout, Non-Alcoholic Fatty Liver Disease and Obesity.

Research outputs are published upon completion of studies and after the requisite processes of data analysis, peer review, and compliance with ethical and regulatory standards. Research projects conducted under various councils and National Institutes follow their respective study timelines. Findings from completed clinical studies are submitted to peer-reviewed journals in accordance with established scientific practice.

Further, Government of India has taken following steps to strengthen scientific testing, standardisation and treatment protocols for Ayush medicines: -

1. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), subordinate office under Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. As per Drugs and Cosmetics Act, 1940 and Drugs Rules 1945, compliance to these quality standards are mandatory for the manufacturing of ASU&H drugs. PCIM&H also acts as the Central Drugs Laboratory for Indian Medicine and Homoeopathy for the purpose of testing or analysis of ASU&H Drugs. Further, PCIM & H impart training to the Drug Regulatory Authorities, State Drug Analyst etc on laboratory techniques and methods used to maintain quality of ASU & H drugs.
2. The Drugs & Cosmetics Act, 1940 and Rules made there under have exclusive regulatory provisions for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha, Sowa-Rigpa and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs Rules, 1945. Further, Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic drugs.
3. Further, 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.
4. Drug Testing Laboratories has been recognized under Rule 160 A to J of the Drugs Rules, 1945 for carrying out such tests of identity, purity, quality and strength of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. 34 Drug Testing

Laboratories of State/UTs are testing quality of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs and raw materials for legal samples.

5. Drug Inspectors collect medicine samples regularly from manufacturing firms or sale 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 products from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder.

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Annexure I

Number of Publications of the Research Activities conducted on Ayush formulations under the component of Research & Innovation in Ayush of Ayurgyan Scheme during the period from FY 2022-23 to 2025-26 are as follows: -

S. No.	System	Number of Publications
1.	Ayurveda	12
2.	Siddha	08
3.	Unani	08
4.	Homoeopathy	06

Annexure II

The details of clinical evidence on Ayush formulations published by research councils under Ministry of Ayush, during the last three years are as follows-

S. No.	System	No. of clinical evidence published in last three years
1.	Ayurveda	72
2.	Siddha	27
3.	Unani	115
4.	Homoeopathy	156