

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH  
RAJYA SABHA**

**UNSTARRED QUESTION NO. 2733**

**TO BE ANSWERED ON 25<sup>th</sup> MARCH, 2025**

**“Sale of AYUSH medicines in the country”**

2733 Shri Derek O' Brien:

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

- (a) the number and details of AYUSH medicines approved for sale in the country in the last five years;
- (b) the number of AYUSH medicines approved for sale that were subjected to clinical trials before their approval;
- (c) whether clinical trials of AYUSH medicines are conducted as a matter of routine; and
- (d) if so, the details thereof and if not, the reasons therefor?

**ANSWER**

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

**(SHRI PRATAPRAO JADHAV)**

(a) and (b) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made there under, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy 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 Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy 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 Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

As per the information received from States/ UTs governments, details of the number of AYUSH medicines approved for sale in the country in the last five years are available at **Annexure-I** and the number of AYUSH medicines approved for sale that were subjected to clinical trials before their approval are available at **Annexure- II**.

(c) and (d) The term 'clinical trial' as such is not mentioned in the context of Ayurveda, Siddha and Unani drugs related provisions of Drugs Rules, 1945. However, experience or evidence of effectiveness of the ASU drug based on textual rationale, published literature and pilot study is required in support of the claim of indication or use for issue of license in accordance with the provisions of Rule 158 B of the Drugs Rules, 1945. Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides for quality standards of Homoeopathic drugs.

Government of India has established Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central Council for Research in Homeopathy (CCRH), Central Council for Research in Siddha (CCRS) and Central Council for Research in Yoga & Naturopathy (CCRYN) 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, 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 Central Council for Research in Ayurvedic Sciences (CCRAS) undertakes clinical studies adopting prevalent guidelines such as Good Clinical Practices Guidelines for ASU drugs (GCP-ASU), guidelines of Ministry of Ayush and Ethical guidelines for Bio-Medical Research (ICMR) as per requirement to generate evidence on clinical efficacy and safety of classical Ayurveda formulations and therapies in various disease conditions. The details of clinical trials conducted by CCRAS during last three years are available at **Annexure- III**. Clinical trials in homoeopathy are conducted as a matter of routine by Central Council for Research in Homoeopathy. The details of the clinical trials published by Central Council for Research in Homoeopathy during the last three years are available at **Annexure- IV**.

As per the information received from States/ UTs governments, the details of the number of AYUSH medicines approved for sale in the country in the last five years are as follows:-

S.no.	Name of the State/ UT	The number of AYUSH medicines approved for sale in the country in the last five years		
1.	Gujarat	11951		
2.	Odisha	S. No.	Year	No. of products
		1	2020	152
		2	2021	231
		3	2022	381
		4	2023	189
		5	2024	309
3.	Tamilnadu	S. No.	Year	No. of products
		1	2020	587
		2	2021	564
		3	2022	643
		4	2023	490
		5	2024	1232
4.	Puducherry	850		
5.	Kerala	1,847		
6.	Karnataka	6752		
7.	Delhi	32102		
8.	Arunachal Pradesh	110		
9.	Andaman Nicobar	NIL		
10.	Manipur	NIL		
11.	Tripura	NIL		
12.	Mizoram	NIL		

**Annexure-II.**

**As per the information received from States/ UTs governments, the number of AYUSH medicines approved for sale that were subjected to clinical trials before their approval are as follows:**

<b>S.no.</b>	<b>Name of the State/ UT</b>	<b>The number of AYUSH medicines approved for sale that were subjected to clinical trials before their approval</b>																		
1.	Gujarat	The registration for conducting Clinical trials on AYUSH medicines is done by the clinical trials Registry India (CTRI) under Indian Council of Medical Research (ICMR).																		
2.	Odisha	As per the clarification issued by Ministry of Ayush, the term 'clinical trial' as such is not mentioned in the context of Ayurveda, Siddha and Unani drugs related provisions of Drugs Rules, 1945. However, experience or evidence of effectiveness of the ASU drug based on textual rationale, published literature and pilot study is required in support of the claim of indication or use. The number of AYUSH proprietary medicines approved during last 5 years are as under- <table border="1" data-bbox="673 966 1412 1192"> <thead> <tr> <th>S. No.</th> <th>Year</th> <th>No.</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>2020</td> <td>35</td> </tr> <tr> <td>2</td> <td>2021</td> <td>61</td> </tr> <tr> <td>3</td> <td>2022</td> <td>47</td> </tr> <tr> <td>4</td> <td>2023</td> <td>68</td> </tr> <tr> <td>5</td> <td>2024</td> <td>55</td> </tr> </tbody> </table>	S. No.	Year	No.	1	2020	35	2	2021	61	3	2022	47	4	2023	68	5	2024	55
S. No.	Year	No.																		
1	2020	35																		
2	2021	61																		
3	2022	47																		
4	2023	68																		
5	2024	55																		
3.	Kerala	As per Rule 158B textual rational and pilot study reports as per relevant protocol for Ayurveda Siddha Unani Drugs are considering for the approval of Patent and Proprietary medicine, need of clinical trials are not mentioned in the act																		
4.	Delhi	All the products are approved as per the provision of Rule 158 B of the Drugs Rules, 1945.																		
5.	Puducherry	NIL																		
6.	Tamilnadu	NIL																		
7.	Arunachal Pradesh	NIL																		
8.	Karnataka	NIL																		
9.	Andaman Nicobar	NIL																		
10.	Manipur	NIL																		
11.	Tripura	NIL																		
12.	Mizoram	NIL																		

**ANNEXURE – III**

**The details of clinical trials conducted by CCRAS during last three years are as follows:-**

<b>S.No.</b>	<b>Name of the project</b>
<b>2021-22</b>	
1.	Clinical evaluation of Shadbindu Taila Nasya and Chitraka Haritaki in the management of Pinasa (Chronic Rhinosinusitis)
2.	Clinical evaluation of Pathyadi Kwatha and Anu Taila Nasya in the management of Ardhavabhedaka (Migraine).
3.	Clinical evaluation of the efficacy of Pushyanuga Churna and Usheerasava in the management of Abnormal Uterine Bleeding.
4.	Clinical evaluation of Jatiphaladya Churna & Chitrakadi Gutika in the management of Grahani
5.	Clinical evaluation of Panchatikta Ghrita and Gandhakadya Malahara in the management of Vicharchika (Eczema)
6.	Clinical Evaluation of Chitraka Haritaki and Lavangadi Vati in the management of Kaphaj Kasa (Stable Chronic Bronchitis)
7.	Clinical evaluation of Agashtya Haritaki Rasayana and Apamarga Kshara in the management of Mild Stable Bronchial Asthma (Tamaka Shwasa)
8.	Clinical efficacy of Kaishore Guggulu and Balaguduchyadi Taila in the management of Gout (Vatarakta)
9.	Clinical evaluation of the efficacy of Soubhaya Shunthi Paka and Dashmularishta in Sutika Paricharya (Post Natal Care)
10.	Clinical evaluation of Drakshavaleha in the management of Pandu (Iron Deficiency Anaemia)
11.	Clinical evaluation of Shatavari Guda and Ashokarishta in the management of Asrigdara (Abnormal Uterine Bleeding)
12.	A Prospective open labelled observational study to document the potential safety issues and prescription trends in Selected Rasausadhi's in CCRAS -OPD'S across India
13.	A Randomized Placebo Controlled Prospective Phase II Clinical Study of an Ayurvedic Coded Drug 'AYUSH-D' on Glycemic control in Pre-Diabetic Subjects
14.	A Randomized Placebo Controlled Phase II Clinical Study of an Ayurvedic Coded Drug 'AYUSH-D' in the management of Type 2 Diabetes Mellitus as add on Therapy to Metformin
15.	Multi-centric Collaborative Double Blind study on clinical evaluation of AYUSH-SL in chronic Filarial Lymphoedema in patients receiving mass drug administration
16.	Documentation of efficacy of select AYUSH Interventions Ayush-64 and Kabasura Kudineer in asymptomatic & mild to moderate COVID-19 patients in home isolation through a mobile app: A prospective multicenter Community based study
17.	Assessment of integration of ayush into the public health system for combating COVID-19
18.	Efficacy and Safety of AYUSH-64 as standalone or adjunct to standard care in COVID-19: A Systematic Review
<b>2022-23</b>	
19.	An open label clinical trial to evaluate clinical efficacy and safety of Ayush AGT in Dandruff (Darunaka)
20.	Clinical Evaluation of Varunadi Kwath Churna and Apamarga Kshara in the management of Mutrashmari (Urolithiasis)

21.	Clinical evaluation of Ayurvedic Formulations Puga Khanda and Ayush PVK Gel in the management of Swetapradara (Pathological Leucorrhoea)
22.	Clinical Evaluation of Nimbatiaktam and Lajjalu Keram Gel in the Management of Psoriasis.
23.	Clinical evaluation of Lavanbhaskara Churna in the management of Amajirna - a randomized parallel group study.
24.	Clinical evaluation of Panchatikta Ghrita and Nalpamaradi Taila in the management of Vicharchika (Eczema)
25.	Clinical evaluation of Jirakadyarishta in the management of Grahani.
26.	Clinical evaluation of Panchatikta Ghrita & Nalpamaradi Taila in the management of Psoriasis.
27.	Clinical evaluation of Mustakarishtha in the management of Grahani
28.	Clinical evaluation of Vajra Kshara in the management of Amajirna - a randomized parallel group study.
29.	An open label clinical Trial to evaluate clinical efficacy and safety of Ayush AGT for external wounds.
30.	Clinical evaluation of the Efficacy of Varunadi Kwatha and Chandraprabha Vati in the management of Mutrasmari (Urolithiasis)
31.	Clinical Evaluation of Lohasava and Amalaki Churna in the management of Pandu Roga (Iron Deficiency Anaemia)
32.	Randomized Double-Blind Trial for clinical evaluation of Ksharsutra prepared manually and by Automated machine in Fistula-in-Ano (Bhagandara)
33.	Clinical evaluation of Ayurvedic formulations Shatavari Gudam & Triphala Kashaya in Shwetapradara (Leucorrhoea)
34.	Feasibility of introducing Ayurveda intervention in Reproductive and Child Health (RCH) in PHCs of selected district (Gadchiroli) of Maharashtra (Effectiveness of Ayurvedic Intervention for Ante-Natal care (Garbhini Paricharya) at Primary Health Care level: A Multi Centre Operational Study)
35.	Randomized control study to evaluate the efficacy of Ayush CCT and Rajyoga Meditation versus conventional treatment on clinical recovery and post operative outcomes following elective adult cardiothoracic surgeries
36.	Validation and Reliability Testing of Ayurveda Diagnostic Methods
37.	Clinical evaluation of the efficacy of “Ayush- SS Granules” in exclusively breastfeeding mothers with Insufficient Lactation (Stanyalpata)-A Randomized double blind placebo control Trial”.
38.	A Randomized control trial to evaluate the efficacy of Ayurvedic interventions (Agastya Haritaki and Ashwagandha) and Yoga in long term effects of COVID -19.
39.	The impact of Chyawanprash on immunogenicity when administered after COVID-19 vaccination in health care personnel - An open-label, prospective randomized controlled study
<b>2023-24</b>	
40.	Evaluation of AYUSH-SR Tablet in occupational stress among Nurses – a randomized double blind placebo controlled clinical study.
41.	Clinical evaluation of Gokshuradi Guggulu and Nimbadi Churna in Vatarakta (Gout)
42.	Evaluation of efficacy and safety AYUSH M-3 in the management of Pre-Hypertension – A double blind randomized control clinical study
43.	Clinical evaluation of Vidanga churna and Vyoshadi Guggulu in the management of Medoroga (Obesity)
44.	Clinical evaluation of Khadirarishta, Kaishor guggulu and Gandhakadya Malahar in the management of Vicharchika (Eczema)

45.	Randomised placebo controlled double blind clinical trial on the efficacy of AYUSH MANAS in the management of Smriti Dourbalya (Cognitive deficit)
46.	Ayurveda Interventions for Cancer: Systematic Review, Meta-analysis; and Revival, Documentation, Validation and analysis of data from practitioners, institutes.
47.	A comparative clinical study of Ayush LND a coded Ayurvedic formulation in the management of Asrigdara (Abnormal Uterine Bleeding)
48.	A Randomized controlled trial to evaluate the efficacy of Marma therapy in Lumbar disc Herniation with Radiculopathy.
49.	Efficacy of Ayurveda nutritional supplements and Yoga protocol in the prevention and reduction of the severity of Acute Mountain Sickness: an open-label randomized controlled study
50.	A pilot study to assess the effect of intranasal oil instillation (Pratimarsha Nasya) on nasal barrier function among healthy individuals
51.	Prospective double blind randomized controlled clinical study on Ayurvedic intervention (Sarpagandha Mishran) vs. Amlodipine in the management of stage-I Primary Hypertension
52.	A study of Ashwagandha administration in participant vaccinated against COVID-19 on safety, immunogenicity and protection: A randomized, double blind placebo controlled multi-centric clinical trial.

The details of the clinical trials published by Central Council for Research in Homoeopathy during the last three years are as follows:-

S. No.	Title
<b>Year 2024-25</b>	
1	Exploring the potential of Homoeopathy: A detailed examination of Systematic Review and Meta- analysis procedure- weighing the Pros and Cons
2	Exploring the Current State of Evidence of Homeopathic Interventions for Substance Abuse: A Scoping Review and Evidence Mapping
3	Optimising the use of polar symptoms in Homoeopathy: Introduction to a pilot study of prognostic factor research in chronic cough
4	Epidemiology and impact of chronic disease multimorbidity in India: a systematic review and meta-analysis
5	Analysing Influences on Homoeopathic Subscriptions in Rural Communities: A Pilot Study
6	Utility of Kent's Repertory in the treatment of candidiasis: An open label, single arm, interventional clinical trial
7	Polycystic ovarian syndrome and homoeopathic management: A case series
8	Utility of individualised homoeopathic medicines in improving social interaction in childhood autism: A prospective, open-label, single arm study
9	A pragmatic, open-label study to evaluate the response of homoeopathic treatment in vitiligo.
10	Homoeopathy in bipolar affective disorder: A review of research evidence
11	Is millet beneficial for thyroid disease? A comprehensive review
12	Homoeopathy vs. conventional primary care in children during the first 24 months of life—a pragmatic randomised controlled trial
13	Effectiveness of Eupatorium Perfoliatum 30C in Preventing Dengue Fever- A Prospective, Community-Based, Open Label, Parallel Cohort Study
14	Homeopathy for Hypertension: A Comprehensive Scoping Review of the Current Evidence
15	EFFICACY OF FERRUM METALLICUM 30C IN RESTORING MENSTRUAL CYCLE IN POLYCYSTIC OVARIAN SYNDROME PATIENTS -A RANDOMISED ,PLACEBO-CONTROLLED,SINGLE-BLIND TRIAL
16	A Comparative randomised controlled trial of Homeopathy –vs- Allopathy in Acute Otitis Media and its recurrence in Children
17	A scoping review on epidemiology and pathogenesis of death due to primary amoebic meningoencephalitis
18	A Review on Hyperuricaemia - A Metabolic disease and its Homoeopathic management
19	Molecular insights into cell signalling pathways in kidney stone formation
20	Psychometric Validation of Patient Satisfaction Assessment Tool for Alternative Medicine Healthcare Facility in India



**Year 2023-24**

1	Corns of feet: Can homoeopathy be a better alternative? A narrative review
2	Homoeopathic approach in thyroid issues induced by Covid-19
3	A Multi-Centric Single-Blind Randomized Placebo-Controlled Trial to Evaluate the Efficacy of the Individualized Homeopathic Intervention in Breast Fibroadenoma
4	Psychological trauma and depression in recovered COVID-19 patients: a telecommunication based observational study
5	An analytical study to establish the role of Calendula Q as a topical wound dressing in partial-thickness burn wound
6	Monkeypox transmission: time to revisit the medical strategy of public health
7	Evaluation of Adjunctive Homoeopathy Treatment in COVID-19 Hospitalised Patients at the Gujarat State's Dedicated COVID-19 Hospitals and Covid-Care Clinics During the First Wave of COVID-19 Pandemic: A Multicentric, Single-Arm Retrospective Data Analysis Study
8	A Systematic Review of Homoeopathic Research on Gout and Hyperuricaemia: Road Ahead
9	A Scoping Review of the Literature on Homoeopathy in Child and Adolescent Psychiatry
10	To evaluate the effectiveness of Homoeopathic Mother tincture <i>Sarothamnus scoparius</i> (also known as <i>Cytisus scoparius</i> ) in managing essential hypertension
11	Effects of Individualized Homoeopathic Medicine in Haemorrhoid: a Single Blind, Simple Randomized, Placebo Control Study
12	Individualised homoeopathic medicine versus placebo in the pain management of knee and hip osteoarthritis: A double-blind, randomised controlled trial
13	ASSESSMENT OF HYPOGLYCEMIC EFFECT OF HOMOEOPATHIC DRUG INSULINUM IN THE PATIENTS SUFFERING FROM TYPE 2 DIABETES MELLITUS - A PROSPECTIVE NON-RANDOMIZED SINGLE BLIND CLINICAL TRIAL
14	Practice, Perception, Habits, Experience and Perception of Indian Homoeopathic Practitioners in treatment of Diabetes Mellitus : An online observational study
15	Physicochemical standardisation of the Homoeopathic drug, <i>Apis mellifica</i> : A preliminary attempt
16	Immunological Responses of <i>Arsenicum album</i> 30CH to Combat COVID-19: Protocol for a Double-Blind, Randomized, Placebo-Controlled Clinical Trial in the Pathanamthitta District of Kerala
17	Homoeopathic Pathogenetic Trial of <i>Catharanthus roseus</i> : A Multicentric, Double-Blind, Randomized, Placebo-Controlled Trial
18	Randomised controlled trial to compare efficacy of standard care alone and in combination with homoeopathic treatment of moderate/severe COVID-19 cases
19	A Scoping review on the utility of homoeopathy in the management of Schizophrenia
20	Impact of homoeopathy along with yoga as an integrated pilot project with the National

	Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke: A cross-sectional study
21	Homoeopathic management of essential hypertension: A narative review
22	Hypothyroidism - Unveiling the Facts Review Article
23	Use of Homoeopathic remedies derived from Animal kingdom in treating Hyperactive Behavior of ADHD children
24	Millets as nutri-cereals and its health benefits: an overview
25	A Narrative Review on Homoeopathy for Obsessive – Compulsive Disorder
26	Evaluation of the Effectiveness of Homoeopathic Mother Tincture Sarothamnus Scoparius in Managing Essential Hypertension
27	Anaemia Mukth Bharat and Role AYUSH systems to address the Increasing Prevalance of Anaemia- Over View
28	Safety of potentised dilutions of Rhus toxicodendron in Wistar albino rats
<b>Year 2022-23</b>	
1	Prevalence of thyroid disorders in an out-patient department setting: a retrospective study
2	Psychological Antecedent of Coronavirus Vaccination: An Observational Study in India
3	Outcome of Homoeopathic Intervention in Psychiatric Inpatients Treated in Rural Homoeopathic Hospital, Palghar, Maharashtra, India, 2014–2018: A Retrospective Analysis
4	A Cross-Sectional Online Survey of Knowledge, Attitudes and Practices about Tuberculosis among Homoeopathy Practitioners and Students in India
5	Disease Characteristics, Care-Seeking Behaviour, and Outcomes Associated With the Use of AYUSH-64 in COVID-19 Patients in Home Isolation in India: A Community-Based Cross-Sectional Analysis
6	Homeopathy as an adjuvant to standard care in moderate and severe cases of COVID-19 – A single-blind, randomized, placebo-controlled study
7	A Case of Nasal Papilloma -Cured by Individualised Medicine
8	Awareness, Perception and Acceptance of Coronavirus Vaccines by Healthcare Workers Approved for Restricted Emergency Use in India: A Web-Based Cross-Sectional Study
9	Role of Homoeopathy in Home Based Newborn Care (HBNC) practices in UP and India
10	Explore the Role of Homoeopathy in Maternal Health Care Practices in UP and India
11	Effectiveness of individualised homoeopathic medicines in treatment of contact dermatitis with the aid of Synthesis repertory- a prospective, non randomised, open label, observational study
12	An Observational Study to Evaluate Response of Homoeopathic Treatment In Psoriasis
13	Adjuvant Approach to Mitigate the Adverse Effects of Cancer Treatments Using Homeopathic Medicines
14	Homoeopathy in the management of chronic kidney disease – A narrative review
15	Comparative study of high-performance thin-layer chromatography and antioxidant potential of Hydrocotyle asiatica mother tincture used in homoeopathy
16	Quantitative Assessment of Antioxidant Potential of Selected Homeopathic Preparations

	in Clinical Practice
17	Kaleidoscopic use of world Health Organization's Study on global AGEing and adult health data set to explore multimorbidity and its outcomes in low and middle- income countries: An insider view
18	Camphora Augments Humoral Mediated Immunity and Decreases Delayed type Hypersensitivity in BALB/c Mice
19	Mental disorders and the homoeopathic healing approach
20	Homoeopathy in nutritional issues induced by Covid-19 crisis and beyond
21	Safety Evaluation of Arsenicum Album in Acute and Sub-Acute Toxicity Studies in Rats
22	Writing effective Introduction of Research Article: Why and How?
23	Unveiling the current landscape of clinical research in Homoeopathy-where do we stand
24	Homeopathic Medicines in the Management of Dermatophytosis (Tinea Infections): A Clinico-epidemiological Study with Pre–post Comparison Design
25	Rating scales in psychiatric disorders -why?
26	Homoeopathic Treatment of young females of age group between 6-18 years with Subclinical Hypothyroidism: A Prospective Observational Study
27	Prevalence of adjustment disorder during COVID-19 in North East India: An observational study
28	Occurrence of Ranunculus sceleratus L. (Ranunculaceae) from the Nilgiri District, Tamil Nadu, India,
29	A Randomised, double-blind and placebo-controlled and parallel-arm trial to assess the effect of homoeopathic medicines on chronic rhinosinusitis
30	Knowledge, Awareness, attitude and practice of Indian homoeopathic physicians about pharmacovigilance in homoeopathy: A web-based, cross-sectional study
31	A Randomised Placebo-Controlled Clinical Trial of Homeopathic Medicines on Osteoarthritis

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