



Generation of Evidence on Clinical Safety and Efficacy of Classical Ayurveda Formulations: A Short Appraisal of CCRAS Initiatives

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ABSTRACT

Ayurvedic medicines are serving the needs of ailing humanity for centuries, but there is a constant need to bring these medicines on a global platform and to give them proper scientific validity. Central council for research in ayurvedic sciences (CCRAS), Ministry of AYUSH, Government of India, since inception is dedicated in the validation of classical Ayurveda formulations through series of clinical studies, to consolidate the use of Ayurveda classical formulations, backed by proper scientific evidence. The Council has generated scientific evidence on clinical safety and efficacy of approximate 100 classical Ayurvedic formulations on 35 diseases/conditions of priority areas. The evidence on clinical efficacy and safety of Ayurvedic formulations which are vogue and available in the market are not only highly useful to practitioners and consumers for their rational use but also will strengthen integration of Ayurveda with other systems of medicine and will be helpful in convincing scientific community across the world which may also improve its market in the country and world at large.

Keywords: Classical ayurveda, Drug validation, Research and development

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INTRODUCTION

The CCRAS, an autonomous organization of Ministry of AYUSH, Government of India, is the apex body in India for the formulation, coordination, development, and promotion of research on scientific lines in Ayurveda and Sowa-Rigpa systems of medicine. The core research activities comprise of clinical research, medicinal plant research, drug standardization and quality assurance, pharmacological research, literary research and docu-

mentation, Public Health oriented research activities (Tribal Health Care Research Program, *Swasthya Rakshan* Program; Ayurveda Mobile Health Care Program and National Program for control diabetes, cancer, cardiovascular diseases, and stroke). The research activities of the council are carried out through its 30 institutes/centers/units located all over India (each institute is assigned with a particular mandate for research) and also through collaborative studies with various Universities, Hospitals, and Institutes.¹

CCRAS Initiatives Toward Validation of Classical Drugs

In present era, when the cost of health care is constantly rising, it is adversely affecting people's ability to afford health coverage. With increasing concerns regarding numerous side effects of the conventional system of medicine, the world is looking for a safer and better alternative. In such stance, Ayurveda is being looked upon as the most promising answer to the health care problems. It is a time tested safe and effective system of medicine being practices since ages, still having all the above beauties, but it's still lagging behind because of the lack of scientific evidence.

The council since inception is dedicated in the validation of classical Ayurveda formulations through a series of clinical studies to generate proper scientific evidence for clinical safety and efficacy of classical Ayurveda formulations.

In order to generate tangible evidence of classical Ayurveda formulations/therapies for their clinical safety and efficacy; the Council has identified classical Ayurveda formulations for identified disease conditions referring from Ayurvedic pharmacopeia/Ayurvedic formulary of India, essential drug list of ASU medicines (2013), Ministry of AYUSH and other Ayurveda classical texts. These formulations are being validated through Council's institutes engaged in clinical research in a phased manner. Some of the formulations are clinically validated for different disease conditions, and some are used in different combinations for the same or different disease conditions.

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CCRAS has undertaken clinical validation of Ayurvedic formulations/therapies in certain identified diseases/conditions of National importance, comprising of musculoskeletal and neuromuscular disorders viz. *Amavata* (rheumatoid arthritis), *Gridhrasi* (sciatica), *Pakshaghata* (hemiplegia) and osteoarthritis, osteoporosis; metabolic disorder viz. *Madhumeha* (diabetes mellitus), *Medoroga* (obesity and lipid disorder); neurological and psychiatric conditions viz. *Manodvega* (anxiety neurosis), *Apasamar* (epilepsy); ophthalmic refractive disorders viz. *Timira* (myopia); respiratory disorders viz. *Tamak Shwasa* (bronchial asthma); diseases of GIT system viz. *Grahani* (irritable bowel syndrome), *Kamala* (Jaundice), *Parinama Shula*

(duodenal ulcer), *Atisar* (diahorrea), *Arsh* (haemorrhoids), *Bhagandara* (Fistula-in-ano); refractory skin disease viz. *Kitibha* (Psoriasis) and infectious diseases viz. *Visam jwara* (Malaria), *Slipada* (Filariasis) and Life style disorders viz. hypertension etc.

The principal objective of these multicentre studies was to ascertain the clinical efficacy and safety of classical Ayurvedic formulations and therapies, observing the protocols and parameters with modest clinical and laboratory facilities available at CCRAS institutes engaged in clinical research. The Council has generated scientific evidence on safety and efficacy of approximate 100 clas-

Table 1: Prioritized area for clinical research: under validation of classical formulations

Status	Prioritized area
Completed	Osteoarthritis, rheumatoid arthritis, sciatica, gout, hemiplegia/paraplegia, osteoporosis/osteopenia bronchial asthma, chronic bronchitis Cognitive deficit, mental retardation, epilepsy, schizophrenia, generalized anxiety disorder dyslipidemia, obesity, Type 2 diabetes mellitus, essential hypertension, heart disease irritable bowel syndrome (ibs), duodenal ulcer, jaundice, diarrhoea Allergic conjunctivitis, dry eye syndrome/computer vision syndrome, refractory errors fistula-in-ano, hemorrhoids Menopausal syndrome, dysmenorrhea, polycystic ovary syndrome Iron deficiency anemia, rasayana for healthy ageing (geriatric health), psoriasis, urolithiasis malaria, filariasis
Ongoing	Psoriasis, urolithiasis, uterine fibroids, rheumatoid arthritis, hemorrhoids, osteoarthritis, gout, osteopenia/ osteoporosis, obesity, iron deficiency anaemia, menopausal syndrome, cervical spondylosis, cognitive deficit and chronic allergic conjunctivitis

Table 2: Details of formulations validated for different disease conditions

S. No.	Research on classical Ayurvedic medicine for generation of evidence of safety and efficacy	Disease /indication/ Use
1.	<i>Mahatriphaladya Ghrita</i>	Allergic conjunctivitis
2.	<i>Mahatriphaladya Ghrita</i>	Dry eye syndrome (<i>Shushkakshi Paka</i>)
3.	<i>Vyaghri Haritaki</i>	Bronchial asthma
4.	<i>Vyaghri Haritaki</i>	Chronic bronchitis
5.	<i>Brahmi Ghrita</i>	Cognitive deficit
6.	<i>Jyotishmati Taila</i>	
7.	<i>Vyoshadi Guggulu</i>	Obesity (Sthaulya)
8.	<i>Haritaki Churna</i>	
9.	<i>Vyoshadi Guggulu</i>	
10.	<i>Haritaki Churna</i>	Dyslipidemia
11.	<i>Saptavimshatika Guggulu</i>	
12.	<i>Haridra Churna</i>	Type II diabetes mellitus
13.	<i>Ashvagandhadyarishta</i>	
14.	<i>Jatamamsi Arka</i>	Essential hypertension
15.	<i>Sarpagandha Vati</i>	
16.	<i>Bilvadi Leha</i>	Irritable bowel syndrome (IBS)
17.	<i>Punarnavadi Mandura</i>	
18.	<i>Dadimadi Ghrita</i>	Iron deficiency anaemia
19.	<i>Ashokarishta</i>	
20.	<i>Ashvagandha Churna</i>	Menopausal syndrome
21.	<i>Pravala Pishti</i>	

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S. No.	Research on classical Ayurvedic medicine for generation of evidence of safety and efficacy	Disease /indication/ Use
22.	<i>Punarnava Guggulu</i>	
23.	<i>Dashmoola Ghrita</i>	Osteoarthritis
24.	<i>Kottamchukkadi Taila</i>	
25.	<i>Laksha Guggulu</i>	
26.	<i>Mukta Shukti Pishti</i>	Osteopenia/osteoporosis
27.	<i>Simhanaada Guggulu</i>	
28.	<i>Brihata Saindhavadya Taila</i>	Rheumatoid arthritis
29.	<i>Ashwagandhadi Lehya</i>	<i>Rasayana</i>
30.	<i>Rajahpravartani Vati</i>	<i>Kastartava</i> (dysmenorrhea)
31.	<i>Pinda Taila</i>	
32.	<i>Amrita Guggulu</i>	Hyperuricemia in gout patients (<i>Vatarakta</i>)
33.	<i>Vajraka ghrita</i>	
34.	<i>Arogyavardhini vati</i>	<i>Kitibha</i> (psoriasis)
35.	<i>Dineshvalyadi taila</i>	
36.	<i>Nisa Amalaki Churna tablet</i>	Type II diabetes mellitus (<i>Madhumeha</i>)
37.	<i>Chandraprabha vati</i>	
38.	<i>Yashada Bhasma</i>	<i>Kitibha</i> (psoriasis)
39.	<i>Triphala Churna</i>	
40.	<i>Pranada gutika</i>	<i>Arsha</i> (hemorrhoids)
41.	<i>Abhayarishta</i>	
42.	<i>Kanchanara Guggulu (tablet)</i>	
43.	<i>Rajahpravartini vati</i>	Polycystic ovarian syndrome (PCOS)
44.	<i>Varanadi Kashaya</i>	
45.	<i>Brahma Rasayana</i>	<i>Manas Mandata</i> (mental retardation)
46.	<i>Brahma Rasayana</i>	<i>Rasayana</i>
47.	<i>Vatari Guggulu</i>	Osteoarthritis knee
48.	<i>Narayana Taila</i>	
49.	<i>Maharasnadi Kashaya</i>	
50.	<i>Ksheerbala taila</i>	
51.	<i>Vatari Guggulu</i>	Rheumatoid arthritis
52.	<i>Brihat Saindhavadya Taila</i>	
53.	<i>Rasnasaptaka Kashaya</i>	
54.	<i>Nishakatakadi Kashaya</i>	Diabetes mellitus
55.	<i>Yashada Bhasma</i>	
56.	<i>Yogaraj Guggulu</i>	Osteoarthritis
57.	<i>Gandharvahasta Taila</i>	
58.	<i>Dhanvantara Taila</i>	
59.	<i>Vasavaleha</i>	Chronic bronchitis
60.	<i>Kutajarishta</i>	Irritable bowel syndrome
61.	<i>Sarasvata Ghrita</i>	Cognitive deficit
62.	<i>Vatari Guggulu</i>	Rheumatoid arthritis
63.	<i>Hingvashtaka Churna</i>	
64.	<i>Brihat Saindhavadya Taila</i>	
65.	<i>Ashwagandha Churna</i>	Osteoporosis/osteopenia
66.	<i>Pravala Pishti</i>	
67.	<i>Kanakasava</i>	Bronchial asthma
68.	<i>Trivrita Churna</i>	
69.	<i>Chyavanaprasha</i>	Rasayana
70.	<i>Kushmandaka Rasayana</i>	Chronic bronchitis
71.	<i>Navayasa Churna</i>	Iron deficiency anaemia
72.	<i>Brihat Gangadhar Churna</i>	Irritable bowel syndrome
73.	<i>Ksheerbala taila</i>	Generalized anxiety disorder (GAD)
74.	<i>Mandukaparni Churna tablet</i>	
75.	<i>Ashvagandha Churna tablet</i>	

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S. No.	Research on classical Ayurvedic medicine for generation of evidence of safety and efficacy	Disease /indication/ Use
76.	Mahatriphaladya Ghrita	Computer vision syndrome
77.	Anu Taila	
78.	Gokshuradi Guggulu	Diabetes mellitus
79.	Guduchi Churna	
80.	Rudraksha Churna	Hypertension
81.	Parthadyarishta (Arjunarishta)	Hypertension
82.	Sarpagandha Vati	
83.	Vyoshadi Guggulu	Amavata (Rheumatoid arthritis)
84.	Panchasama Churna	
85.	Panchtiktaguggulu Ghrita	Psoriasis
86.	Brihanmarichadya Taila	
87.	Kanchanara guggulu	Uterine fibroids
88.	Khadirarishta	

sical Ayurvedic formulations on 35 diseases/conditions of priority areas² (Tables 1 and 2).

Validation of approximate 35 classical Ayurvedic formulations is continuing for generation of scientific evidence on safety and efficacy on 14 diseases/conditions.

The research outcomes of these studies are being published in journals for wider dissemination which may be accessed through Ayurveda Research Portal.³ Due to lack of scientific validation of classical Ayurveda formulations, this precious science is trailing. Evidence-based research is highly needed for global recognition and acceptance of Ayurveda, hence the evidence generated by the Councils through a series of clinical studies will help in resolution of controversies in Ayurvedic drug and it will not only be beneficial to practitioners and consumers for their rational use but also strengthen integration of Ayurveda with other systems of medicine. It will also help in convincing the scientific community across the world which may also improve its market in the country and world at large.

CONCLUSION

Standardization and validation are the measures to ensure the quality and these include all measures from the manufacturing process and quality control and

proper clinical studies leading to a reproducible quality, safety and efficacy of the drug. Ayurvedic medicines are serving the needs of ailing humanity for centuries, but there is a constant need to bring these medicines on a global platform and to give them proper scientific validity. The Council is dedicatedly working toward this goal and has already validated more than 100 classical drugs in various disease condition of national importance. Further, the council has laid its research policy to meet the objective of quality research in Ayurveda.⁴

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