GOVERNMENT OF INDIA MINISTRY OF AYUSH

LOK SABHA UNSTARRED QUESTION NO. 1094 ANSWERED ON 08.12.2023

'Research Study on Medicinal Plants'

1094. SHRI CHANDRA SEKHAR BELLANA:

Will the Minister of AYUSH be pleased to state:

(a) whether the government has recently commissioned any research study on medicinal plants regarding their uses to treat modern diseases and if so, details thereof;

(b) whether the government is aware of the research study published in the World Journal of Diabetes stating that evidence based trials in natural products could lead to development of 'novel drugs in the modern management of Diabetes' with over 400 medicinal plants having the potential to combat Type-2 Diabetes;

(c) if so, whether the government has taken/ proposed to take any steps to generate more research on this in view of the increasing number of diabetic patients in India; and

(d) if so, the details thereof?

ANSWER THE MINISTER OF AYUSH (SHRI SARBANANDA SONOWAL)

Ans. (a): Yes, Sir. The Ministry of Ayush, through its various Research Councils, are actively involved in research on various aspects of medicinal plants, including their uses to treat modern diseases.

Central Council for Research in Ayurvedic Sciences (CCRAS), an autonomous institution under the Ministry of Ayush, has been actively engaged in comprehensive research

activities in Ayurveda, including clinical research. An objective of CCRAS is to generate a robust evidence base for the safety and efficacy of Ayurveda formulations and medicinal plants in addressing various diseases and conditions such as osteoarthritis, rheumatoid arthritis, stroke rehabilitation, infertility, osteoporosis, insomnia, bronchial asthma, parkinson's disease, dyslipidemia, psoriasis, hypothyroidism, COVID-19 etc. through robust research. This also includes exploring traditional knowledge and modern scientific methodologies to assess the therapeutic potential of medicinal plants. Details are placed in **Annexure-I.**

Central Council for Research in Homoeopathy (CCRH), through its National Institute of Homoeopathy (NIH), Kolkata has been engaged and conducted a fundamental research work on COVID-19 by using "*Cinchona officinalis*" (Homoeopathic preparation) in collaboration with National Institute of Pharmaceutical Education and Research (NIPER), Kolkata. *In silico* and *in vitro* evidence on the mother tincture of *Cinchona officinalis* has promising antiviral properties against SARS-COV-2 infection.

National Institute Siddha (NIS), has conducted various clinical studies with good clinical outcomes, viz. (i) *Manjitti kudineer*, Siddha herbal concoction in non-healing diabetic and non-diabetic foot ulcers and bedsores; (ii) NIS has initiated *Venthamarai churnam* randomized controlled clinical trial in collaboration with Directorate of Public Health, Govt. of Tamil Nadu; (iii) NIS has evaluated herbal concoctions *Kabasura Kudineer*, *Adathodai Kudineer* and *Nochi Kudineer* against mild, moderate and severe COVID-19 through randomized controlled clinical trials. Further, NIS has completed clinical trials in diabetes and prediabetes patients with *Aavaarai Kudineer* in a project made through grant support from the Tamil Nadu State Department of Science & Technology under the DST of Govt. of India and published papers.

Further, various organizations in the country, like the Council of Scientific & Industrial Research (CSIR), Indian Council of Medical Research (ICMR) and Department of Biotechnology (DBT), are also actively involved in research studies on medicinal plants regarding their uses to treat modern diseases.

CSIR constituent laboratory, CSIR-NEIST, has been working on one project entitled "Bio-evaluation and identification of lead molecules for Lung and Colon cancer from selected Medicinal Plants" for study on medicinal plant and their uses to treat modern diseases. Also, CSIR's constituent laboratory, CSIR-IIIM, is actively involved in antidiabetic drug discovery and development from natural as well as semi-synthetic sources. CSIR-IIIM has programs to develop natural product-driven drug candidates for disorders such as diabetes mellitus and obesity. Currently, the lab is investigating natural and semi-synthetic compounds from plants such as *Parthenium hysterophorus*, *Andrographis paniculata* and *Marrubium vulgare* for their anti-inflammatory and antidiabetic activities. The institute is also pursuing research and developmental work on *Bergenia ciliata* for treating rheumatoid arthritis and *Crocus sativus* for neurodegenerative disorders.

The Department of Biotechnology (DBT) has been providing funding support to conduct R&D in important medicinal and aromatic plants at various institutions/ universities/ other organizations in Pan-India on various aspects of medicinal plant research. The Department has also supported the establishment of antiviral screening facilities for novel molecules against COVID-19 and other viral diseases at the Institute of Life Sciences (ILS), Bhubaneswar and the Institute for Stem Cell Science and Regenerative Medicine (InSTEM), Bangalore.

Indian Council of Medical Research (ICMR) has commissioned several recent studies on medicinal plants for treating modern diseases, including projects such as:

- i. Developing a standardized formulation of *Trigonella foenum-graecum* seeds for preventing Type-2 diabetes.
- ii. Formulating treatments for sleep disorders using *Nardostachys jatamansi* and *Withania somnifera*.
- iii. Studying the antiarthritic potential of *Holoptelia integrifolia* and *Plumbago zeylanica* documenting genetic and phytochemical variations in *Gymnema sylvestre*.
- iv. Evaluating the efficiency of herbal anti-diarrheal agents.
- v. Assessing the anti-inflammatory and analgesic activities of *Plumbago zeylanica* in osteoarthritis.
- vi. Validating the diabetic wound healing activity of essential oil from *Mammea suriga* flower buds.
- vii. Evaluating the role of Gymnemagenin in regulating glucocorticoid action.
- viii. Identifying potential herbal drug candidates from traditional practices against viral hepatitis through preliminary in-silico screening.

In addition, the National Medicinal Plants Board (NMPB), Ministry of Ayush, under its Central Sector Scheme on 'Conservation, Development and Sustainable Management of Medicinal Plants' provides project-based financial support to carry out research activities on various aspects of medicinal plants to government as well as private universities/research institutions/organizations across the country. Details of the project supported in the last three years are in **Annexure-II**.

Further, to explore the possibility of cooperation, convergence and synergy and to bring biotechnological intervention into the AYUSH sector, the National Medicinal Plant Board (NMPB), Ministry of AYUSH and DBT signed an MoU on 31.12.2018. Under this, joint R&D projects were supported in a network mode to evaluate medicinal plants and preparations against the SARS-Cov-2 virus and COVID-19 infection. These projects were implemented at the following institutes:

- i. Regional Centre for Biotechnology (RCB), Faridabad
- ii. Institute of Bioresources & Sustainable Development (IBSD), Imphal
- iii. Jadavpur University, Kolkata
- iv. Translational Health Science and Technology Institute (THSTI), Faridabad

- v. Institute of Life Sciences (ILS), Bhubaneswar
- vi. Kalinga Institute of Industrial Technology (KIIT), Bhubaneswar
- vii. Regional Plant Research Centre (RPRC), Bhubaneswar.

(**b**, **c** & **d**). Yes, Sir. Various established Research Institutes / Centres / Units under different Research Councils of the Ministry of Ayush, Government of India, are already actively engaged in diabetes and associated complications. Details are appended in Annexure-III.

Apart from this, other various organizations in the country, like the Council of Scientific & Industrial Research (CSIR), constituent laboratory CSIR-Institute of Himalayan Bioresource Technology (CSIR-IHBT), conducting and supporting antidiabetic research to generate more data on tea catechins, Epigallocatechin gallate (EGCG), Phlorizin as well as its derivative Phloretin. Also, the CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM) is involved in developing natural product-driven drugs for disorders such as diabetes mellitus.

Indian Council of Medical Research (ICMR) has published one monograph on the potential of medicinal plants in diabetes management entitled "Perspectives of Indian Medicinal Plants in the Management of Diabetes Mellitus"—Indian Council of Medical Research, New Delhi. Further, ICMR has initiated a phase-I clinical study on the phytopharmaceutical product of *Trigonella foenum-graecum* seeds in the prevention/ treatment of type-2 diabetes in 2022, which will be completed by January 2024.

Recent research studies performed by CCRAS on medicinal plants regarding their uses in treating modern diseases.

I. Intra Mural Clinical Research (IMR) Projects

- 1. Clinical evaluation of *eladi churna* and *draksharishta* in the management of *kasa* (stable chronic bronchitis).
- 2. Clinical evaluation of the efficacy of *pushyanug churna* in the management of *sweta pradara* w.r.t. Bacterial vaginosis (leucorrhoea).
- 3. Clinical study on efficacy and safety of an ayurvedic formulation *kutajavleha* in the management of *grahani roga*.
- 4. Clinical evaluation of *svadamshtradi kashaya* and *hajarulayahuda bhasma* in the management of *mutrashmari* (urolithiasis).
- 5. Clinical evaluation of *drakshasava* in the management of *pandu* (iron deficiency anaemia).
- 6. Clinical evaluation of *shadbindu taila* nasya and *chitraka haritaki* in the management of *pinasa* (chronic rhinosinusitis).
- 7. Clinical evaluation of *pathyadi kwatha* and *anu taila nasya* in the management of *ardhavabhedaka* (migraine).
- 8. Clinical evaluation of the efficacy *of pushyanuga churna* and *usheerasava* in the management of abnormal uterine bleeding.
- 9. Clinical evaluation of *jatiphaladya churna* & *chitrakadi gutika* in the management of *grahani*.
- 10. Clinical evaluation of *panchatikta ghrita* and *gandhakadya malahara* in the management of *vicharchika* (eczema).
- 11. Clinical evaluation of *chitraka haritaki* and *lavangadi vati* in the management of *kaphaj kasa* (stable chronic bronchitis).
- 12. Clinical evaluation of *agashtya haritaki rasayana* and *apamarga kshara* in the management of mild stable bronchial asthma (*tamaka shwasa*).
- 13. Clinical efficacy of *kaishore guggulu* and *balaguduchyadi taila* in the management of gout (*vatarakta*).
- 14. Clinical evaluation of the efficacy of *soubhaya shunthi* paka and *dashmularishta* in *sutika paricharya* (post natal care).
- 15. Clinical evaluation of *drakshavaleha* in the management of *pandu* (iron deficiency anaemia).
- 16. Clinical evaluation of *shatavari guda* and *ashokarishta* in the management of *asrigdara* (abnormal uterine bleeding).
- 17. An open label clinical trial to evaluate clinical efficacy and safety of AYUSH AGT in dandruff (*darunaka*).
- 18. Clinical evaluation of *varunadi kwath churna* and *apamarga kshara* in the management of *mutrashmari* (urolithiasis).

- 19. Clinical evaluation of ayurvedic formulations *puga khanda* and AYUSH PVK gel in the management of *swetapradara* (pathological leucorrhoea).
- 20. Clinical evaluation of nimbatiktam and lajjalu keram gel in the management of psoriasis.
- 21. Clinical evaluation of *lavanbhaskara churna* in the management of *amajirna* a randomized parallel group study.
- 22. Clinical evaluation of *panchatikta ghrita* and nalpamaradi taila in the management of *vicharchika* (eczema).
- 23. Clinical evaluation of *jirakadyarishta* in the management of grahani.
- 24. Clinical evaluation of *panchatikta ghrita & nalpamaradi taila* in the management of psoriasis.
- 25. Clinical evaluation of mustakarishta in the management of grahani.
- 26. Clinical evaluation of *vajra kshara* in the management of *amajirna* a randomized parallel group study.
- 27. An open label clinical trial to evaluate clinical efficacy and safety of AYUSH AGT for external wounds.
- 28. Clinical evaluation of the efficacy of *varunadi kwatha* and *chandraprabha vati* in the management of *mutrasmari* (urolithiasis).
- 29. Clinical evaluation of *lohasava* and *amalaki churna* in the management of *pandu roga*) iron deficiency anaemia (.
- 30. Clinical evaluation of ayurvedic formulations *shatavari gudam* & *triphala kashaya* in *shwetapradara* (leucorrhoea).
- 31. Randomised placebo controlled double blind clinical trial on the efficacy of AYUSH MANAS in the management of *smriti daurbalya* (cognitive deficit).
- 32. Evaluation of AYUSH-SR tablet in occupational stress among it professionals –a randomized double blind placebo controlled clinical study.
- 33. Evaluation of AYUSH-SR tablet in occupational stress among nurses- a randomized double blind placebo controlled clinical study.
- 34. Evaluation of efficacy and safety AYUSH- M3 in the management of pre-hypertension- a double blind randomized control clinical study.
- 35. Effectiveness of the role of *astangalavana* and *srikhandasava* as add on treatment of *madatyaya* (alcohol dependence) –an open level clinical trial.
- 36. Clinical evaluation of gokshuradi guggulu and nimbadi churna in vatarakta (gout).
- 37. Clinical evaluation of *vidanga churna* and *vyoshadi guggulu* in the management of *medoroga* (obesity).
- 38. Clinical evaluation of *khadirarishta, kaishore guggulu* and *gandhakadya malahar* in the management of *vicharchika* (eczema).
- 39. Evaluation of efficacy and safety AYUSH- HR in the management of pre-hypertension- a double blind randomized control clinical study.
- 40. Clinical efficacy and safety of *arogyavardhani vati* and *pippalyasava* in the management of non-alcoholic fatty liver disease (NAFLD)- an open label prospective clinical trial.

- 41. A randomized, placebo controlled, double blind clinical trial to evaluate the effect of *trikatu* in subclinical hypothyroidism.
- 42. Clinical evaluation of *lekhaniya gana kashaya* and *arogyavardhini gutika* in the management of *medoroga* (obesity).
- 43. Clinical evaluation of *lashunadi vati* and *pippaladyasava* in the management of *agnimandya*.
- 44. Clinical evaluation of *triphala ghrita* as topical (*tarpana*) and internal medication in the management of dry age related macular degeneration symptoms.
- 45. Efficacy and safety of Ayurveda formulation '*trikatu*' in dyslipidemia a prospective randomized double blind placebo controlled trial.
- 46. Clinical assessment of the efficacy of ayurvedic management in PCOS a randomized open label control trial.
- 47. Clinical evaluation of *nimbadi churna, khadirarista* and *arjuna lepa* in the management of acne (*yuvan pidika*).
- 48. Clinical evaluation of *sanjivani vati* and *pippaladyasava* in the management of *agnimandya* a randomized parallel group study.
- 49. Topical oil pooling (*karnapurana*) with *kshirabala taila* and supple mentation of *ashwagandha churna* (topmac) in presbycusis an exploratory randomized controlled trial.
- 50. Evaluation of the efficacy and safety of *chandraprabha vati* with *gokshuradi guggulu* in the management of benign prostatic hyperplasia a randomized standard controlled clinical trial.
- 51. Clinical evaluation of ayurvedic regimen (*virechana karma* followed by oral administration of *kankayana vati, kanchanara guggulu* and *kumaryasava*) in the management of polycystic ovarian syndrome a randomized controlled open label clinical trial.

II. Collaborative Clinical research Projects

- 1. Evaluation of add on efficacy & safety of an ayurvedic coded formulation in the management of dengue fever & prevention of its complications a double blind clinical study.
- 2. A randomized placebo controlled prospective phase II clinical study of an ayurvedic coded drug 'AYUSH-D' on glycemic control in pre-diabetic subjects (collaborative).
- 3. 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 (collaborative).
- 4. Multi-centric collaborative double blind study on clinical evaluation of AYUSH-SL in chronic filarial lymphoedema in patients receiving mass drug administration.
- 5. 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).

- 6. 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.
- 7. A comparative clinical study of AYUSH-LND a coded ayurvedic formulation in the management of *asrigdara* (abnormal uterine bleeding).
- 8. Clinical evaluation of the efficacy of "Ayush SS granules" in exclusively breast feeding mothers with insufficient lactation (*stanyalpata*)-a randomized double blind placebo control trial.
- 9. Evaluation of hepatoprotective activity of PTK as an add on therapy in the patients of tuberculosis on ATT a double blind randomized controlled clinical study.
- 10. Study the physiological basis and gut bacterial modulations induced by *virechana* (purgation therapy) in healthy adults: a prospective longitudinal study.
- 11. Evaluating the efficacy of ayurvedic intervention as add on to conventional treatment and explore the interaction of epigenetics, neuro/gut biomarkers and neuroimaging in pediatric ADHD (attention deficit hyperactivity disorder).
- 12. Prospective double blind randomized controlled clinical study on ayurvedic intervention (*sarpgandha mishran*) vs amlodipine for the management of stage I primary hypertension.
- 13. A randomized controlled trial to evaluate the efficacy of *marma* therapy in lumbar disc herniation with radiculopathy.
- 14. Double blind randomized placebo controlled multicentric clinical trial of AYUSH M-3 in the management of migraine.
- 15. Evaluation of AYUSH-GMH in the subjects of mild to moderate non-alcoholic fatty liver disease (NAFLD)-a double blind randomized control clinical study.
- 16. A randomized controlled trial to evaluate the efficacy of multimodal Ayurveda interventions in *jaanu sandhigatavata* (primary knee osteoarthritis).
- 17. A pilot study to assess the effect of intranasal oil instillation (*pratimarsha nasya*) on nasal barrier function among healthy individuals.
- 18. A double blind, double dummy prospective randomized controlled study to evaluate the efficacy of classical Ayurveda management versus methotrexate in rheumatoid arthritis-(AMRA study).
- 19. Ayurveda therapeutic regiman as on add-on to optimized conventional management of parkinson's disease: an RCT for assessment of clinical cortical excitability neuroimmune and autonomic function parameters.
- 20. 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.

- 21. A randomized controlled study to assess the effect of *marsha nasya* karma in motor, sensory, memory and cognitive parameters elicited through F MRI in apparently healthy individuals.
- 22. Efficacy and safety of Ayurveda formulation *trikatu* as add on to standard care in dyslipidemia a randomized controlled trial.
- 23. Efficacy of Ayurveda regimen (mild purgation and internal oleation) in comparison with allopathic regimen (letrozole) along with yoga module in the management of unexplained and anovulatory female infertility: a RCT.
- 24. Clinical evaluation of ayurvedic management in allergic rhinitis- a randomized controlled trial.

III. COVID-19 related clinical research studies

- 1. Evaluation of the efficacy of an Ayurvedic intervention (chyawanprash) in the prevention of COVID-19 pandemic among Health Care Personnel An open label single arm prospective study.
- 2. Evaluation of Efficacy and Safety of Ayurveda Intervention (AYUSH -64) in the management of COVID-19 infection (Asymptomatic & Mild to Moderate symptoms) An open label single arm prospective clinical trial.
- 3. Evaluation of the efficacy of an Ayurvedic intervention (Chyawanprash) in the prevention of COVID-19 among Health Care Personnel An open label single arm prospective study.
- 4. A Pilot Study to assess the efficacy of AYUSH 64 in COVID 19 Cases.
- 5. Evaluation of Efficacy and Safety of Ayurveda Intervention (AYUSH 64) add-on-therapy for patients with Covid-19 infection (Stage-I) A Randomized controlled clinical trial.
- 6. A Randomized, Open Label, Parallel Efficacy, Active Control, Exploratory Clinical Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation (AYUSH 64) as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients.
- 7. A Prospective Randomized Controlled Clinical Trial to evaluate the Efficacy and Safety of Ayurveda Interventions (*Ashwagandha* Tablet and *Shunti* Capsule) in the management of COVID-19 infection (Mild to Moderate symptoms).
- 8. A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation (AYUSH 64) as adjunct Treatment to standard of care for the management of Mild to Moderate COVID-19 Patients.
- 9. A Study of *Ashwagandha* in the Prophylaxis Against COVID-19 and its benefits on General Health in High Risk Health Care Workers: A Randomized Controlled Comparison with Hydroxychloroquine Sulphate (HCQS).

- 10. A prospective non-randomized open label controlled interventional study on the effect of *Guduchi Ghan Vati/ Sudarshan Ghan Vati* as a prophylactic measure among high risk population (Health Care Workers/Containment Zone population) exposed to COVID-19.
- 11. A prospective non-randomized open labeled controlled interventional study on the effect of *Ashwagandha (Withania somnifera)* as a prophylactic measure among high risk population (Health Care Workers/ Containment Zone Population) exposed to COVID-19.
- 12. A prospective non-randomized open labeled controlled interventional study on the effect of *Chyavanprash Lehyam* as a prophylactic measure among high risk population (Health Care Workers/ Containment Zone Population) exposed to COVID-19.
- 13. Prospective non-randomized open labeled controlled interventional study on the effect of *Guduchi (Tinospora cordifolia)* as a prophylactic measure among high risk population (Health Care Workers/Containment Zone Population) exposed to COVID-19.
- 14. Prospective non randomized open label control interventional study on the effect of *Ayurvedic Raksha* Kit (*Chavanprash*, *Samsahmani vati & Haritaki*) as Prophylactic measure among police personal working in the vicinity of COVID -19 facilities.
- 15. Prospective non randomized open label control interventional study on the effect of *Ayurvedic Raksha* Kit-1 (AYUSH-64, *Samshamani vati & Chayvanprasha*) as Prophylactic measure among Ayush healthcare workers working in the vicinity of COVID -19 facilities
- 16. In-silico evaluation of compounds of an Ayurvedic drug, AYUSH-64, for their action against SARS-CoV-2 Main Protease.
- 17. Effect of an Ayurvedic formulation as add-on therapy to Standard of Care in COVID-19 positive patients in a tertiary hospital.
- 18. A Prospective Randomized Controlled Clinical Trial to evaluate the Efficacy and Safety of *Guduchi Ghan Vati* in the management of COVID-19 infection.
- 19. A prospective open label controlled interventional study on the effect of Ayurvedic intervention (*Ayurveda Raksha* Kit) as a prophylactic measure in the Pandemic of COVID-19 A community based study.
- 20. Impact of Ayurvedic Interventions in prevention of COVID-19 infection in containment areas of Delhi- A community based study.
- 21. Impact of Ayurvedic intervention (*Guduchighan Vati*) in prevention of COVID-19 infection in containment areas of Himachal Pradesh-A community based study.
- 22. 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.
- 23. A study of *Ashwagandha* administration in participants vaccinated against COVID-19 on safety, immunogenicity and protection: A randomized, double blind, placebo controlled, multi-centric clinical trial.

Annexure-II

Sr No	Project no	Project title and organization details	Sanctioned amount	Objectives
1	HP- 01/2021- 22	In vivo and in vitro study on synergistic effect of medicinal plants in breast cancer of mice. Central University of Himachal Pradesh Shahpur Campus, Kangra, Himachal Pradesh PIN: 176206	40.10229	 To study synergistic effect of Withania somnifera, Curcuma longa, Emblica officinale and Ocimum sanctum on histology, hormonal and biochemical parameters of mice having breast cancer. To study micronuclear assay and chromosomal study in breast cancer and Withania somnifera, Curcuma longa, Emblica officinale and Ocimum sanctum plant extract treated group of mice. To analyze the in vitro synergistic impact of Withania somnifera, Curcuma longa, Emblica officinale and Ocimum sanctum against breast cancer cells of mice. To establish effective synergistic dose of Withania somnifera, Curcuma longa, Emblica officinale and Ocimum sanctum against breast cancer of mice Plant species: Withania somnifera, Curcuma longa, Emblica officinale and Ocimum sanctum.
2	TN- 02/2022- 23	Decipheringtheresponse of FicusfruitpolysaccharidesonMajorHistocompatibility	38.05252	1. Collection and authentication of different <i>Ficus</i> fruit species and further processing by hot water extraction, alcohol precipitation, ultrasonic-assisted extraction, and

Details of the project supported on various aspects of medicinal plants, including their uses to treat modern diseases in the last three years, are as below:

Complex (MHC) in	enzyme-assisted extraction.
Inflammatory Bowel	
Disease (IBD).	2. Evaluation of nutritional, anti-
	nutritional and analysis of primary and secondary metabolites, including their
	<i>in vitro</i> - antioxidant and anti-
Department of Botany,	inflammatory potentials.
Bharathiar University,	initialititatory potentials.
Coimbatore, Tamil	3. Separation and purification of
Nadu.	polysaccharides cellulose anion-
	exchange column and characterization
	of its physical and chemical properties.
	4. Expression profiling of Ficus
	polysaccharides on IL 37b in intestinal
	epithelial cells to understand the
	pathophysiology of inflammatory
	bowel disease.
	5. Analyzing the effect of fruit
	polysaccharides on cytokine release
	from human neutrophils by ELISA
	technique.
	6. Polysaccharide- dependent
	modulation of NF-kB reporter activity
	will be assessed in the human colon
	adenocarcinoma cell line,
	Colo320DM.
	7. In vivo study of Ficus
	polysaccharides against inflammatory
	bowel disease on Wistar albino animal
	models.
	8. Effect of polysaccharides on gene
	expression and cytokine release,
	measured by RT-PCR and ELISA,
	respectively and further evaluation on
	colitis mice colon cultures.
	Diant graning Eigen Di
	Plant species- Ficus racemosa, Ficus auriculata, Ficus amplissima,
	Ficus microcarpa.

Annexure-III

Details of Research activities have been undertaken by the various Research organizations/institutes across the country in the management of diabetes mellitus

I. Central Council for Research in Ayurvedic Sciences (CCRAS)

A. Clinical studies for validation of Ayurveda classical medicines in the management of Type II diabetes mellitus

The Council has validated 08 Ayurveda classical medicines *viz. Saptavimshatika guggulu*, *Haridra churna*, *Nisha amalaki*, *Chandraprabha vati*, *Nisha katakadi kashaya*, *Yashada bhasma*, *Gokshuradi guggulu* and *Guduchi churna* apart of *Mamajjaka ghana vati* in the management of Type II diabetes mellitus to generate the tangible evidence on their clinical safety and efficacy. The research outcomes of these studies have been published in peer-reviewed journals as follows:

- a. Jain AK, Sharma SK, Sahu D, Kumawat VB, Sharma OR, Dua P *et al*. A multicenter clinical trial on the antidiabetic efficacy and safety profile of *Saptavimshatika guggulu* and *Haridra churna* in the management of type 2 diabetes mellitus. J Res Ayurvedic Sci 2021; 5:87-94.
- b. Mangal A, Jadhav AD, Ota S, *et al.* Evaluation of *Gokshuradi guggulu* and *Guduchi churna* in the Management of Type II diabetes mellitus (*Madhumeha*). J Res Ayurvedic Sci 2019; 3(2):48–54.
- c. Srinivas P, Subhose V, Deep VC, Sharma SK, Ota S, Prasad AJVS, Babu G, Radhakrishnan P, Sharma OR, Dua P, Rana R, Singhal R, Narayanam S. Clinical Evaluation of *Nisha katakadikashaya* and *Yashada bhasma* in the Management of Type-2 DM (*Madhumeha*)- A Multicentre, Open Label Prospective Study. J Res Ayurvedic Sci 2018; 2(2):108-121.
- d. Ota S, et.al. Clinical Safety of Selected Ayurvedic Formulations in Diabetes Mellitus– A Pharmaco-epidemiological Perspective. J Res Ayurvedic Sci 2018; 2(3):180-187.
- e. Shubhashree MN, Das B, Nanda GC, Swamy GK, Ota S, Doddamani S, Rao MM, Tewari V, Sharma BS, Khanduri S, Rana R, Singhal R, Kumar A, Srikanth N. Efficacy and safety of *Mamajjaka ghanavati* in the treatment of type 2 diabetes mellitus: A prospective open-label multicenter clinical study. Clin Trials Degener Dis 2019; 4:7-13

B. Research studies on coded Ayurveda formulations (developed through rigorous R & D by CCRAS) for Type II diabetes mellitus

i. AYUSH 82

The Council has developed a polyherbal Ayurveda formulation, Ayush 82, for managing Type II diabetes mellitus. The research outcomes are published in peer-reviewed journals. The same technology has been transferred to 11 Ayurveda manufacturing units through National Research Development Corporation (NRDC).

ii. AYUSH D

The Council has undertaken scientific validation of AYUSH-D, a polyherbal Ayurveda formulation, taking leads from LHTs through a systematic drug development process. The clinical trial of Ayush D in managing Type 2- diabetes mellitus as an add-on therapy to Metformin has been undertaken in collaboration with reputed institutes such as AIIMS, New Delhi, etc. The study has been completed, and the statistical analysis is being done.

- C. The list of clinical research projects on Type II Diabetes Mellitus carried out is as follows:
- 1. Clinical evaluation of *Saptavimshatika guggulu* and *Haridra churna* in the management of Type II diabetes mellitus
- 2. Clinical Evaluation of *Nisha amalaki kashaya* and *Chandraprabha vati* in the Management of Type II diabetes mellitus (*Madhumeha*)
- 3. Clinical Evaluation of *Nisha katakadi kashaya* and *Yashada bhasma* in the Management of Type II diabetes mellitus (*Madhumeha*)
- 4. Clinical evaluation of *Gokshuradi guggulu* and *Guduchi churna* in the management of *Madhumeha* (Type II diabetes mellitus)
- 5. Clinical Evaluation of the Efficacy and Safety of *Mamajjaka ghanavati* in *Madhumeha* (Type 2 diabetes)
- 6. 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

II. Central Council for Research in Homoeopathy (CCRH)

CCRH has implemented the Integration of Ayush (Homeopathy along with Yoga) in the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS): A pilot project at Krishna District (Andhra Pradesh), Darjeeling (West Bengal) covering 16 Community Health Centers/district hospitals/area hospital/block primary health care centre. The program has been undertaken in collaboration with the Ministry of Health and Family Welfare under the NPCDCS programme.

Apart from this, various research studies have been done on diabetic mellitus, the results of which have been published in various journals, the details of which are as follows:

- 1. Sampath S, Narasimhan A, Chinta R, Nair KR, Khurana A, Nayak D, et al. Effect of homoeopathic preparations of *Syzygium jambolanum* and *Cephalandra indica* on gastrocnemius muscle of high fat and high fructose-induced type-2 diabetic rats. Homeopathy. 2013 Jul;102 (3):160-71.
- 2. Pal A, Misra BB, Das SS, Gauri SS, Patra M, Dey S. Antidiabetic effect of *Cephalandra indica* Q in diabetic rats. Indian J Res Homoeopathy 2013;7(2):81-90.
- 3. Maiti S, Bera TK, Chatterjee K, Ghosh D. Study of the effect of mother tincture of Syzygiumjambolanum on metabolic disorders of Streptozotocin induced diabetic male albino rat. Indian J Res Homoeopathy 2014;8:129-35.
- 4. Rastogi DP., Saxena AC., Kumar S.Pancreatic beta-cell regeneration: a novel antidiabetic action of Cephalendra indica mother tincture.British Homoeopathic Journal 1988; 77(3): 147-151.
- 5. Nayak C, Oberai P, Varanasi R, Baig H, Ch R, Reddy GR, Devi P et al. A prospective multi-centric open clinical trial of homoeopathy in diabetic distal symmetric polyneuropathy. Homoeopathy 2013;102(2):130-8.
- 6. Tiwari ML. Diabetes mellitus defining the scope and clinical approach for homoeopathic management. Indian Journal of Research in Homœopathy 2008;2(3):28-36.
- 7. Nayak C, Singh V, Singh K, Singh H, Gupta J, Ali Mohd.S, et al. A prospective observational study to ascertain the role of homeopathic therapy in the management of diabetic foot ulcer. American Journal of Homeopathic Medicine 2011; 104(4):166-76.
- 8. Baig H, Singh K, Sharma A, Kaushik S, Mishra A, and Chug S. *Rhus aromaticus* in management of Diabetes mellitus. Clinical Research Studies-Series II. New Delhi: CCRH; 2009:21-7.
- 9. Baig H, Singh K, Sharma A, Oberai P, Kaushik S, Nayak D, et al. Role of *Cephalandra indica* Q in the management of diabetes mellitus as an add-on medicine along with conventional antidiabetics. Indian Journal of Research in Homeopathy 2008; 2(3):22-7.
- 10. Baig H, et al. Management and homoeopathic treatment of peripheral vascular disease in relation to diabetes mellitus. CCRH Quarterly Bulletin1995;17(3-4):10-6.