



EVIDENCE-BASED USE OF AYURVEDA IN GLOBAL HEALTH PROBLEMS



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Evidence base of Ayurveda

- ❑ Codified - Original dimensions of Ayurveda are inbuilt in the ancient compendia of Indian wisdom called Veda, documented around 6000 years back.
- ❑ Updation and addition - The knowledge expanded from time to time with systematization of classical texts like Charaka Samhita, Sushruta Samhita and Astanga Sangraha.
- ❑ Present form of Ayurveda - Several research studies have established the efficacy in indicated diseases as described in the text of Ayurveda.



Strength of Ayurveda

Chronic and life style disorders

- ❑ Rheumatoid Arthritis
- ❑ Complications of Diabetes
- ❑ Quality of life in Cancer patients
- ❑ Cardiovascular disorders/Hypertension
- ❑ Bronchial Asthma
- ❑ Obesity
- ❑ Other Non communicable diseases



Ayurveda in India

- ❑ Registered Practitioners: 3,87,976
- ❑ UG colleges: 261
- ❑ PG colleges : 76
- ❑ Universities: 2
- ❑ Annual admission capacity, UG: 10,472
- ❑ Annual admission capacity PG: 1709
- ❑ Hospitals: 2408
- ❑ Hospital bed capacity: 42,830
- ❑ Dispensaries: 15,927
- ❑ Drug manufacturing units: 7744



IPGT&RA Jamnagar, Gujarat



National Institute of Ayurveda,
Jaipur, Rajasthan



Organizational Setup

Central Level

- ❑ Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) under Ministry of Health & Family Welfare, Govt. of India
- ❑ Central Council of Indian Medicine
- ❑ Central Research Councils
- ❑ Universities/National Institutes/Colleges
- ❑ National Medicinal Plant Board
- ❑ Pharmacopoeial Commission of Indian Medicine
- ❑ Central Pharmacopoeia Laboratories
- ❑ Manufacturing Units
- ❑ Hospitals & dispensaries



AYUSH Research Councils





Organizational Setup

State level

- ❑ AYUSH Department or Ministry
- ❑ State Directorates
- ❑ State Boards/Councils for Registration of Practitioners
- ❑ State Licensing/Drug Control Authorities
- ❑ State Colleges/Institutions
- ❑ State Pharmacies
- ❑ State Drug Testing Laboratories
- ❑ State Medicinal Plant Boards
- ❑ Hospitals & Dispensaries



Banaras Hindu University, Varanasi



Rajiv Gandhi Govt. PG Ayurvedic College, Paprola



Important Policies/Guidelines

National

- ❑ Udupa Committee Report -1958
- ❑ The National Health Policy of 1983
- ❑ The National Population Policy 2000
- ❑ The National Policy on ISM&H 2002
- ❑ National Rural Health Mission- 2005
- ❑ Guidelines for GAP, GMP, GLP, GCP etc.



Global

- ❑ WHO Alma Ata 1978
- ❑ WHO documents and guidelines
- ❑ Commonwealth Health Ministers Conference 1998 and so on.....





Regulatory Structure

Cont...

Major Acts -

- ❑ Indian Medicine Central Council (IMCC) Act, 1970 for regulation of education standards & clinical practices.
- ❑ Drugs & Cosmetics Act, 1940 and Rules 1945 with a dedicated chapter for regulation of Ayurveda, Siddha and Unani drugs.
- ❑ Drugs & Magic Remedies (Objectionable Advertisements) Act 1954.



Regulatory Structure

Other Relevant Acts

- ❑ Indian Forests Act 1927 to conserve the medicinal plants species used in medicines.
- ❑ Wild Life Protection Act 1972.
- ❑ The Narcotic Drugs and Psychotropic Substances Act 1985.
- ❑ Bio-diversity Act 2002 to regulate the exploitation of certain plants and animal species used in medicines etc.
- ❑ Food Standard & Safety Act 2006 to regulate the safety and standards of food items etc.



Traditional Knowledge Digital Library

Cont...

- ❑ Collaborative project between Council of Scientific and Industrial Research and Department of AYUSH.
- ❑ Created to prevent the misappropriation of Traditional Knowledge at International Patent Offices so that the cases on bio piracy such as Turmeric and Neem could be prevented.





Traditional Knowledge Digital Library

- ❑ Traditional knowledge existing in local languages is converted into English, French, German, Spanish and Japanese in International Patent Classification format for the convenience of its use by the international patent examiners.
- ❑ European Patent Office (EPO), one of the International Search Authorities has signed the TKDL Access Agreement. EPO is a regional office with 34 member states such as UK, France, Germany, Italy, Poland, Norway, etc.
- ❑ Negotiations with USPTO for providing access to the TKDL database are continuing.



Global Scenario of Ayurveda

- ❑ Ayurveda can offer management of chronic and degenerative diseases. There is a resurgence of interest in Ayurveda among the consumers over the World.
- ❑ At policy level in countries like Myanmar, South Africa, Malaysia, Hungary, Sri Lanka Ayurveda is officially recognized. In many countries, there is no restriction to practice Ayurveda, though it is not officially recognized.
- ❑ However, this Indian system is also popular in many foreign countries including USA and Europe. People use Ayurvedic medicines, which are marketed as dietary/nutritional/herbal supplements.
- ❑ There are several educational institutions imparting Ayurveda courses/training

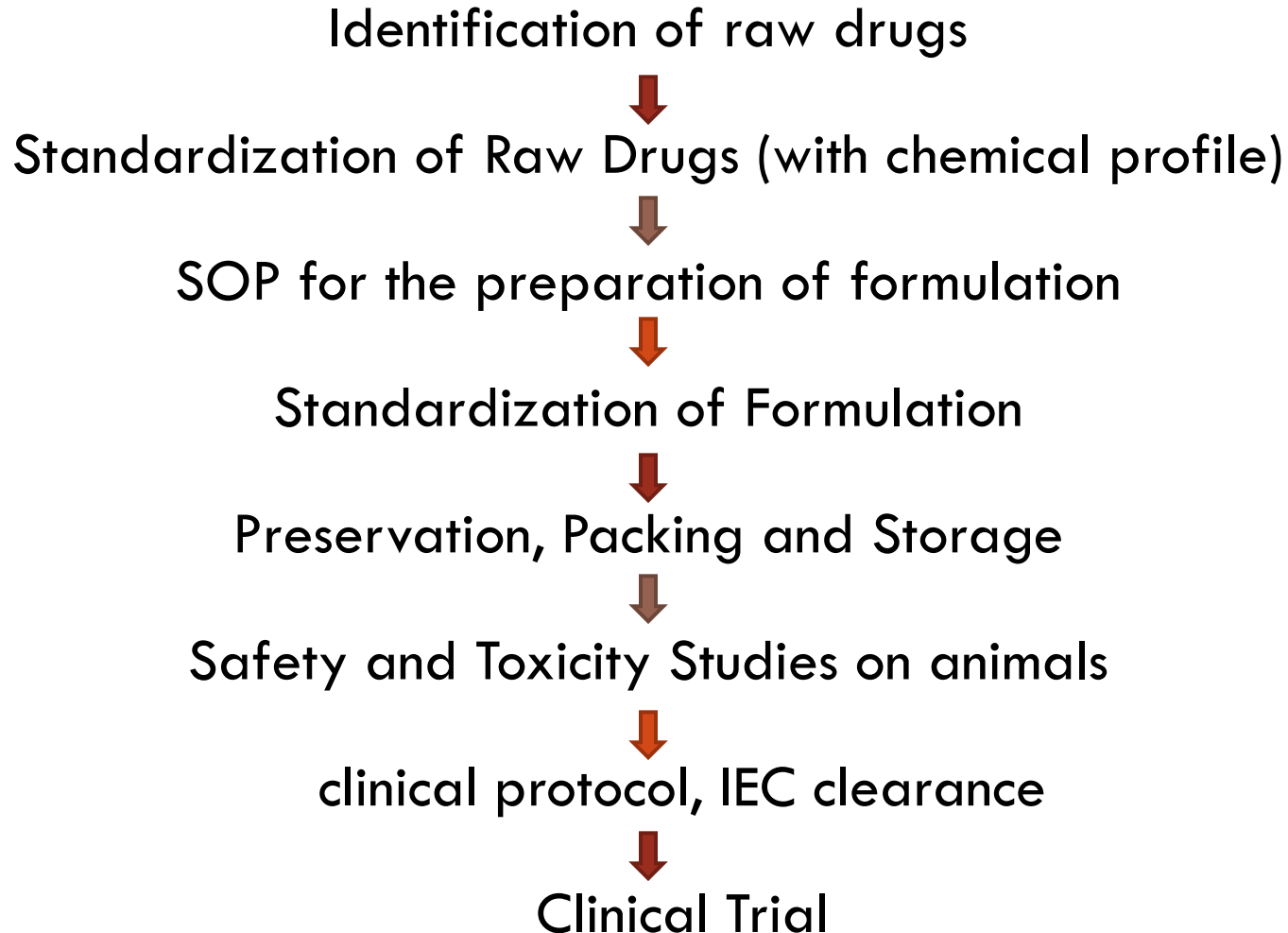


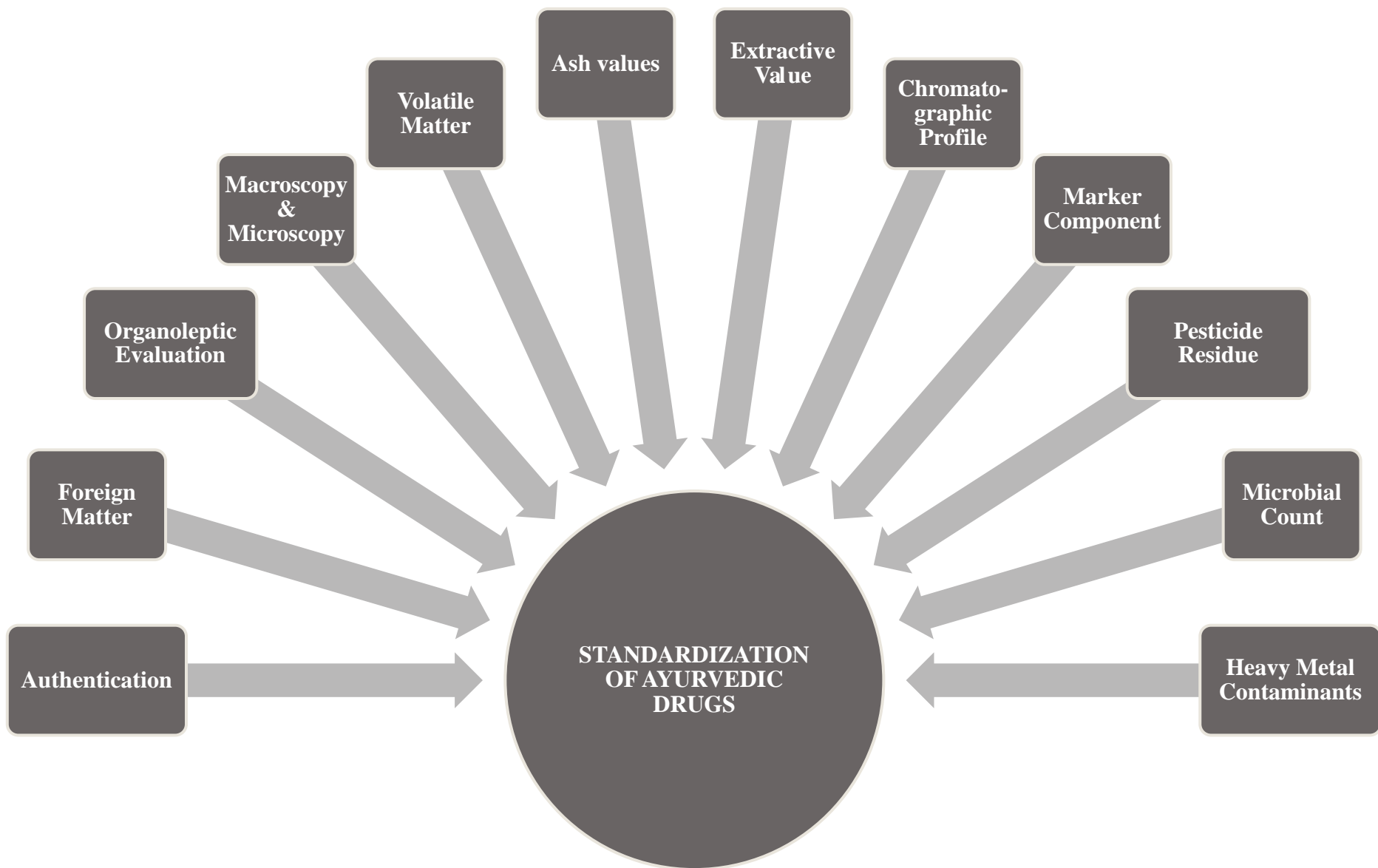
Central Council for Research in Ayurvedic Sciences (CCRAS)

- ❑ Apex body for research and development in the field of Ayurveda and Sowa-Rigpa under Dept. of AYUSH, Ministry of Health and Family Welfare, Government of India
- ❑ Nationwide network of 30 Institutes with varied focus areas namely:
 - ❑ Literature and Basic concepts
 - ❑ Survey & Cultivation of Medicinal plants
 - ❑ Drug research
 - ❑ Clinical Research
 - ❑ Tribal Health Care Research
 - ❑ Reproductive and Child Health Research



Phases of Drug Development





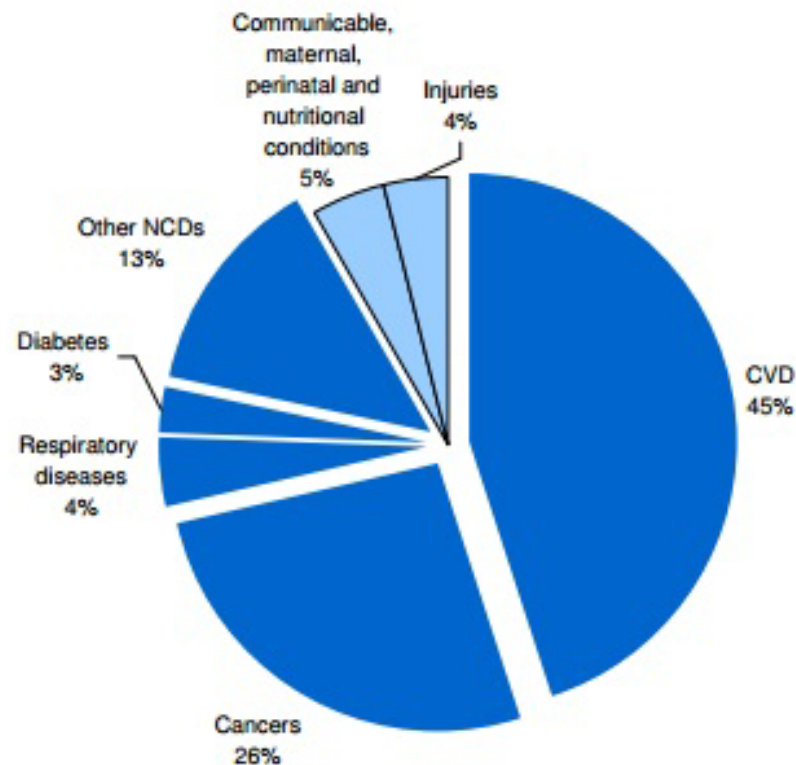


Other important issues in drug development

- ❑ Good Cultivation Practices- stress on organic farming
- ❑ Good Collection Practices- parts of the plants to be used, the time place and season of collection, conservation, sustainable use
- ❑ Good Manufacturing Practices - mandatory to all manufacturing units
- ❑ Animal experimentation as per Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and other guidelines.
- ❑ All clinical trials should comply with Good Clinical Practices Guidelines

Country Profile of Diseases/Death Germany

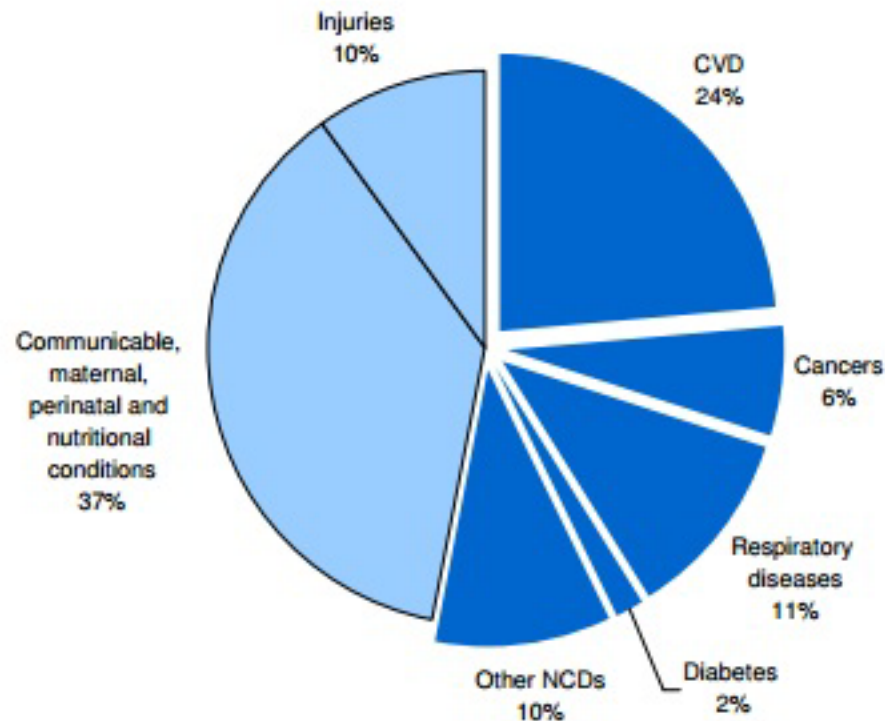
Proportional mortality (% of total deaths, all ages)



NCDs are estimated to account for 92% of all deaths.

Country Profile of Diseases/Death India

Proportional mortality (% of total deaths, all ages)



NCDs are estimated to account for 53% of all deaths.



Comparison of Mortality Rate

Disease	Germany	India
Cardio Vascular Diseases	45%	24%
Cancer	26%	06%
Respiratory Diseases	04%	11%
Other Non-Communicable Diseases	13%	10%
Communicable Diseases	05%	37%
Injury	04%	10%



Status of TM/CAM in Germany

- ❑ National policy was formed on TM/CAM in 1976.
- ❑ Herbal medicines are regulated as prescription medicine, OTC medicines and self-care purposes.
- ❑ Approximately 7700 traditional/herbal/homoeopathy medicines are registered in Germany.
- ❑ The Herbal Medicinal Products Directive (THMPD) was established to provide a regulatory approval process for herbal medicines in the European Union (EU).
- ❑ Since 30 October 2005, herbal medicines in the EU are controlled under the EU regulation, 2004/24/EC (THMPD).

Main Source: National Policy on Traditional Medicine and Regulation of Herbal Medicines - Report of a WHO Global Survey, 2005



THMPD

- The company needs to demonstrate the safety and efficacy of the herbal medicine through traditional use for at least 30 years out of which 15 years should be within the EU.
- From 1st May 2011 all unlicensed herbal products marketed in the EU now have to be either registered as traditional herbal medicinal product or get marketing authorization as regular medicinal product, or carry on as dietary supplements.



Steps taken by the Department of AYUSH

Cont...

- ❑ India exports various herbal ingredients to European Union.
- ❑ In the past Department of AYUSH has been persistently voicing its concerns on the THMPD against requirement of 15 years of documented usage in a European country and suggested to replace with 30 years safe usage criteria anywhere in the world with supportive bibliographic evidence.
- ❑ The 5th India-EU Summit held at The Hague on 8th November, 2004 resulted in Draft Joint Action Plan which included initiation of discussion on harmonization of registration procedures for Indian Pharmaceutical products in the EU.

Steps taken by the Department of AYUSH



- As a result of India's efforts market authorization of Ayurveda products was included as an Agenda Item in the India – EU Joint Working Group on Pharma & Bio-technology set up in 2006 under the aegis of India EU Strategic Partnership.
- An Indian team of officials and experts made a presentation on Ayurveda to the European Medicine Evaluation Agency (EMA) in London in May, 2006 on the Evidence Base of Ayurveda and quality control of Ayurveda medicines.



Steps taken by the Department of AYUSH

Cont...

- ❑ A three member EU Commission team visited India in January, 2007 and had discussions with experts from Deptt. of AYUSH, CSIR, ICMR and AYUSH drug industry and also visited R&D, health care and manufacturing facilities.
- ❑ On Jan. 19th 2011 a delegation from Dept. of AYUSH along with officials from Dept. of Commerce visited Brussels for negotiations with European Commission officials on 2004/24/EC directive.
- ❑ EC officials explained their stand on the Directive and agreed for further negotiations and inputs from India on Committee on Herbal Medicinal Products (HMPC) monographs.
- ❑ Relevant information for HMPC monographs are being uploaded on HMPC Secretariat website (<http://www.ema.europa.eu>) by CCRAS from time to time.



Evidence Based Research Profile

- ❑ Standard process is followed by in accordance with the guidelines for Ayurvedic drug development in India.
- ❑ Revalidation of classical medicines/ procedures are the subject of research
- ❑ Development of new combinations are also undertaken.
- ❑ Majority of clinical studies are conducted mostly on formulations and not on single plants.
- ❑ Some examples are.....



Evidence Based Research Profile

Cont...

Amalaki (*Emblica officinalis*)

Classical Reference: Charaka Samhita and others

Standards: Ayurvedic Pharmacopoea of India (API)

Pharmacology: Antioxidant activity

References:

Adaptogenic properties of Six Rasayana herbs used in Ayurvedic Medicine, Phytotherapy Research, Vol. 13, 275-291, 1999.

Antioxidant activity of active tannoids principles of *Emblica officinalis* (Amla), I.J.Expul. Biology, vol. 37(7), P.676-680.

Clinical: Rasayana and antidiabetic activity

References:

Clinical evaluation of Rasayana Prabhava of Amalaki Rasayana, Journal of Research in Ayurveda and Siddha, Vol. XXIII, issue 3-4, 22-38, 2002.

Increase in *Drosophila melanogaster* longevity due to rasayana diet: Preliminary results, Journal of Ayurveda and Integrative Medicine 04/2010; 1(2):114-9.

Ayurvedic Amalaki Rasayana and Rasa-Sindoor suppress neurodegeneration in fly models of Huntington's and Alzheimer's diseases, Current Science, Vol. 105, No. 12, 25 December 2013





Evidence Based Research Profile

Cont...

Aswagandha (*Withania somnifera*)

Classical Reference: Charaka Samhita and others

Standards: Ayurvedic Pharmacopoea of India

Chemical Constituents: Withaferin A, Withanolides, Withaferins, Sitoinsides

Pharmacology: Immunomodulatory, Adaptogenic

Reference:

Curr. Med. Pract. 23(1) 50,1981.

Intl. Journal of Crude Drugs Research, 29: 29, 1982

Intl. Journal of Crude Drugs Research, 24: 90, 1986.

Clinical: Anxiolytic action

Reference:

Studies on the psychotropic effect of an indigenous Rasayana drug Ashwagandha, Part-1, clinical studies, Journal of Research in Indian Medicine, Yoga and Homoeopathy, Vol.13, (1), 14-24, 1978.





Evidence Based Research Profile

Cont...

Tulasi (*Ocimum Sanctum*)

Classical Reference: Veda/Ayurveda

Standards: Ayurvedic Pharmacopoea of India

Chemical Constituents: Eugenol, B-caryophyllene, Bornyl-acetate etc.

Pharmacology: Found to protect guinea pigs against histamine and *Acacia arabica* induced asthma. Reported to be safe.



Reference: Evolution of Immunomodulatory potential of *Ocimum sanctum* seed oil and its possible mechanism of action, *Journal of Ethnopharmacology* Vol.80, 15-20, 2002

Radioprotective, anticarcinogenic and antioxidant properties of the Indian holy basil, *Ocimum sanctum* (Tulasi). *Ind. J. of Experimental Biol.* V. 39, p.185-190, 2001

Clinical: Anti-stress effect

Reference: Study of ageing and the anti-stress effect of Tulasi in the aged, *JRAS*, Vol. XXII, No.3-4, 135-147, 2000



Evidence Based Research Profile

Cont...

Guggulu (*Commiphora mukul*)

Classical Reference: Charaka Samhita, Sushruta Samhita

Standards: Ayurvedic Pharmacopoea of India

Chemical Constituents: Guggulusterone-E, Guggulusterone-Z, Guggulusterone-I-VI, Cholesterol, Sesamin, Camphorene, Cambrane A etc.



Pharmacology: Significant anti-inflammatory, anti-stress, safe in prescribed dose

Reference: Gujral, M.L. et al., 1960: Anti-arthritic and anti-inflammatory activity of Gum Guggulu (*Balsamodendron mukul* Hook). Indian J. Physiol. Pharmacol. 4, 267. Arora, R.B. et al, 1971: Isolation of crystalline steroidal compound from *Commiphora mukul* and its anti-inflammatory activity. Indian J.

Clinical: Anti-obesity, hypocholesterol effect

Reference: Ayurvedic treatment of obesity: a randomized, double blind, placebo controlled clinical trial, Journal of Ethnopharmacology, Vol.29,1-11,1990.



Evidence Based Research Profile

Cont...

Eranda (*Ricinus communis*)

Classical Reference: Charaka Samhita

Standards: Ayurvedic Pharmacopoeia of India

Chemical Constituents: Ricinine, albumin, ricin, 1-methyl-3 cyano-4-methoxy-2-pyridine, β sitosterol, octacosanol, ricinine, gallic acid

Pharmacology: Anti-inflammatory property,

Reference: Annual Report, P.R.U., Calcutta.

Further studies on the Anti inflammatory activities of *Ricinus communis* in albino rats, Indian Journal of Pharmacology, Vol. 23,149-152, 1991.

Clinical: Rheumatoid Arthritis

Reference: Role of virechana karma in Amavata by Gandharwahastadi Kwatha, JRAS, Vol.19, 3-4, 132-138, 1998.





Evidence Based Research Profile

Cont...

Guduchi (*Tinospora cordifolia*)

Classical Reference: Charaka Samhita

Standards: Ayurvedic Pharmacopoeia of India

Chemical Constituents: Tinosporine, Tinosporon, Tinosporic acid, Tinosporide



Pharmacology: Inhibit lipid peroxidation. Free radical scavenging and metal chelation capabilities must be acting in a competitive and comprehensive mode to ameliorate the radiation induced oxidative stress.

Reference: Free radical scavenging and metal chelation by *Tinospora cordifolia*, a possible role in radioprotection. Ind.J. of Experimental Biol. V.40. P. 727-734, 2002.
Adaptogenic properties of Six Rasayana herbs used in Ayurvedic Medicine, Phytotherapy Research, Vol. 13,275-291,1999

Clinical: Antidiabetic activity

Reference: Clinical evaluation of the effect of Amrita Pippali, Nimba yoga in Diabetes Mellitus with special reference to the role of Agni and Ojus, JRAS, Vol.XXII, No. 3-4,183-197, 2001



Evidence Based Research Profile

Cont...

Haridra (*Curcuma longa*)

Classical Reference: Charaka Samhita

Standards: Ayurvedic Pharmacopoeia of India

Chemical Constituents: Curcumin, ar-tumerone, methyle curcumin etc.



Pharmacology: Significant anti-inflammatory activity in comparison with hydrocortisone acetate and phenylbutazone.

Reference: Chemical, Pharmacological and Toxicological studies of *Curcuma longa* (Turmeric). II Indo Soviet sym. Chem.. Nat. Products including Pharmacol, p. 133, 1970.

Clinical: Nishamalaki is antidiabetic

Reference: Database on medicinal plants used in Ayurveda, CCRAS, Vol. 1, 154, 2000



Evidence Based Research Profile

Cont...

Pippali (*Piper longum*)

Classical Reference: Charaka Samhita

Standards: Ayurvedic Pharmacopoeia of India

Pharmacology: Hepato-protective, gastric ulcer healing activity, bioavailability enhancer. Reported safe.

Reference:

Hepatoprotective activity of the fruits of *Piper longum* Linn. India Journal of Pharmaceutical sciences, Vol.65 (4): p. 363-366, 2003.

Effect of *Piper longum* Linn., *Zingiber officinale* Linn. and *Ferula* species on gastric ulceration and secretion in rats, Indian Journal of Experimental biology, Vol 38, No 10, 994-998, 2000.

Scientific evidence on the role of Ayurvedic herbals on bioavailability of drugs, Journal of Ethnopharmacology, Vol.4, 229-232, 1981.





Evidence Based Research Profile

Cont...

Arjuna (*Terminalia arjuna*)

Classical Reference: Charaka Samhita

Standards: Ayurvedic Pharmacopoeia of India

Chemical Constituents: Arjunolic acid, masilinic acid, arjunic acid, arjuetic acid, arjuolitin, arjuolone, tomentosic acid, maslinic acid.

Pharmacology: Dose-dependent decrease in blood pressure and heart rate and inhibits carotid occlusion response without affecting the pressure responses. It has also been demonstrated that the hypotensive and bradycardic effects are mainly of central origin.

Reference: Indian Drugs 1992; 29: 144.

Mechanism of Cardiovascular action of *Terminalia arjuna*; Planta medica, Vol.45,102-104,1998

Clinical: Useful in Chronic Stable Angina

Reference: Effect of chronic treatment with bark of *Terminalia arjuna*: a study on the isolated ischemic-reperfused rat heart, Journal of Ethnopharmacology , Vol.75, 197-201,2001.





Evidence Based Research Profile

Cont...

Anti anxiety effect of an Ayurvedic compound drug – A cross over trial

Double blind study with a sequential crossover design comparing the efficacy of Ayurvedic preparation with modern control.

Ayurvedic preparation Vs. Diazepam and Placebo

Ayurvedic formulation of Mandukaparni (*Centela asiatica*), Yasti (*Glycyrrhiza glabra*), Jatamansi (*Nardostachys Jatamansi*) in the ration of 1:1:2 suspended in Ksirabala taila.

Results: Psychological parameters show that Ayurvedic drug is more effective in enhancing the perceptual discrimination and Psychomotor performance than the other two control drugs.

Source: Select research papers on evidence based drugs in Ayurveda, CCRAS, New Delhi





Evidence Based Research Profile

Cont...

Effects of a Composite Indian Herbal Preparation (CIHP) on combat effectiveness in low-intensity conflict operations.

Drug & Dosage: CIHP Vs Placebo

CIHP is a combination of following extracts

1. *Asparagus racemosus* : Root
2. *Withania somnifera*: Root
3. *Pueraria tuberosa*: Tubers
4. *Mucuna pruriens*: Seeds
5. *Dioscorea bulbifera*: Rhizomes
6. *Argyria speciosa*: Whole plant
7. *Piper longum*: Fruit
8. Sphatik



Results: Assessment through various tests indicated that CIHP helps to cope with combat stress and sustain mental performance in adverse environment.



Evidence Based Research Profile

Cont...

Role of the Ayurvedic Drug Brahmi (*Bacopa monnieri*) in the management of Senile Dementia

Brahmi Vs Placebo Brahmi in the form of powdered organic extract in doses of 1 gm. twice a day.

Duration : 5 years

Results: The drug not only arrests further memory loss but slows the process of subsequent acetylcholine reduction in person suffering from senile dementia.

Reference: Pharmacopschoecologia (1990), 3, 47-52.





Evidence Based Research Profile

Cont...

Double blind Randomized controlled trial of Sallaki Vs Diclofenac in treatment of Rheumatoid arthritis.

Sallaki (*Boswellia serratta*) Vs Diclofenac sodium

Sallaki, 600 mg 3 times in a day.

Diclofenac sodium, 50 mg 3 times in a day.

Duration: 4 weeks

Results: Efficacy of Sallaki was comparable to that of Diclofenac in relieving the symptoms of RA. Sallaki is even better tolerated than Diclofenac sodium who have demonstrable predisposition for gastric intolerance with anti-inflammatory medication.



Source: Select Research Papers on Evidence based drugs in Ayurveda, CCRAS, New Delhi



Evidence Based Research Profile

Cont...

Comparative clinical study on Musta, Aswagandha and Pancha karma therapy in Amavata- Rheumatoid Arthritis

Study was conducted on 120 patients in 3 groups

Gr.1-Musta churna 3 gm with Valuka sweda, 90 days

Gr.2-Aswagandha churna 3 gm TID with Valuka sweda, 90 days

Gr.3-Pancha karma therapy with murchita taila Shaddharana churna (7 days) along with Valuka sweda)

Results: Though significant result was obtained in all the 3 groups, Panchakarma group was better in comparison with other 2 groups.

Reference: Select research papers on Rheumatoid Arthritis, 2009, CCRAS Publication, Page-166-173





Evidence Based Research Profile

Shirodhara - For Neurological and Psychological problems

A psycho-physiological profile in healthy volunteers, Journal of Ayurveda and integrative medicine 01/2013; 4(1):40-4.





AYUSH Research Portal

Department of AYUSH/CCRAS have maintained an open access web portal (www.ayushportal.ap.nic.in) containing around 17,790 abstract/full research papers of AYUSH Systems of medicine till now.

In this portal, information on researches related to Ayurveda, Unani, Siddha, Homoeopathy, Yoga & Naturopathy, conducted in India and other countries are being updated from time to time.

AYUSH RESEARCH PORTAL
Evidence Based Research Data of AYUSH Systems at Global Level
Department of AYUSH, Ministry of Health & Family Welfare, Government of India

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Future of Ayurveda in Europe

Cont...

- ❑ Ayurveda is an ancient Indian codified holistic system of medicine.
- ❑ It is evidence based and being further validated by using modern scientific parameters from time to time.
- ❑ Ayurveda can play an important role in improving healthcare scenario globally.
- ❑ There is consumer awareness and demand but some regulations are very stringent.
- ❑ To bridge the gap between the consumers and the Government, feasible and realistic policy interventions are essential keeping in view the benefit of the consumer.
- ❑ The provisions for relaxation of norms may be considered for already validated and proven products.



Thanks!

