

EVIDENCE BASED AYURVEDA



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CODIFIED SYSTEM OF HEALTH CARE



- **Ayurveda**- the science of life is a comprehensive system of health care of great antiquity, based on experiential knowledge and grown with perpetual additions
- **Original dimensions of Ayurveda** are inbuilt in the ancient compendia of Indian wisdom called **Vedas**, which are believed to be documented around 6000 years back. *Rigveda* and *Atharvaveda* are replete with information on health and maladies and their management with natural modes and modalities.
- **The knowledge expanded further** with laying down of fundamentals and concepts of Ayurveda and systematization in classical texts like *Charak Samhita*, *Sushruta Samhita* and *Astang Sangrah*.
- **Present form of Ayurveda** is the outcome of continued scientific inputs that has gone in to the evolution of its principles, theories and guidelines of healthy living and disease management.

EVALUATION OF PHARMACOPOEIA OF INDIGENOUS DRUGS

Period	Approx. no. of plants used	Remarks on changes	Literature
3000 BC to 1000 BC	289	Building a Pharmacopoea. (Atharvaveda)	Vedic texts
1500 BC to 500 AD	650	1. Incorporation of new drugs 2. Discharging old drugs	- Charaka - Sushruta -Ashtanga Samgraha - Astanga Hridaya
500 AD to 1900 AD	Approx 2000	I)Incorporation of new drugs I)Discharging old drugs II)Varieties identified III)Substitutes identified IV)Expansion in applications	16 major Nighantus (like Dhanvantari Bhavprakasha, Raja upto Shaligram)

- India is having the world's richest flora, comprising of about 120 families of plants, comprising 1.30,000 species.
- Ayurvedic texts cover about 2400 species of plants with their medicinal uses as described by ancient Indian medical scholars.
- 10,000 herbs are used worldwide for medicinal purposes regularly.

REVERENCE AND STRENGTH



- Considering health of an individual as **dynamic integration** of environment, body, mind and spirit, *Ayurveda* lays great emphasis on preservation and promotion of health and preventing the occurrence of disease.
- Besides, it advocates employing **holistic approach** to understand all aspects of human life including diagnosis and management of diseases.
- *Ayurveda* attributes **primary importance** to preventive medicine and the maintenance of positive health.

- **The major preventive approaches** for maintaining and improving the quality of life include individualized specific daily regimen (*Dinacharya*), seasonal regimen (*Ritucharya*), behavioral and ethical considerations (*Sadvritta*).

- **Healthy lifestyle is emphasized** as the determinant of longevity of life, which by and large depends on the Prakriti (bio-identity i.e. body-mind constitution) of an individual.

THERAPEUTIC STREAMS



- Proper understanding of Prakriti leads the physician in making right diagnosis, prognosis and treatment plan and in guiding patients as well as disease-free individuals what dos and don'ts they need to follow for restoration and maintenance of health.
- The therapeutic streams advocated in *Ayurveda* comprise
 - *Daivavyapasraya chikitsa* (Spiritual measures)
 - *Yuktivyapasraya chikitsa* (Pharmacological therapies)
 - *Satvavajaya* (Non-pharmacological Psychotherapies)
- The treatment plan is worked out on the basis of underlying morbidity keeping in mind the strength of the disease and the tolerability of the patient.



SOURCE OF DRUGS

- **Ayurveda considers all the substances in the world as drugs if used appropriately according to status and severity of disease as well as patient.**
- **There are three main sources of drugs**
 - Plant sources**
 - Animal sources**
 - Metals/Mineral, marine sources**



IDEAL DRUG/THERAPY

- **An ideal drug or therapy should cure the disease alone, but not to create any adverse/toxic effects and must restore the homeostatis of somatic/psychic environment of human body (Dhatu-Samyatwva).**
- **Safety of a drug also depends upon its dosage.**
- **Dose of a drug plays a pivotal role in clinical practice as Ayurveda says “Poison in proper dose acts a wonder drug while an effective drug in higher dose acts as Poison ”.**



FOUR-PRONGED TREATMENT PLAN

1. Avoidance of causative and precipitating factors of disease (*Nidan parivarjan*)
2. Bio-purification (*samshodhan*)
3. Use of palliative remedies (*samshamana*)
4. Health-promoting regimen (*pathya Vyavastha*)

is the hall mark of Ayurvedic therapeutics recommended for physicians to prescribe.

- Specific diet and lifestyle guidelines are always prescribed along with the drugs and therapies so as to facilitate restoration of bio-humoral balance and health status.



CREDIBLE THERAPEUTIC MODALITIES OF AYURVEDA

- Bio-purification therapy – *Panchakarma*
- Minimal invasive *para surgical* measure for management of *fistula-in-ano* and *piles* -*Ksharsutra*
- Specialized health promotive & rejuvenative approach for geriatric health care - *Rasayana*.
- These modalities are proven to have an edge over conventional medical approach in dealing with chronic and refractory disease conditions.



MERITS

- **Culturally competent & sensitive**
- **Holistic approach**
- **Cost-effective**
- **Natural/ eco-friendly**
- **Minimal adverse effects**
- **Easily accessible**
- **Emphasis on prevention**
- **Health promotion and Quality of life concerns especially in**
 - **Chronic illness**
 - **Refractory conditions**



GLOBAL SCENARIO

- **During last decade, use of Ayurveda and traditional systems of medicine (TM) has expanded globally and has gained popularity.**
- **It has not only continued to be used for primary health care of the poor in developing countries, but has also been used in countries where conventional (Allopathic) medicine is predominant in the national health care system.**

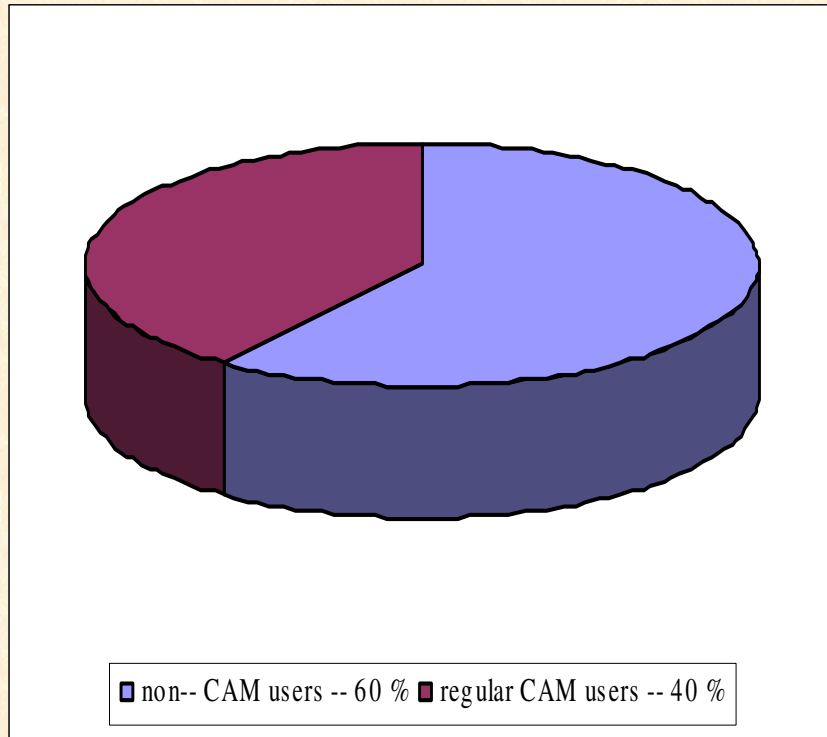


- The most prevalent users of Ayurveda /TM are individuals who have incurable, non-life-threatening conditions that may be chronic viz. neurological disorders, arthritis etc.
- The second largest group of users are those struggling with chronic, potentially life-threatening diseases, such as cancer and HIV/AIDS etc.
- Both groups turn to Ayurveda /TM for a variety of reasons, such as to improve immune functioning, to improve overall functioning, to increase quality of life, to cope with side effects from conventional therapies, and to relieve symptoms related to their illness.
- Most therapies are for chronic diseases such as Neuromuscular disorders, Life style disorders, allergies, arthritis and insomnia HIV/AIDS cancer and so on.

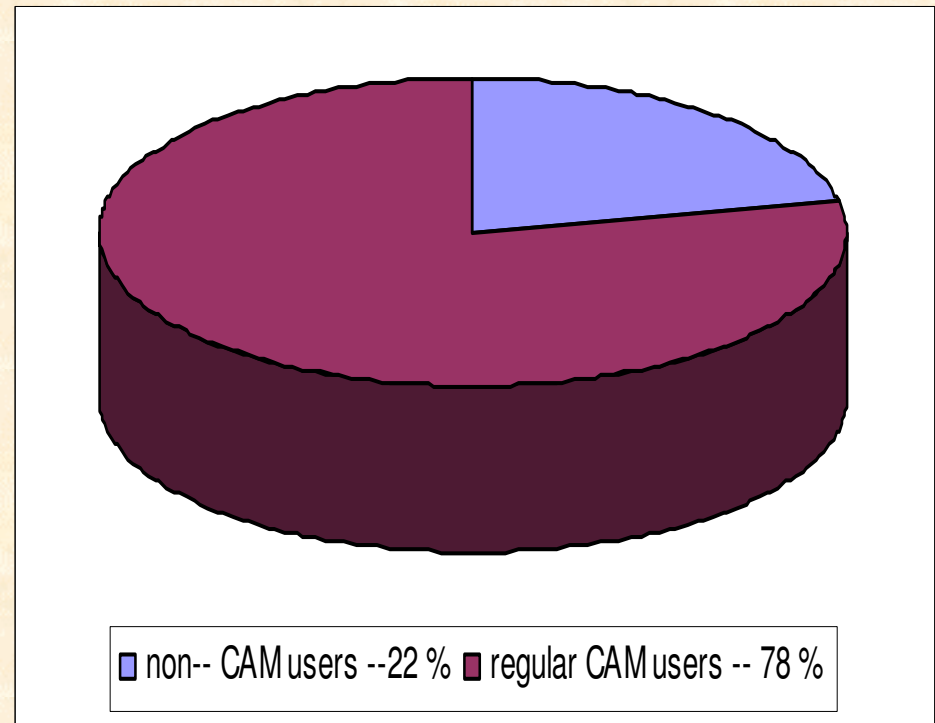
POTENTIAL ROLE OF TM/CAM IN REFRACTORY ILLNESS



USE OF CAM BY PEOPLE LIVING WITH HIV/AIDS IN USA



GENERAL ADULT POPULATION



PEOPLE LIVING WITH HIV/AIDS



GLOBAL SITUATION OF USE OF TRADITIONAL MEDICINE

CHINA	40%
CHILE	71%
COLUMBIA	40%
INDIA (use of Ayurveda)	65%
AUSTRALIA	48%
BELGIUM	70%
CANADA	70%
FRANCE	49%
USA	42%
UK	70%
NORTH IRELAND	90%

SOURCE : WHO traditional medicine strategy 2002-2005. Document WHO/EDM/TRM/2002.

SAFETY AND EFFICACY



- The health care services of *Ayurveda* are being successfully catered to the masses in India through a huge network of **443634** registered practitioners, **13887** government dispensaries, **2394** hospitals with **42087** beds, **225** colleges conducting degree course, **61** post graduate centres, **7786** manufacturing units and **39** research institutes functioning under the Central Council for Research in Ayurveda and Siddha (CCRAS).
- Manufacturing of medicines is regulated under **Drugs & Cosmetics Act** and licensing of manufacturing premises and products within **GMP** requirements is mandatory legally.

SAFETY AND EFFICACY



- **About 65% of population in India** is reported to use *Ayurveda* and medicinal plants to help meet their primary health care needs and the safety of this vibrant tradition is attributed to time-tested use and textual reference.
- **Besides, synergy of ingredients** in conjunction with individualized Prakriti-based treatment plan forms the basis of efficacy and safety of Ayurvedic formulations.
- Specific guidelines are prescribed for the use of apparently **toxic medicinal plants with certain detoxification** processing that also enhance the bioavailability and efficacy of the final product.

EVIDENCE BASED RESEARCH



- In Ayurveda the process of learning, research and clinical practice are scientific and evidence based.

- The knowledge is scientifically validated through evidence based approaches; the *Pramanas*,

 - Pratyaksa* (Direct perception),

 - Anumana* (Logical inference),

 - Aptopadesa* (authentic documentary testimony),

 - Yukti* (Experimental evidence)



APEX BODY FOR RESEARCH

The Government of India set up Central Council for Research in Ayurveda and Siddha (CCRAS) as an apex body in the country for the :

- Formulation
- Co-ordination
- Development
- Promotion

of research in Ayurveda and Siddha Systems of Medicine on scientific lines.

THE MISSION

- To prioritize research needs of the country and constantly strive for excellence and global leadership .
- To develop quality assured and cost effective research products for health promotion, prevention, management /cure of the disease to meet the needs of the country through establishing the state of art research facilities for comprehensive research with a focus on public health needs for masses.



THE VISION

- To develop CCRAS into a dynamic vibrant and model state of art research organization for achieving global leadership
- To focus research on the needs of India with a view to emerging health requirement of the country.

THE AREAS OF FOCUS

- AYUSH Literature Research and Research on Basic concepts
- Drug research
- Clinical Research
- RCH Research
- Neutraceutical Research
- Cosmeceutical Research
- Bio Medical Instrumentation Research.

SOME SIGNIFICANT LEADS



DRUG DEVELOPMENT

- **Ayush -64 for Malaria**
- **777oil for Psoriasis**
- **Ayush-56 for Epilepsy**
- **kshara sutra** -minimal invasive para-surgical procedure for Anal Fistula
- **Nutraceutical supplements-Ayush poshaka peya & Ayush Poshaka Yoga**
- **Ayush Face pack for Melasma**
- **Ayabringaraja karpam in leucoderma**
- **Brahmyadiyoga for acute schizophrenia**
- **Ayushman-8 for (Mental retardation)**
- **Shunthi Guggulu for Rheumatoid Arthritis**
- **Ayush-82 for Diabetes mellitus**
- **Guggulu in Obesity and Lipid disorders**
- **Pippalyadi yoga - An Ayurvedic Oral contraceptive for females**

PROJECTS OF NATIONAL IMPORTANCE

1. **Feasibility of introducing Indian systems of medicine (Ayurveda & Siddha) In the “National RCH at the primary health care (PHC) Level- CCRAS-ICMR**
2. **Safety/Toxicity Evaluation of Metal Based Bhasmas/Rasa Kalpas**
3. **Evaluation for Heavy Metals and safety profiles of Ayurvedic formulations (Published in JAMA**
4. **Bio-medical/Therapeutic instrumentation research**



Identification of priority area



Literature Survey



Hypothetical Basis (single components/compound formulations)



Drugs for identified conditions
SOP ,Standardization, Pre-clinical safety , Biological activity



Specific Protocols



Approval by Task Force



Clinical Trial

AYUSH 64– AN AYURVEDIC ANTI-MALARIAL DRUG



Drug : Ayush-64 Vs Chloroquine
[*Picrorhiza kurroa*, *Alstonia scholaris*,
Swertia chirata&*Caesalpinia bonducella*]



Findings :

- * Temperature tends to normalcy.
- * Maintenance of Thymol turbidity [P<0.05]
- * Significant decrease in lymphocytes, total disappearance of parasite & clinical improvement were seen in 72.4 -95.4 % in comparison with 100 % in control group in various level of studies



SIDE EFFECTS: No side/toxic effects in prescribed doses



(Double blind)

IPR Status -Patent No. 152863 dated 28.7.198

Ref ;M.V.Chary *et al.*, Double-blind Clinical Trail with Ayush-64 an Ayurvedic drug in *P.Vivax* Malaria, *Journal of Rersearch in Ayurveda and Siddha* Vol.VI No.1, 3&4:105-116,1985.

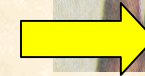
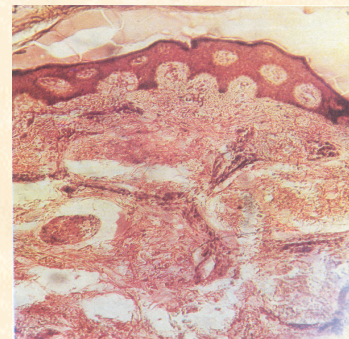
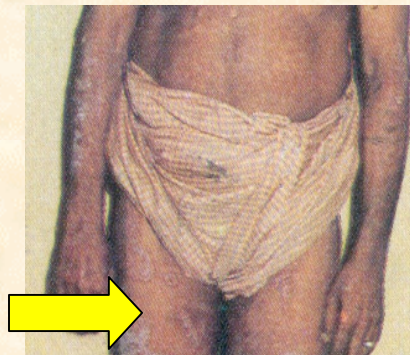
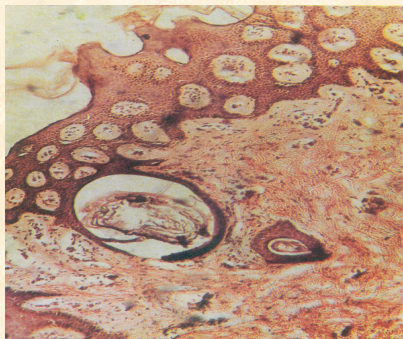
777 OIL FOR PSORIASIS



DRUG : 777 OIL
[*Wrightia tinctoria*]

FINDINGS : Significant response was observed in 80% patients .
The recurrence is postponed and the Intensity of the lesions is very much minimized .The efficacy of the drug is also supported by histopathological studies.

(open study)



Before treatment

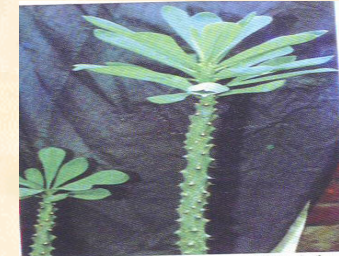
After treatment

IPR Status - Patent No. 166740 dated 11.9.1987

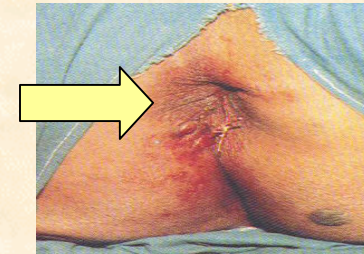
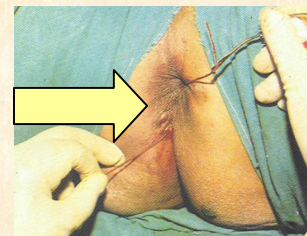
KSHARA SUTRA -MINIMAL INVASIVE PARA-SURGICAL PROCEDURE FOR ANAL FISTULA(BHAGANDARA)

Ingredients

- Snuhi Ksheera-latex of *Euphorbia neriifolia*
- Apamarga Kshara (*Achyranthus aspera*)
- Fine powder of haridra-(*Curcuma longa*)
- Barbour's surgical thread No. 20



Ksharasutra offers effective ambulatory and safe alternative to surgery in fistula in ano. Recurrence rate was 4% in Ksharasutra group when compared 11 %with surgery.



Findings : The study revealed 98.7% cure rate. In this OPD procedure Cutting and Healing took place simultaneously so that no raw area was left besides Minimal tissue damage and less pain. No recurrence has been reported.

(Randomized controlled study)

IPR Status - Patent No.186243 dated 15.2.2002

AYURVEDIC NUTRACEUTICAL SUPPLEMENTS -AYUSH POSHAKA PEYA & AYUSH POSHAKA YOGA

FINDINGS

Clinical trial was conducted on Antarctic Expedition members (n=20, trial group) for a period of 6 weeks.

The study revealed, Potential adaptogenic properties. Immuno-stimulant and anti oxidant effects besides significant anti stress effect against a series of stress like extreme cold, mental stress. (isolation and some psychological factors),and nutritional stress .

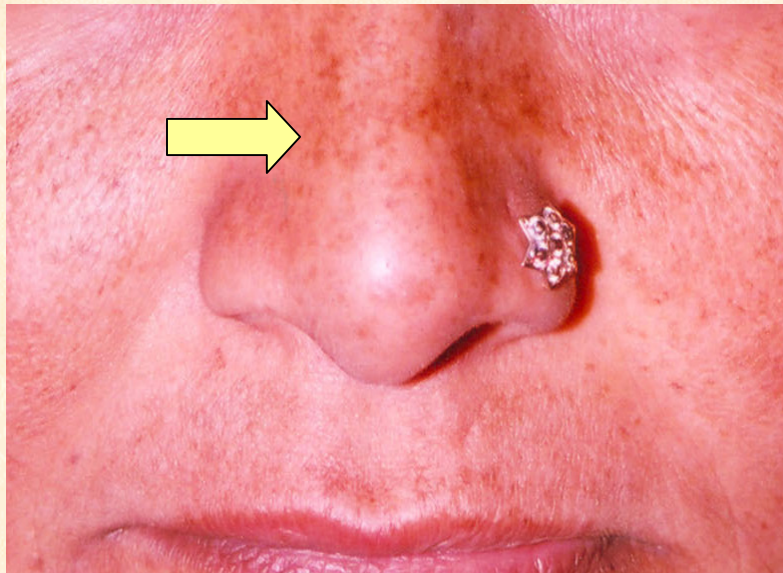
No clinical toxicity was noticed and lipid profile as well as body weight, body mass Index / lean body mass were not effected.



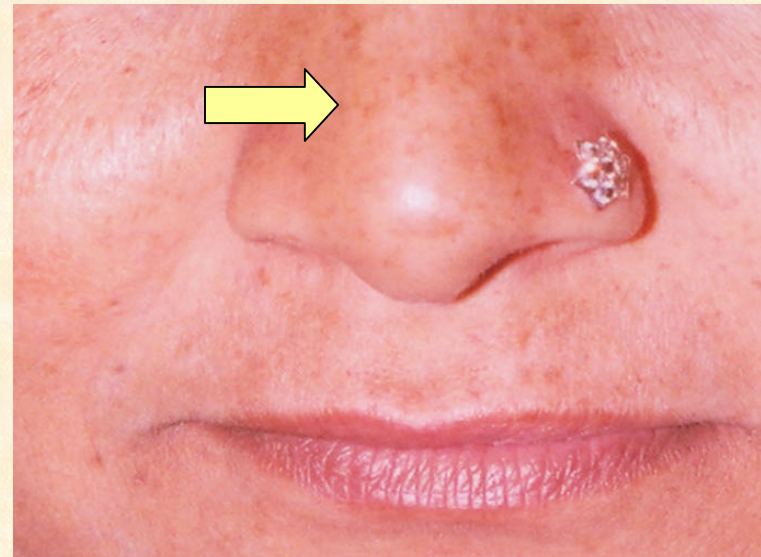
AYUSH FACE PACK FOR MELASMA

Findings

- The result was assessed using Melasma. Area & Severity Index (MASI score) (n=20).
- The response was statistically significant with $P < .05$. the average score was 7.32 compared with 19.25 pretreatment score. No side effect was recorded in all the treated patients.



Before treatment



After treatment

SHUNTHI GUGGULU FOR RHEUMATOID ARTHRITIS

DRUG : **SHUNTHI GUGGULU**
[*Zingiber officinale* &
Commiphora mukul]

FINDINGS : Significant response was observed in 72% cases. There was marked improvement of signs and symptoms besides significant changes in lab. parameters like, ESR etc.



(open study)

AYUSH-82 FOR DIABETES MELLITUS



DRUG : *AYUSH-82 [Mangifera indica, Syzygium cumini, Gymnema sylvestris, Momordia charantia]*

FINDINGS : *Fall in FBS, PPBS after treatment was significant (0.001) besides 75% good response on subjective assessment.*

(open study)

Ref;CCRAS Research An Over View, Central Council for Research in Ayurveda and Siddha. Janakpuri, New Delhi-2002

A CONTROLLED CLINICAL TRIAL OF *GUGGULU* AND P.E. EXT. OF *GUGGULU* IN OBESITY AND LIPID DISORDERS

Drugs : *Guggulu* , P.E. Ext. of *Guggulu* Vs Placebo

Findings:

- Reduction in serum cholesterol was observed in all cases.
- Significant weight reduction was found in P.E. extract treated group [2 kg/month] when compared with *Guggulu* group [1 kg/month].



(Double blind)

Ref;Clinical and Experimental Trial of Guggulu (Medo-Roga). 1989Central Council for Research in Ayurveda and Siddha. Janakpuri, New Delhi.

AYUSHMAN-8 IN MENTAL RETARDATION

DRUGS : AYUSHMAN-8 VS PLACEBO[STARCH]
[*Centella asiatica* & *Bacopa monierri*]



Age Group : 5-16 years

Findings : * Binet-Kamat Test-Numerical increase in mental age was greater in drugs group [$p=0.05 < P < 0.1$].
* SEGUIN- Form board Test: Increase in mental age shown was significant when compared to Placebo group [$P > 0.01$]
* Clinical improvement.

Ref V. Rajagopalan *et al* Effect of Ayushman-8 in Mental retardation, *Journal of Research in Ayurveda and Siddha*, Vol.XIX-No.3-4 (1998), p. 89-97.

ADouble BLIND CONTROLLED STUDY ON THE ROLE OF BRAHMYADIYOGA AND TAGARA IN ACUTE SCHIZOPHRENIA

Drugs : 1. Brahmyadi Yoga

INGREDIENTS

- i. Manduk parni (*Centella asiatica*)
- ii. Jatamansi Root (*Nardostachys jatamansi*)
- iii. Kustha (*Sausurea lappa*)
- iv. Sarpagandha (*Rauwolfia serpentina*)
- v. Vacha (*Acorus calamus*)



2.Tagara.

3.Standard control : Chlorpromazine Vs Placebo[Starch]

Findings :

1. The mean difference effectiveness of Brahmyadi Yoga is better than that of Tagara [$P < 0.005$] and Placebo [$P < 0.001$] besides clinical improvement.
2. The mean effectiveness of Brahmyadi Yoga and chlorpromazine is not significant [$P > 0.05$].
3. The Anti-psychotic effect of Brahmayadi Yoga is better than Tagara and Placebo and comparable to standard control.

Ref;CCRAS Research An Over View, Central Council for Research in Ayurveda and Siddha. Janakpuri, New Delhi-2002

ANTI ANXIETY EFFECT OF AN AYURVEDIC COMPOUND DRUG – A CROSS OVER TRIAL



- Double blind study with sequential crossover design comparing the efficacy of Ayurvedic preparation with modern control.
- Ayurvedic preparation- Mandukaparni (*Centella asiatica*), Yasti (*Glycyrrhiza glabra*), Jatamansi (*Nardostachys Jatamansi*) in the ration of 1:1:2. Vs. Diazepam and Placebo

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

Ref .K. Kuppurajan, C. Seshadri, V Rajagopalan, Kanchan Srinivasan, R. Sitaraman, Janak indurathi & S Venkatraghavan – Dr. A Lakshmipathi
Research Center for Ayurveda (CCRAS) VHS Campus, Chennai

ROLE OF THE AYURVEDIC DRUG BRAHMI (*BACOPA MONNIERI*) IN THE MANAGEMENT OF SENILE DEMENTIA.

Drug & Dosage:

**Brahmi Vs Placebo
Brahmi extract 1 gm. BD .**



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.

Ref ;Pharmacopschoecologia (1990), 3, 47-52.

AYUSH -56 AN AYURVEDIC ANTI-EPILEPTIC DRUG

DRUG : **AYUSH -56**
[*Nardostachys jatamansi* & *Marseliaminuta*]
(N=273)

Adult 2 tablets of 50mg. TDS for 6 months Children – 1 tablet TDS (<11 years)

FINDINGS : **SIGNIFICANT DECREASE IN FREQUENCY OF ATTACKS & DURATION OF SEIZURE .**

• **Post seizure symptoms like headache, confusion, excitement, sleeplessness, excessive sleep, anorexia, lethargy, amnesia, irritability and mood changes etc. also decreased considerably in epileptics after treatment with Ayush -56.**

• **No Drug interaction or toxic effects were observed even after prolonged used up to 10 years.**

Ref;CCRAS Research An Over View, Central Council for Research in Ayurveda and Siddha. Janakpuri, New Delhi-2002

(Double blind)

KATUKI (*Picrorhiza kurroa*) FOR LIVER DISORDERS



- Hepatoprotective activities of Katuki which is a common ingredient in many of Ayurvedic formulations have been demonstrated through experimental studies.
- Alcoholic extracts of *Picrorhiza kurroa* has been tested against CCl_4 induced hepatotoxic studies on experimental rats revealed hepatoprotective effect viz. improvement of biochemical parameters - SGOT, SGPT, and liver glycogen.
- Powdered rhizome of Katuki 4 gm. Per day in four divided doses for 6 weeks has shown remarkable recovery of liver function and inhibition of HBV replication.

Ref;CCRAS Research An Over View, Central Council for Research in Ayurveda and Siddha. Janakpuri, New Delhi-2002



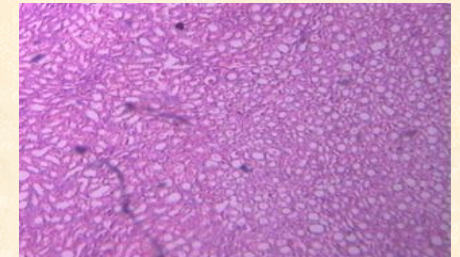
DEVELOPMENT OF AYUSH QOL-2A ; A CODED DRUG FOR IMPROVING QUALITY OF LIFE IN HIV/AIDS

-**Keeping the global prevalence** of HIV/AIDS and potentials of Ayurveda in view, the council has formulated and developed AYUSH QOL-2 for symptom management, Improvement of quality of Life through extensive pre clinical standardization /safety /targeted activity studies.

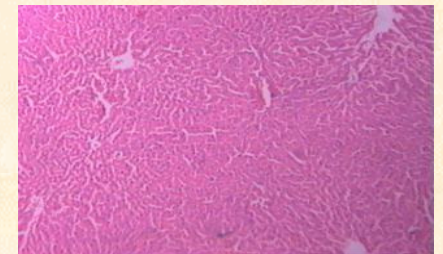
-**AYUSH QOL-2 has been formulated** and standardized adopting the WHO/Global norms (including microbial growth, estimation of pesticides, presence of adulterants, heavy metals etc).

-**The preclinical safety and toxicity studies** have been conducted adopting WHO/International norms and revealed its safety.

- **The Biological activity** study revealed significant immunomodulator, adaptogenic activities(antagonized the effect of Cyclophosphamide and confirmed immunomodulatory effect * $P < 0.001$) which are essential for improvement quality of life and symptoms management in HIV/AIDS.



Section of kidney showing normal glomeruli (Ayush QOL 2(TD), Female).

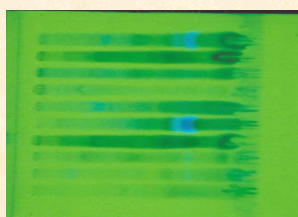


Section of Liver showing normal portal areas and hepatocytes. (VC, Female).

STANDARDIZATION AYUSH – QOL-2

Ayush – QOL-2	Description: Dark brown moderately fine powder with characteristic smell.			
	Parameters			
	Ash %	11.63	11.60	11.62
	Acid-insoluble ash %	0.79	0.30	0.63
	Water-soluble extractive %	51.39	53.61	52.50
	Alcohol-soluble extractive %	21.75	22.33	22.04
	Loss on drying at 105°C %	14.10	14.80	14.45
	pH (5% aq. solution)	4.60		
	Bulk density g/cc	0.55		
	Tap density g/cc	0.63		
	Calcium %	0.30	0.295	0.30
	Total sugar %	12.37	12.44	12.41
	Reducing sugar %	5.65	5.69	5.67
	Non reducing sugar %	6.72	6.75	6.74

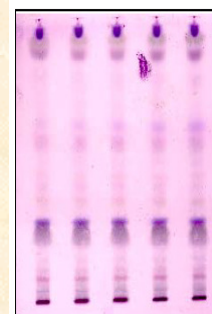
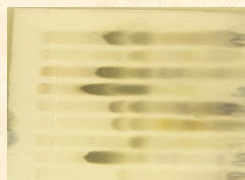
Microbiological analysis	3.3 x 10³ col/g
Total viable aerobic count	Nil
Total Enterobacteriaceae	Nil
Total fungal count	Nil
Test for specific Pathogen	Nil
E. coli	Nil
Salmonella sp.	Nil
S. aureus	Nil
Pseudomonas aeruginosa	Nil
Lethal dose	No mortality and toxic symptoms upto a dose level of 5 g/kg body wt.
TLC	Done



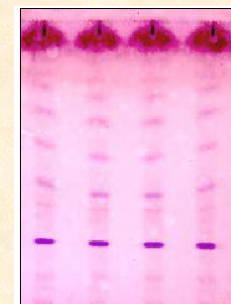
TLC of Ayush QOL - 2



Solvent system: n-Butanol :
Acetic acid : Water 63:27:10

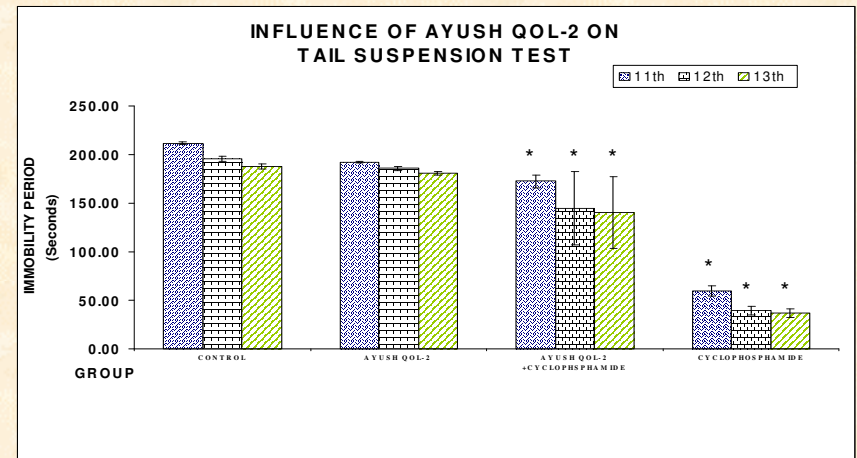
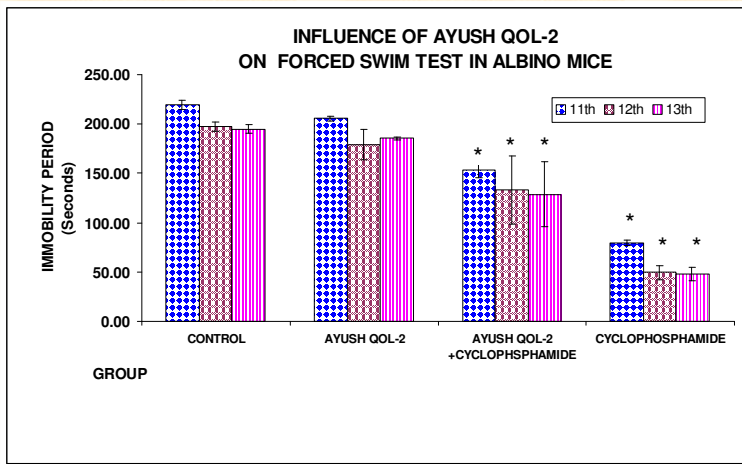


Toluene : Ethyl
Acetate 93 : 7



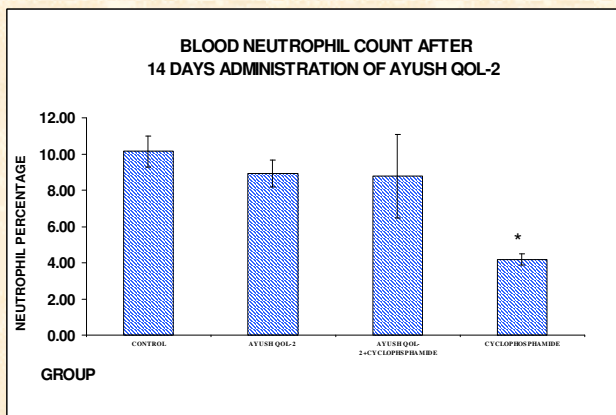
Chloroform :
methanol 90 : 10

TLC profiles of ingredients



INFERENCE

1. Cyclophosphamide has significantly decreased the immobility period when compared to control * $P < 0.001$
2. Ayush QOL-2 has antagonized the effect of Cyclophosphamide and confirmed immunomodulatory effect * $P < 0.001$



Inference:

1. Cyclophosphamide has significantly decreased the neutrophils counts * $P < 0.001$
2. Ayush QOL-2 has antagonized the effect of Cyclophosphamide and neutrophil count is comparable with central group

TARGETED ACTIVITIES

1. the effect of Aush QOL-2 on body weight and hematological parameters such as TLC, DLC & Hb.
2. preliminary effect of Ayush QOL-2 on stem cell proliferation.
3. the effect on the T Cell subsets CD4+ & CD8+ cells.
4. effect on macrophage mediated Phagocytosis.
5. To study the effect on the proliferation of lymphocytes.
6. effect of Ayush QOL-2 on the level of cytokines liberated by TH1 (IL-2, IFN-7), TH2 (IL-4, EL-6, IL-10) and macrophages (IL-12, ILN-8)
8. effect of Ayush-QOL2 on the expression of TH1 and TH2, Cytokines.
8. In vitro anti retro viral activity on cell lines.

EVIDENCE BASED OPERATIONAL STUDIES

The study was executed in 13 states through CCRAS field units

Objective	Subjects /population covered
1.Prakriti and its relation to disease causation and susceptibility	56,600
2. Disease Prevalence studies	49,992
3. Clinical observational studies on efficacy of certain Ayurvedic drugs in various common clinical conditions in rural areas	21,348

OBJECTIVES

- study the role of *Prakriti* in relation to the socio-economic and demographic aspects,
- the relation between the food habits and the incidence of diseases
- the nature and frequency of prevalent diseases
- ways and means of prevention of diseases and maintenance of positive health.

OUTCOME

1. The majority of the population covered during the study was found of *Dvandaja Prakriti* - Personality with combination of two humors, i.e. 64.53%.
2. Of these, the highest rate was observed in *Vatakapha Prakriti* (25.58%).
3. The over all incidence rate of illness in the whole of the population 49,992 covered during the study period remained at 735.10 per thousand.
4. Among the specific diseases, the highest incidence rate was observed in *Jwara (Fevers)* 106.66 per thousand followed by *Kasa (respiratory problems)* 63.65 per thousand. Other ailments found prevalent were *Atisara* (diarrhoea), *Pratishyaya* (rhinitis), *Vata Vyadhi* (neurological diseases),) and *Pandu(anaemia)*

INTEGRATION AND MAIN STREAMING

Feasibility of introducing Indian systems of medicine (Ayurveda & Siddha) In the “National RCH at the primary health care (PHC) Level”: (CCRAS-ICMR Collaborative venture)

OBJECTIVE

-Main streaming of practices of Indian Systems of Medicine (Ayurveda and Siddha) by integrating them with the Reproductive and Child Health (RCH) Programme at Primary Health Centre (PHC) level in five states of the country

-Focus on prevention & management of on common conditions that lead to morbidity & mortality during Ante-natal to post- natal periods.

-Evolved Special Modules and Imparted Training -Developed Pharmacopoeal standards/Q.A parameters for 17 Ayurveda and 16 Siddha formulations .

-Acute/sub chronic and chronic toxicity studies reveled safety

-The project will be launched shortly

EVIDENCES ON SAFETY ISSUES

SAFETY EVALUATION OF METAL BASED BHASMAS/RASA KALPAS

OBJECTIVES

- 1. Preparation of selected Ayurvedic Bhasmas and Rasakalpas**
- 2. Formulation of SOPs for preparation.**
- 3. Physio-Chemical analysis of prepared Bhasmas.**
- 4. Evaluation of safety & toxicity profiles**
- 5. Formulation of Pharmacopoeial standards of identified Bhasmas.**

OUT COME (two samples at two labs)

-Physio-Chemical analysis of prepared Bhasmas revealed heavy metal contents within permissible limits .

-The acute /sub chronic and chronic toxicity study profiles of Bhasmas and Rasakalpas revealed safety .

Evaluation for Heavy Metals and safety profiles of Ayurvedic formulations Published in JAMA, December 15, 2004-/Vol. 292 No. 23

- It has been reported in JAMA, December 15 2004-/Vol. 292 No. 23 for having heavy metal contents in some Ayurvedic medicines .
- This has created fear and misconception among Physicians, Scientists and consumers as well.
- In view of this the dept of AYUSH has taken up chemical analysis for heavy metal contents and evaluation of safety profiles of these drugs biologically through sub-chronic and chronic toxicity studies

OUT COME

- The outcome of the study has reassured the chemical and biological safety .

S.N.	Drug	Chemical Analysis (CCRAS) (ppm)	Acute toxicity	Sub-acute toxicity	Chronic Toxicity 90 days
1.	Swaran Mahayogaraj Guggulu(Baidyanath)	Hg-0.04 As-4.79 Pb-46 Cd-0.42	Non toxic upto 10 times more dose even the sample exceed permissible limit	NA	Histopathologically Shows no toxic effect
2.	Navaratna Rasa(Unjha Pharmacy)	Hg-0.05 As-4.18 Pb-47.05 Cd-0.48	Non toxic upto 10 times more dose even the sample exceed permissible limit	NA	Histopathologically Shows no toxic effect
3.	Mahayogaraj Guggulu(Baidyanath)	Hg-0.07 As-5.19 Pb-25.8 Cd-0.94	Non toxic upto 10 times more dose even the sample exceed permissible limit	NA	Histopathologically Shows no toxic effect
4.	Mahalaxmibilas Rasa with Gold (Baidyanath)	Hg-0.06 As-5.39 Pb-164.04 Cd-0.54	Non toxic upto 10 times more dose even the sample exceed permissible limit	NA	Histopathologically Shows no toxic effect

Permissible limit (ppm) Hg- 1, As-10 (FDA), Pb-10, Cd-0.3 (WHO)

5.	Mahasudarshan Ghan Vati (Zandu)	Hg-0.07 As-6.96 Pb-9.96 Cd-0.27	Non toxic up to 10 times more dose	NA	Completed
6.	Karela Capsules (Himalaya)	Hg-below det. limit As-2.01 Pb-4.58 Cd-0.08	Non toxic upto 10 times more dose	Histopathological y Shows no toxic effect	NA
7.	Mahasudarshan Churna (Zandu)	Hg-below det. limit As-1.08 Pb-3.8 Cd-0.16	Non toxic upto 10 times more dose	Histopathological y Shows no toxic effect	NA
8.	Gesari Pills (Harinarayana Pharmacy)	Hg-0.40 As-0.20 Pb- below det. limit Cd-below det. limit	Non toxic upto 10 times more dose	Histopathological y Shows no toxic effect	NA
9.	Balghutti Kesaria (Kesari Ayurved Pharmacy)	Hg-below det. limit As-26.60 Pb- 11.56 Cd-below det. Limit	Non toxic upto 10 times more dose even the sample exceed permissible limit	NA	Histopathologica ly Shows no toxic effect

Permissible limit (ppm) Hg- 1, As-10 (FDA), Pb-10, Cd-0.3 (WHO)

- **Rasakalpas and Bhasmas are safe**, if they are prepared and used as per the specifications mentioned in the Literature (Ayurvedic Pharmaceutical practices strongly recommend various aspects like GAP, GFCP and GMPs)
- **Drug Design:** Bhasmas and Rasa Kalpas are prepared with metals as basic ingredients and they naturally possess certain amount of original ingredients in native form.
- **Natural biological form:** Besides this certain plants used for processing these preparations also possess metals in **natural biological form** e.g. *Vitis Vinifera L.* (Draksha) - 0.02-9 ppm lead *Glycyrrhiza glabra* (Liconci/Yastimadhu)-24 ppm Tin (<http://www.levity.com/alchemy/metals.html>).
- These factors may sometimes appear in the finished products if not properly observed, the manufacturing procedure.

BIO-MEDICAL / THERAPEUTIC INSTRUMENTATION RESEARCH

(Development of Automated instruments in collaboration with IIT Delhi)

- Automated Sarvngadhara yantra (Commercialization is in pipe line)
- Automated Bhaspasweda yantra (Lab. Prototype is developed)
- Automated Kasharasutra preparing machine (Lab. Prototype is developed)

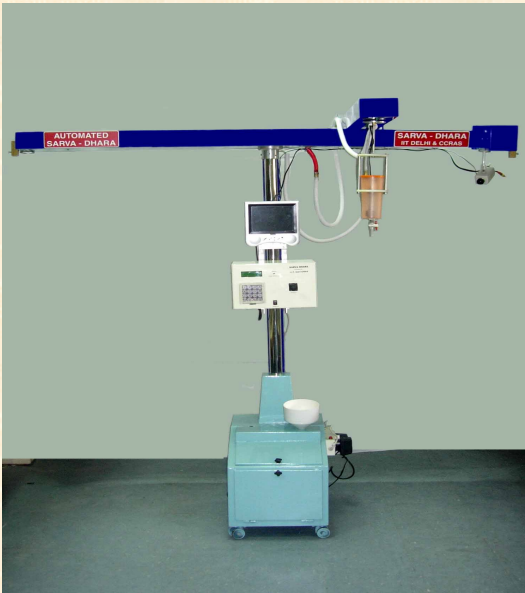
ADVANTAGES OF THE AUTOMATED SYSTEM

Standardization: Entire X-Y locus motion suiting body profile can be online set, stored and replayed and unaffected by operator's fatigue. Temperature and flow can be preset and clean oil used to dispense standardized treatment.

Minimal fluid & energy: The pumping, filtering and temperature control utilizes small medicated fluid volumes and hence less of the costly fluid is required per patient. It also saves electrical energy. Only one trained operator is needed.

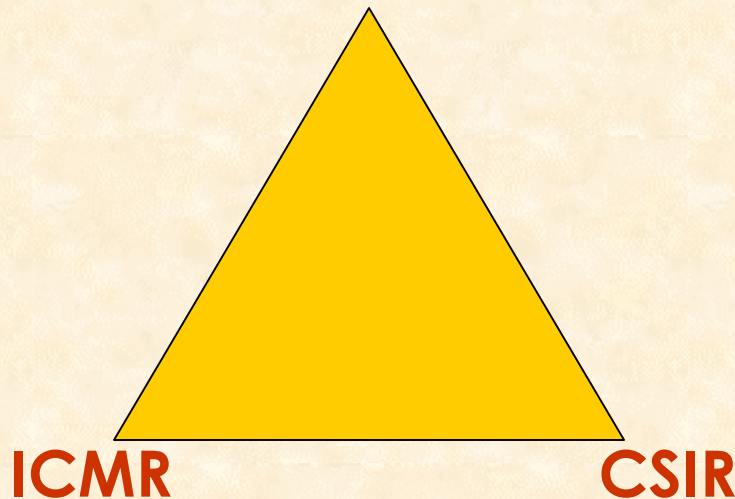
Programmability : The therapy time is programmable suiting the different needs of the patients and treatments.

Easy setting: Digital camera with a Flat Screen display and joystick help quick setting of dispensation locus.



**GOLDEN TRIANGLE” PARTNERSHIP (GTP) SCHEME FOR
VALIDATION OF TRADITIONAL ASHU DRUGS
(AYURVEDA, SIDDHA, HOMOEOPATHY & UNANI)
AND DEVELOPMENT OF NEW DRUGS**

AYUSH –RESEARCH COUNCILS



Department of AYUSH/ CCRAS,CSIR and ICMR decided to work together to achieve safe, effective and standardized classical ASHU products for the identified disease conditions and to develop new Drugs effective in disease conditions of national/global importance.

OBJECTIVES

- To bring safe, effective and standardized ASHU (Ayurveda, Siddha, Homoeopathy & Unani) products for the identified disease conditions;
- To develop new Ayurvedic / Siddha / Unani / Homeopathic products effective in the disease conditions of national/global importance. Products should be better than the available products in the market for such disease conditions;
- The criteria will be to have best quality, safe and effective products. Mechanism will be evolved to make products affordable for the domestic market;
- To utilize appropriate technologies for development of single and poly-herbal products to make it globally acceptable;
- To promote collaborative research on AYUSH with modern medicine/modern science institutions.

DISEASES/AREAS OF PRIORITY

- 1. Rasayana (Rejuvenators / Immunomodulators) for healthy ageing.**
- 2. Joint disorders**
- 3. Memory disorders**
- 4. Menopausal syndrome**
- 5. Bronchial allergy**
- 6. Infertility**
- 7. Cardiac disorders (cardio-protective & anti-atherosclerosis)**
- 8. Sleep disorders**
- 9. Irritable Bowel Syndrome (IBS)**
- 10. Vision disorders**
- 11. Urolithiasis & Benign Prostrate Hypertrophy (BPH)**
- 12. Malaria/Filariasis / Lishmaniasis**
- 13. Diabetes**
- 14. Obesity**
- 15. Cancer**
- 16. Bhasmas/ Rasa Kalpas (Herbomineral Preparations)**
- 17. Development of Pharmacopoeial software**
- 18. Development of Research Council Labs as per NABL / GLP**
- 19. Fundamental and Basic Research in ASHU disciplines**



KEY ELEMENTS FOR RESEARCH & DEVELOPMENT

- ✓ **Standardization and Quality Control of traditional drugs**
- ✓ **Creation of scientific evidences on Safety and Efficacy**
- ✓ **Refractory and Chronic disease Management**
- ✓ **Mainstreaming of strengths of Ayurveda through integration**

SUGGESTED APPROACHES FOR CREATION OF BETTER SCIENTIFIC EVIDENCE IN TM/CAM



- ✓ **EVOLVING OBJECTIVE PARAMETERS OF BASIC CLASSICAL METHODS (STANDARDIZATION/ DIAGNOSTIC/THERAPEUTIC ASSESSMENT) FOR VALIDATION OF TSM/CAM**
- ✓ **EVOLVING CRITERIA FOR PRIORITIZING RESEARCH OPPORTUNITIES IN TSM/CAM**
- ✓ **EMPHASIS ON INTEGRATION – A KEY SOLUTION FOR RESEARCH IN TSM/CAM**



EVOLVING CRITERIA FOR PRIORITIZING RESEARCH OPPORTUNITIES

- **Quantity and quality of available preliminary data to help determine the most appropriate type of research (basic versus clinical research; phase I or II clinical trial versus phase III trial).**
- **Extent of use by the public (greatest weight given to interventions in wide use).**
- **Public health importance of diseases being treated (greatest weight to diseases associated with highest mortality or morbidity or for which conventional medicine has not proved optimal).**
- **Feasibility of conducting the research.**



PRIORITY AREAS FOR RESEARCH

- ✓ **Effects of each individual therapy: efficacy, safety and cost-effectiveness.**
- ✓ **Research into mechanisms of action of individual therapies, including patterns of response to treatment.**
- ✓ **Research into new research strategies which are sensitive to the TM/CAM paradigm.**
- ✓ **Research into efficacy of diagnostic methods used.**



RESEARCH FOCUS ON CHRONIC AND REFRACTORY DISEASE

It would be worth to direct our research efforts to those traditional drugs which may be of use

- (a) in combating the so-called 'Refractory Diseases' for which modern medicine has not been able to offer any lasting remedies so far; and
- (b) as supplementary remedies to well-established modern chemotherapy.



AMONG THE REFRACTORY DISEASES, THE FOLLOWING MAY PRIORITISED FOR DEVELOPMENT OF SAFE, EFFECTIVE TM/CAM REMEDIES

(i) Cancer/HIV/AIDS (ii) Rheumatoid arthritis and Allied conditions; (iii) Conditions with an allergic component in their etiology (e.g. bronchial asthma, skin allergies, eczema, psoriasis etc.); (iv) Liver disorders (including viral diseases like poliomyelitis, herpes, zoster; (v) Urolithiasis; (vi) Obesity, Hyperlipidaemia and Atherosclerosis; (vii) Metabolic disorders like diabetes mellitus; (viii) Peptic ulcer; (ix) Cerebrovascular disorders like Hemiplegia and Paraplegia; (x) Malabsorption syndromes included Ulcerative colitis; (xi) Ischemic Heart Disease; (xii) Epilepsy; (xiii) Mental disorders including psychosis, anxiety neurosis, stress disorders, drug dependence etc.



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Thank You



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