DRUG DEVELOPMENT FOR SELECT DISEASES

Evidence Based Approach

Based on CCRAS R&D Contributions

Central Council for Research in Ayurvedic Sciences (CCRAS)

Ministry of AYUSH, Govt. of India

New Delhi

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Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan

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PREFACE

The Central Council for Research in Ayurvedic Sciences has been engaged in clinical research and drug development of new/ coded formulations based on leads from classical texts, contemporary scientific and pharmacological leads for important diseases of National importance based on strength of Ayurveda.

The Council has been putting efforts to translate the research findings into practice and make available to the needful at large. In this direction, the technologies of new coded drugs and formulations developed by the Council such as Ayush-64 for Malaria, Ayush-56 for Epilepsy, Ayush-82 for Diabetes mellitus etc have been transferred to the Industry through National Research Development Corporation, Department of Scientific and Industrial Research, Ministry of Science & Technology, Government of India.

I am pleased to present this concise and comprehensive document comprising the fifteen important drugs / formulations developed by the Council through systemic drug development process such as standardization, Pre Clinical studies and Clinical studies. I appreciate the effort put in by officers of the Council in developing this document. I sincerely hope the readers would find this document useful.

(Prof. Vd. K. S. Dhiman)
Director General
Central Council for Research in Ayurvedic Sciences
New Delhi

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1. AYUSH -64

An Ayurvedic anti-Malarial Drug

Background

Malaria, a tropical diseases is widely prevalent all over the world and has claimed millions of lives. However, by using modern anti-malarial drugs like quinine, chloroquine & also insecticides to kill mosquitoes the disease is temporarily controlled. Nevertheless, it has been found that mosquitoes have developed immunity to the insecticides and their breeding, continues unabated. It has also been realized that the modern allopathic anti-malarial drugs are highly toxic and their repeated use causes numerous side- effects resulting in ocular disturbances etc.

Descriptions concerning its aetiopathogenesis, clinical features and line of management are detailed under '*Vishamajwara*' in ancient classical literature of Ayurveda. Ayurvedic classics vividly recount the sign, symptoms and phase wise clinical consequences of mosquito bite. This may range from symptoms like itching, swelling and mild pain to severe form of fever, vomiting etc. Malaria may be comparable to the clinical entities emerging out of mosquito bite as described in Ayurvedic classics

In order to provide safe, inexpensive and effective remedy for malaria, CCRAS has developed a poly herbal safe, anti-malarial drug **'Ayush-64'** through extensive pharmacological, toxicological and clinical studies. This has been patented by the Council through National Research and Development Corporation, New Delhi.(Patent No:152863)

Drug Profile

S.No.	Ingredients	Botanical name	Part used
1.	Kiratatikta	*Swertia chirata* Buch-Ham. ex Wall.	Whole Plant
2.	Saptaparna	*Alstonia scholaris* (L.) R.Br	Stem Bark
3.	Katuki	*Picrorhiza kurroa* Royle ex Benth.	Root
4.	Kuberaksha	*Caesalpinia crista* L.	Seed

Pharmacological/Safety/Toxicity Studies

- In albino mice, oral administration of Ayush -64 at doses of 250-750mg/kg for five days exhibited significant anti-malarial property.[3]
- Ayush-64 administered in dose of 500 mg/ kg body weight in rats for 12 weeks was considered safe and non-toxic.[3]

Clinical efficacy

- Clinical trials of Ayush-64 were conducted on 1442 positive cases of malaria at various Research institutes and Centres of the Council located in different part of the country. The response of treatment was 89% and the findings were comparable with known Anti-malarial drugs-chloroquine and primaquine.[1,2,3] (Figure-1).

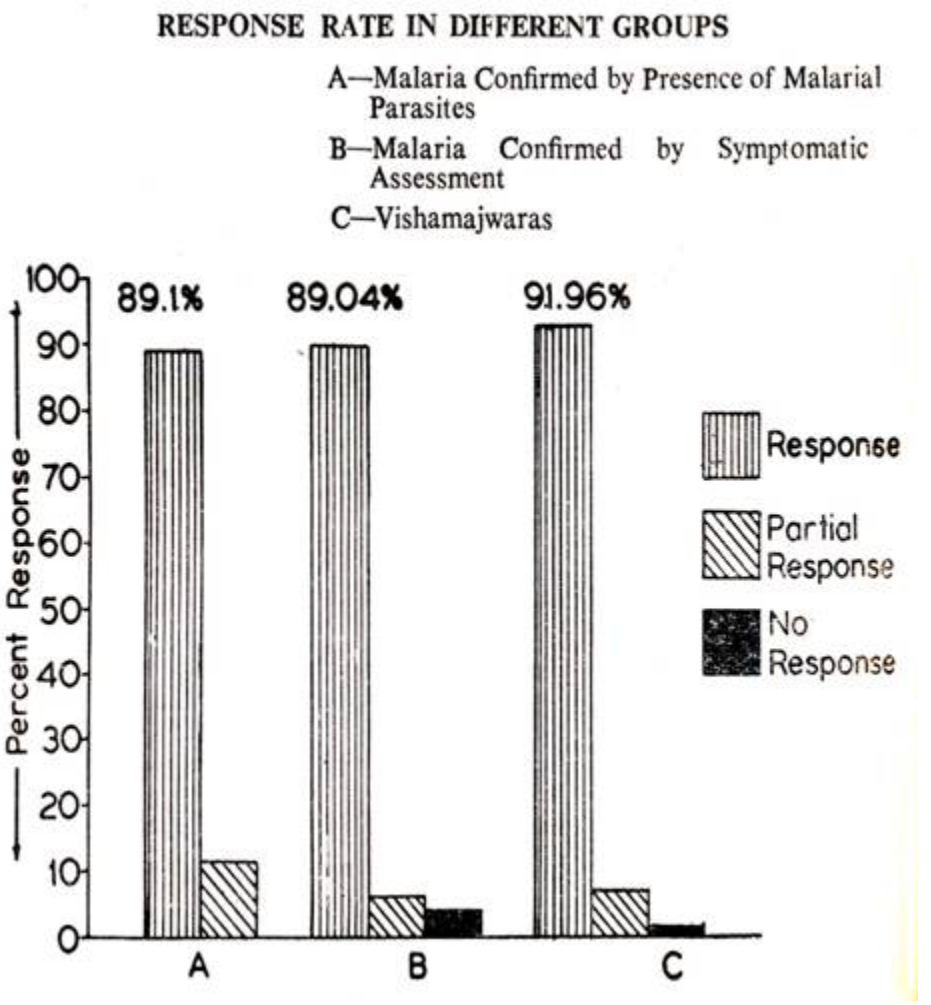

Figure -1

Source: Ayush-64 A New Ayurvedic Anti- Malarial Compound ,Central Council for Research in Ayurveda & Siddha 1987

- OPD & IPD level double blind studies were conducted on 178 patients revealed that the formulation is effective in 95.4% of patients. Normal temperature besides clearance of malarial parasite was achieved within 5-7 days. [1,2,3] **(Figure-2).**

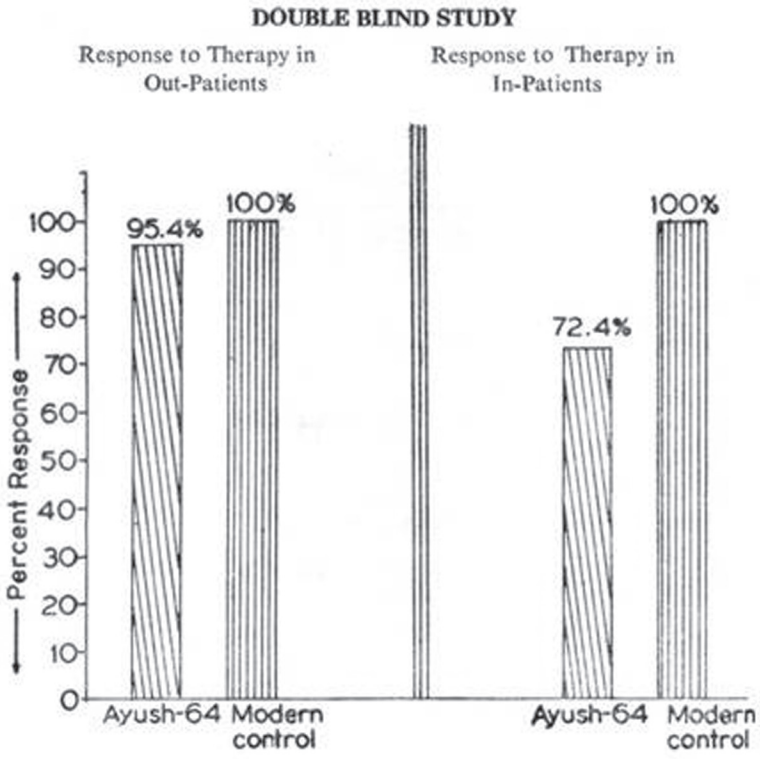

Figure-2

Source: Ayush-64 A New Ayurvedic Anti- Malarial Compound, Central Council for Research in Ayurveda & Siddha 1987

- **Collaborative studies with National Malaria Eradication programme (Govt. of Haryana & Tamil Nadu):** These studies conducted on 496 patients have shown clearance of parasites and clinical improvement in 72-90% in 5-7 days.[1,2]

- **Epidemic Malaria control programme (Western Rajasthan 1984, Assam, 1995)** During epidemic Malarial control programmes at Rajasthan and Assam approximately 3,600 and 10,000 *P.vivax* cases were treated respectively. Clinical improvement was observed in almost all cases. Positive *P.falciparum* was observed in some cases and parasite clearance and clinical improvement was found in few numbers of cases. [1,2]

Side effects: No side/toxic effect in prescribed doses

Recommended Dose: As mentioned below or as directed by the physician

Adult	:	4 tablets (500 mg each) thrice daily for 5-7 days
Children (5-12 years)	:	2 tablets thrice daily for 5-7 days
Infants (below 5 years)	:	Powder of 1 tablet with honey, three times a day

Ingredients

Katuki (*Picrorhiza kurroa* Royale)

Kuberaksa (*Caesalpinia crista* Linn.)

Kiratatikta (*Swertia chirata* Buch-ham)

Saptaparna (*Alstonia scholaris* R.Br)

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2. CCRAS Research an Overview, CCRAS, Year:2002, Page no.35-36

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2. AYUSH-56

An Ayurvedic Anti-Epileptic Drug

Background

Epilepsy*(Apasmara)* is a transient loss of consciousness with terrifying physical movements born of derangement of memory, intellect and mind. Epilepsy is a Greek word meaning "A condition of being overcome or seized or attached". The clinical picture of *Apasmara* presented in Ayurveda and that of epilepsy in modern medicine are almost identical. Ayurveda considered the involvement of both body and mind in the causation of the disease. About 30%of the patients of epilepsy do not respond to the current available modern drugs besides their adverse effects.

In view of this, the Central Council for Research in Ayurvedic Sciences, through extensive pharmacological/ toxicological and clinical studies has evolved a new safe and effective coded drug Ayush-56 for the management of epilepsy. This has been patented by the Council through National Research and Development Corporation, New Delhi. (Patent No: 141170)

Drug Profile

S. No.	Ingredients	Botanical name	Parts used
1.	Sunisannaka	*Marsilea minuta* L.	Whole Plant
2.	Jatamansi	*Nardostachys jatamansi* (D. Don) DC.	Root/Rhizome

Safety/Toxicity Profile: Acute and sub-acute toxicity studies revealed no toxic effects of the drug.[1]

Clinical Efficacy:

Clinical studies on 273 subjects were carried out at three peripheral research Institutes/Units of the Council to ascertain the efficacy of **Ayush-56** in the treatment of Epilepsy (*Apasmara*). The study showed significant reduction (65%) in frequency and duration of epileptic fits. It is found useful as an add on therapy to the modern anti-epileptic treatment. No adverse event in prescribed doses was reported. Further, no withdrawal effect was observed after slowly tapering the modern medicine with this drug.[2,3.] The overall effect of the drug Ayush-56 is given in the **Table-1.**

Table- 1: Showing the overall effect of the drug Ayush-56 (n = 273)

Sl. No.	Result	No. of cases
1.	Complete control	87
2.	Marked control	48
3.	Moderate control	41
4.	No control	97

Recommended Dose

Adults	:	Two tablets (250 mg each), three times a day for six months or as directed by physician
Children	:	One tablet (250 mg each), three times a day for six months or as directed by physician

Ingredients

Jatamansi (*Nardostachys jatamansi* DC. *)*

Sunisannaka (*Marsilea minuta* Linn*)*

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1. Pharmacological Investigations of certain Medicinal Plants and Compound Formulations used in Ayurveda and Siddha; Central Council for Research in Ayurveda & Siddha (CCRAS), 1996.

2. CCRAS Research an Overview; Central Council for Research in Ayurveda & Siddha (CCRAS), Year: 2002, Page no. 22-23.

3. Ayush-56 An Ayurvedic Anti- Epileptic Drug; Central Council for Research in Ayurveda & Siddha (CCRAS), 1997.

3. AYUSH-82

An Ayurvedic Drug for Diabetes Mellitus

Background

Diabetes mellitus (*Madhumeha*) is a group of metabolic diseases marked by high level of blood glucose resulting from defects in insulin production, insulin action or both. Diabetes may lead to serious complications involving multiple organs. Ayurvedic literatures vividly describe about the aetiology, pathogenesis, prognosis, complications, its management and scientifically attributed the causal relationship of dietary, lifestyle, environmental and genetic factors.

CCRAS has developed a polyherbal formulation, **Ayush-82** for the management of Diabetes mellitus.

Drug Profile

Sl.No.	Drug name	Botanical/English name	Part used
1.	Jambu	*Syzygium cumini* (L.) Skeels	Seed
2.	Karvellaka	*Momordica charantia* Linn.	Seed
3.	Meshashringi	*Gymnema sylvestre* R.Br.	Leaf
4.	Amra	*Mangifera indica* Linn.	Seed

Safety/toxicity profile

Acute Toxicity Studies of Ayush-82 administered orally in Swiss Albino (I.B) mice revealed no pre-terminal deaths, no toxic signs and abnormal behavior in the animals at 10 times of intended therapeutic dose.

Sub-Acute Toxicity Studies of **Ayush -82** in Wistar rats showed no significant effect in the blood biochemistry, haematology and weight of the vital organs in comparison to the control suggestive of its safety.

Clinical efficacy

The study has been carried out on 886 patients (497 completed cases and 389 drop outs) at Council's peripheral Central Research Institutes wherein **Ayush-82** was administered thrice daily. The results indicate statistically significant reduction in fasting and post prandial blood sugar level along with clinical improvement. No adverse events were reported during the treatment period[1,2,3,4].

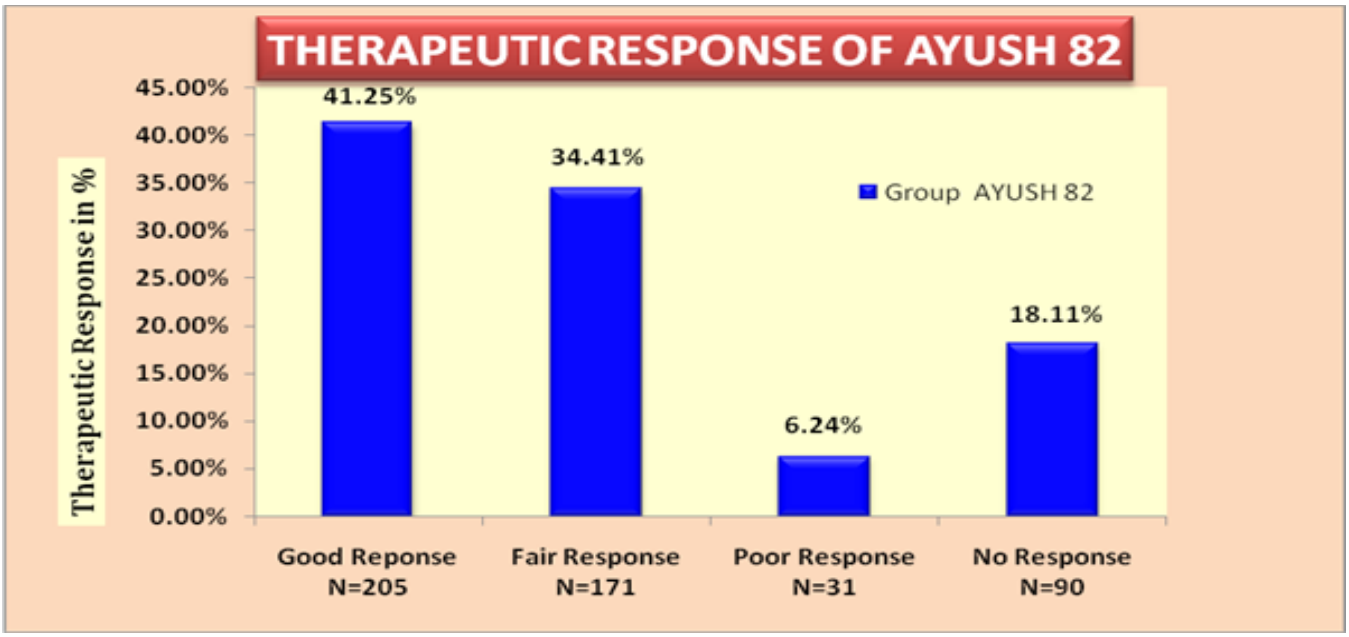

Figure-3

Recommended Dose

15 g per day in 3 divided doses along with 500 mg Shuddha Shilajita twice daily[3,4].

Ingredients

Jambu (*Syzygium cumini* (L.) Skeels)

Meshashringi (*Gymnema sylvestre* R.Br)

Amra (*Mangifera indica* Linn.)

Karvellaka (*Momordica charantia* Linn.)

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4. NIMBATIKTAM

An Ayurvedic Drug for Psoriasis and Duodenal ulcer

Background

Nimba is one of the most commonly used plant in Ayurveda. Ayurveda mentions the therapeutic use of it's fruits, seeds, seed oil, stem bark, leaves & flowers. Ayurveda classics advocate the use of seed oil in various disease conditions like skin disease, ulcers, diabetes, fever etc. Owing to its therapeutic importance, Central Council for Research in Ayurvedic Sciences has developed **Nimbatiktam** , the major bitter component obtained from the seed oil of Nimba (Az*adirachta indica* A. Juss.) . The Council has conducted studies of Nimbatiktakam for its efficacy in Psoriasis and Duodenal Ulcer

Drug Profile

Ingredients	Botanical name	Part used
Nimba	*Azadirachta indica* A. Juss	Seed Oil

Safety/toxicity profile:

In albino rats and mice acute toxicity studies, Nimbatiktam showed no toxicity up to 2000 mg/kg orally and 1000mg/kg intra peritoneally. Sub acute toxicity studies in albino rats up to 100 mg/kg daily for 6 weeks and 10 and 20 mg/kg orally in dogs for 4 weeks did not reveal any systemic toxicity. Teratogenic studies in rats also did not reveal any toxic manifestations or foetal abnormalities.[1]

I. NIMBATIKTAM FOR PSORIASIS

Clinical efficacy

- **Nimbatiktam with Lajjalukeram**

A combination of internal administration of Nimbatiktam 200 mg twice daily and Lajjalukeram as external application for 60 days were taken for trial at Councils peripheral institute. The trial has been conducted on 386 patients and about 56% of the patients have shown good and fair response.[2,3]

- **Nimbatiktam with Aragwadha kera**

A double blind clinical study was carried out on 40 patients randomly grouped into 2 groups (20 in each) at Council's peripheral institute to assess the therapeutic activity of Nimbatiktam in Psoriasis (Discoid Psoriasis). One group was treated with Nimbatiktam 200 mg capsule twice daily and the other group with

Lactose (Placebo) 200 mg capsule orally for 60 days and Aragwadha kera 50 ml for external application daily in both the groups. This double-blind study proved that the effect of Nimbatiktam in the treatment of psoriasis is statistically significant at 5% level. P<0.05 than the placebo.[4]

Case Report: A 60 year old male patient with well defined psoriatic lesions and no complication was administered Nimbatiktam 100mg (Capsule) thrice daily orally and 1g Nimbatiktam mixed in 100 g of Coconut oil externally for 72 days. The patient recovered from all the symptoms of Psoriasis.[5]

II. NIMBATIKTAM FOR DUODENAL ULCER

Pharmacological Profile:

Antiulcer effects[6]

- In rats, Nimbatiktam in 20 mg/kg dose level given orally, exhibited significant protection (P<0.001) against Shay ulcers in rats. Significant reduction was observed in both free and total acid output (P<0.001) and peptic activity (P<0.05) of the gastric fluid. At 80 mg/kg daily for 10 days it showed significant (P<.05) reduction in ulcer index with a healing rate of 57.8% in acetic acid induced gastric ulcers in rats. The drug significantly suppressed the chronic glandular stomach lesions induced by steroid in rats. The test drug also significantly suppressed serotonin (SHT) induced gastric ulcers in rats.

- In guinea pigs, Nimbatiktam in 20 mg and 40 mg/kg doses administered orally gave significant (P<0.01) protection against histamine ulceration. At 40mg/kg dose, the intensity of ulceration was considerably reduced and ulcer score was observed to be lower than the controls(P<0.001). The test drug showed significant(P<0.02) antipeptic activity.

- In histamine-induced duodenal ulcers in guinea pigs, Nimbatiktam at 80 mg/kg prior to histamine, significantly (P<.01) reduced ulcer incidence and severity.

- In mongrel dogs, oral dosing of Nimbatiktam (10 & 20 mg/kg) for 28 days significantly accelerated the healing of acetic acid induced chronic gastric ulcers. It significantly prevented gastric lesions induced by non-steroidal anti-inflammatory compounds (NOSAC) like aspirin (ASA) and indomethacin and this effect was more marked at the higher dose level of 80 mg/kg.

The drug in 20 mg/kg dose level (p.o) was found to have significant anti ulcer activity in shay ulcers in rats and histamine ulcer in guinea pigs. The same dose had significant anti peptic activity in rats and guinea pigs. However, 40 mg/kg dose possessed anti-secretary effect in shay rats. The ulcer healing effect of Nimbatiktam could be attributed to its antisecretary and anti-peptic activity associated with an enhancement of local healing process.

Clinical efficacy

- Nimbidin Extract 100 mg was administered twice daily in 13 cases of active duodenal ulcer for 60 days. Ulcer completely healed as observed in the review endoscopy in 3 patients, ulcer healing was in process in 5 patients, no healing effect was observed in 5 patients at the end of trial.[7]

- Nimbatiktam 150 mg was administered thrice daily with water for 30 days at Council's peripheral institute. The results seem quite significant as 16 (40%) cases had relief of more than 75% and 4(10%) cases had moderate relief (51%-74%).[8]

Recommended Dose

- For Psoriasis : Nimbatiktam 200mg twice daily orally for 60 days along with external application lajjalu kera or Aragwadha kera

- For Duodenal ulcer: Nimbatiktam 100mg-150 mg twice or thrice daily orally for 30-60 days

INGREDIENT OF NIMBATIKTAM

Nimba (A*zadirachta indica* A. Juss)

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5. AYUSH POSHAK YOGA AND PEYA

For Immunomodulatory, Antistress and General Health Promotion

Background

Ayurveda emphasizes on prevention of disease and improve the quality of health as well as life span. A number of medicinal plants have been recommended for this purpose. These plants provide specific resistance and make the body strong to counteract any adverse physical, chemical or biological stress.

The people belonging to Antarctica region are exposed to environmental stress viz. cold, mental and nutritional stress including others factors like radiations, food preservatives etc. which generate free-radicals in the body thus suppressing the immune system and causing early ageing. To combat such adverse situations, Council developed *Ayush poshak yoga* and *peya* for improving general well being.

Drug profile

Ayush Poshak Yoga

Sl.No	Name	Botanical/English name	Part Used
1.	Kaju	*Anacardium occidentale* L.	kernel
2.	Badam	*Prunus amygdalus* Stokes	kernel
3.	Pista	*Pistacia vera* L.	kernel
4.	Akhrot	*Juglans regia* L.	Cotyledons
5.	Khas khas	*Papaver somniferum* L.	Seeds
6.	Safed musli	*Chlorophytum tuberosum* (Roxb.) Baker	Tuberous root
7.	Pumpkin	*Cucurbita pepo* L.	Seed
8.	Trapush	*Cucumis sativus* L.	Seed
9.	Tarbooj	*Citrullus vulgaris* Schrad.	Seed
10.	Kharbooj	*Cucumis melo var.Utilissimus* Dutt & Fueller	Seed
11.	Shunthi	*Zingiber officinale* Rosc.	Rhizome
12.	Pippali	*Piper longum* L.	Fruit
13.	Maricha	*Piper nigrum* L.	Fruit
14.	Aswagandha	*Withania somnifera* (L.) Dunal.	Root
15.	Saunf	*Foeniculum vulgare* Mill.	Fruit
16.	Guduchi	*Tinospora cordifolia* (Willd.) Miers	Stem
17.	Sita	Sugar Candy	-

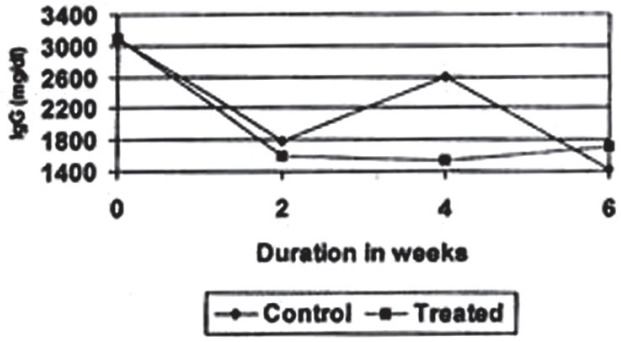
Ayush Poshak Peya

Sl. No.	Sanskrit / Local Name	Botanical name	Part Used
1.	Tea Leaf	*Camellia sinensis* (L.) O.Kuntze	Leaf
2.	Sukshmaila	*Elettaria cardamomum* Maton	Seed
3.	Tvak	*Cinnamomum verum* Breyn.	Stem bark
4.	Kumkuma	*Crocus sativus* L.	Style & Stigma
5.	Arjuna	*Terminalia arjuna* (Roxb.) Wight & Arn.	Stem bark

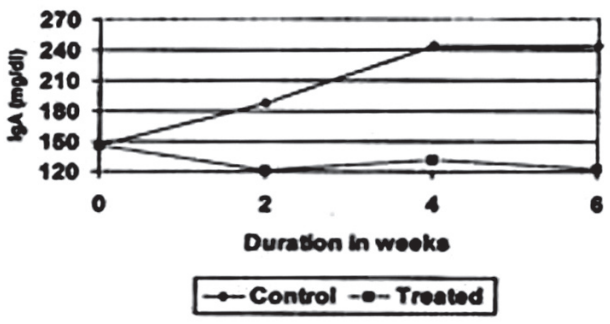
Clinical efficacy

The combined intake of Ayush Poshak Yog and Peya helped in the management of stress related symptoms as evident by notable changes in immunoglobulin level and antioxidant enzymes. The formulations significantly improved quality of life of individuals. [1, 2]

Effect of APY and APP on igA



Effect of APY and APP on igG



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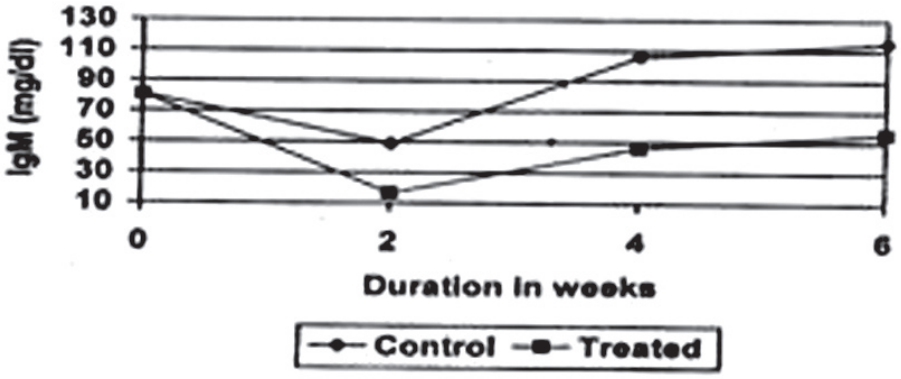

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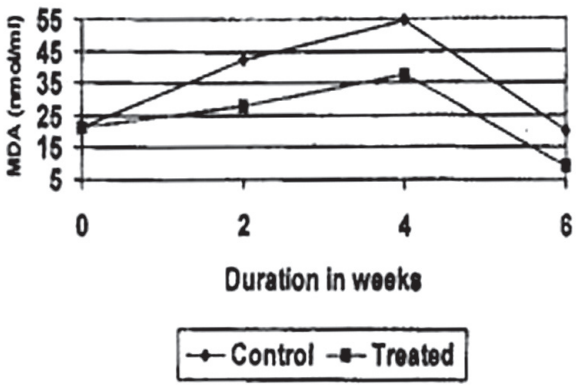
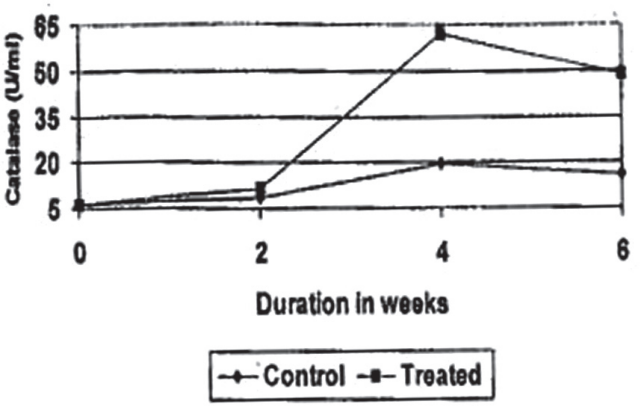
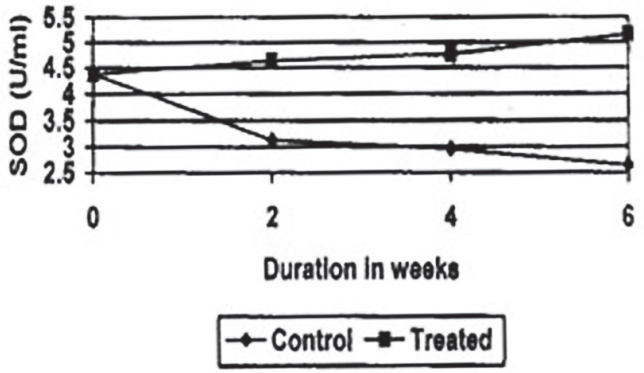


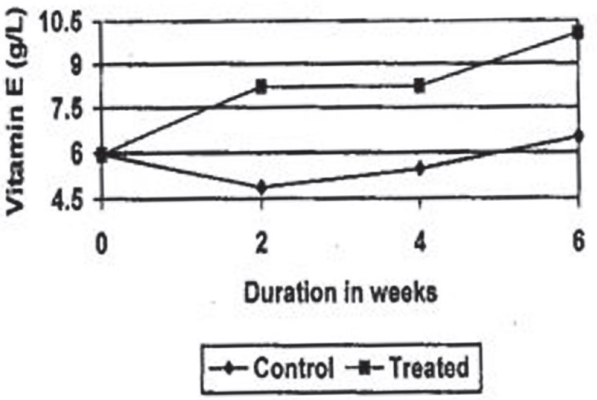
Effect of APY and APP on Malondladohyde (MDA)



Effect of APY and APP on Vitamin E



Effect of APY and APP on Suparoxldedismutase (SOD)



Source: Unpublished technical dossier on Ayush Poshak Yoga and Peya(CCRAS).

Recommended Dose

- Ayush Poshak Yoga 45-50gm.
- Ayush Poshak Peya 125-150 ml.

SOME IMPORTANT INGREDIENTS OF AYUSH POSHAK YOGA

Badam (*Prunus amygdalus* Batsch)

Kaju (*Anacardium occidentale* Linn)

Akhrot (*Juglans regia* Linn.)

Pista (*Pistacia vera* Linn.)

Saunf (*Foeniculum vulgare* Mill.)

Ashwagandha (*Withania somnifera* (L.) Dunal.)

Guduchi (*Tinospora cordifolia* (Willd) Miers)

Ingredients of Ayush Poshak Peya:

Tea Leaf (*Camellia sinensis*) (L.) O. Kuntze

Sukshmaila (*Flettaria cardamomum Maton*)

Tvak (*Cinnamomum verum Breyn*.)

Kumkuna (*Crocus sativus L.)*

Arjun (*Terminalia arjuna (Roxb.)* Wight & Arn)

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6. SHUNTHI GUGGULU

For Rheumatoid Arthritis (*Amavata*)

Background

Rheumatoid Arthritis (*Amavata*) is an autoimmune inflammatory disease that causes pain, swelling, stiffness, destruction, and functional disability in the affected joints. In chronic cases, the disease may cause deformity and total incapacitation. Descriptions concerning aetiopathogenesis, clinical features and line of management are detailed under *Amavata* in Ayurveda. According to Ayurveda, the main cause of the disease is formation of *Ama* due to *Agnimandya* i.e gastrointestinal dysfunction.

The cardinal features of *Amavata* are swelling and severe pain that seems to be of scorpion bite over the joints and other symptoms include body pain, loss of appetite, excessive thirst, laziness, heaviness of the body and fever. The general principles of treatment of this disease in Ayurveda lay emphasis on stimulating and normalizing the impaired *Agni* for the correction of digestion and metabolism. Based on the cardinal features and other associated features, use of different herbal, herbo-mineral preparations & regimens are described in Ayurvedic classics. CCRAS has developed a herbal safe Ayurvedic Drug Shunthi Guggulu for Rheumatoid Arthritis (*Amavata*) through a series of clinical studies.

Drug Profile

Sl. No.	Ingredient	Botanical Name	Part Used
1.	Shunthi	*Zingiber officinale Rosc.*	Rhizome
2.	Guggulu	*Commiphora wightii (Arn.) Bhandari*	Gum resin

Clinical efficacy

Multicentre observational study revealed satisfactory improvement of symptoms viz. reduction in pain, morning stiffness, swelling in joints besides reduction in ESR levels. The observations made on 497 patients showed that about 2/3rd patients (67%) have very good effect under a course of 6 weeks treatment. General functional capability and improvement in general condition of the patients was noticed.[1, 2, 3,]

The clinical study was conducted at then CRI, Bhubaneswar on 63 patients of Amavata *(Rheumatoid arthritis)* recruited into 2 groups viz. Group-A *(Shunthi Guggulu)* & Group-B *(Yogaraja guggulu, Amavata-Rasa/ Vatagajankusha-rasa & Maharasanadi-kwatha).*

The result indicated better effect of *Shunthi guggulu* (Group-A) as compared to the other set of medicines (Group-B) **Figure-1.** [2]

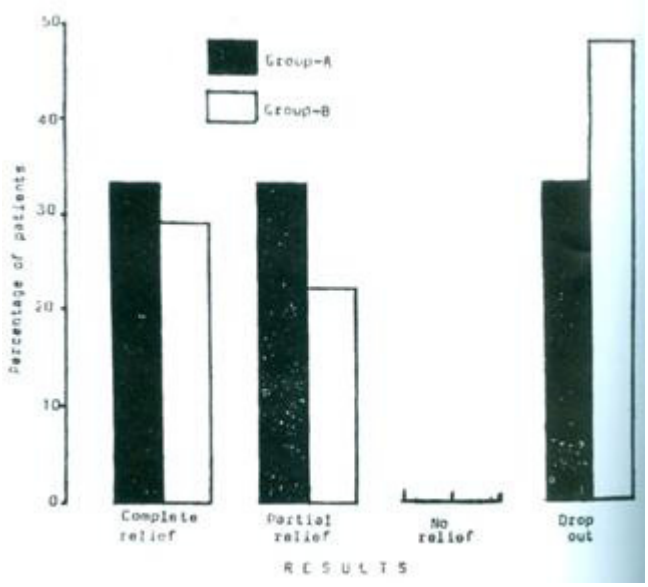

Figure-1

Source: Prem Kishore *et.al.,* Clinical Studies on the treatment of Amavata-Rheumatoid Arthritis with Shunthi-Guggulu, JRAS, 1988 vol.3, No3 & 4, pp-133-146).

The observations in another clinical trial of Shunthi-Guggulu on 50 patients of Amavata-Rheumatoid Arthritis showed significant effect as about 80% of the patients who completed full course of treatment showed either marked or complete relief (table-1).[3]

S. No.	Results	No. Of cases
1.	Complete relief	13
2.	Marked relief	19
3.	Moderate relief	5
4.	Mild relief	2
5.	No relief	-
6.	Dropout	1
Total		**50**

Table-1

Source: Prem Kishore *et.al*., Further Clinical Evaluation of Shunthi Guggulu in the Treatment of Amavata-Rheumatoid Arthritis, JRAS, | Year : 1988 |Volume : IX | Issue : 3-4 | Page : -89-104).

Recommended Dose

2 gm- 4 g thrice a day for six weeks with warm water.

Ingredients of Shunthi Guggulu

Guggulu (*Commiphora wightii)*

Shunthi (*Zingiber officinale)*

References:

1. CCRAS Research an Overview, Central Council for Research in Ayurveda & Siddha (CCRAS), Year:2002, page no.49-50.

2. Prem Kishore *et.al.,* Clinical Studies on the treatment of Amavata-Rheumatoid Arthritis with Shunthi-Guggulu, JRAS, 1988 vol.3, No3 & 4, pp-133-146).

3. Prem Kishore *et.al*., Further Clinical Evaluation of Shunthi Guggulu in the Treatment of Amavata-Rheumatoid Arthritis, JRAS, | Year : 1988 |Volume : IX | Issue : 3-4 | Page : -89-104).

7. KSHARASUTRA

In Ano Rectal Disorders

Background

Improper food habits and faulty life styles are the main causes of ill health. This may lead to abnormal bowel movement, which if persists, causes various ano-rectal diseases. Besides the above, heredity also has its contribution towards this disease. Commonly occurring ano-rectal diseases are fistula-in-ano, piles and fissure in-ano. Ayurveda classifies fistula-in ano and piles under Mahagadas (major diseases). The chronicity and recurrent nature of these diseases leaves physical and psychological agony to the sufferer.

Ksharasutra, a unique para surgical measure is advocated in Ayurveda to treat these disorders. *Ksharasutra* involves insertion of a medicated thread into the fistulous tract. It has many advantages over the modern surgical measure. Application of *Ksharasutra* is an OPD measure; which does not require hospitalization, heavy medication and is completely safe with an advantage of simultaneous cutting and healing. Tissue damage is very less, hence chance of infection is very minimal and rate of recurrence is negligible .It is economic and minimal invasive and the patients can carry out their routine work during the treatment. This measure has been very well accepted/ adopted by the practitioners of Ayurveda and such services are being provided at various clinical facilities of CCRAS in the country.

Drug Profile

Sl.No	Ingredients name	Botanical Name	Part Used
1.	Snuhi	*Euphorbia nerrifolia* L.	Latex
2.	Apamarga	*Achyranthus aspera* L.	Whole plant
3.	Haridra	*Curcuma longa* L.	Rhizome

Clinical efficacy

A study was conducted at Clinical research enquiry on *Ksharasutra* Therapy (unit of CCRAS) at Institute of Medical Science, Banaras Hindu University, Varanasi. In this study total 805 patients were registered and 700 patients (500 non-recurrent cases and 200 recurrent cases) completed the study[1].

The *Ksharasutra* result showed efficacy in almost all patients (98.77%). Out of 700 cases, 691 were completely cured. Further, out of 200 recurrent cases 197(98.5%) patients were cured without much difficulty **(Figure-1).**

The result also revealed that the average Unit Cutting Time(UCT) in the total (n=700) patients was 5.68 days/cm and the average UCT in recurrent (n=200) was 6.55 days/cm **(Figure-2).**

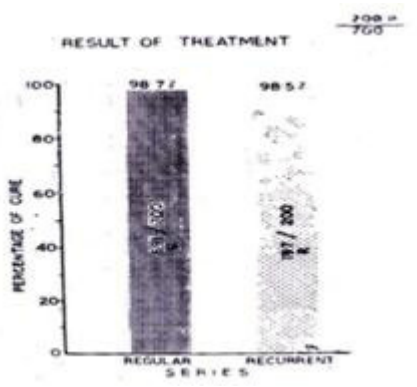

Figure-1 Result of treatment in regular and recurrent patients.

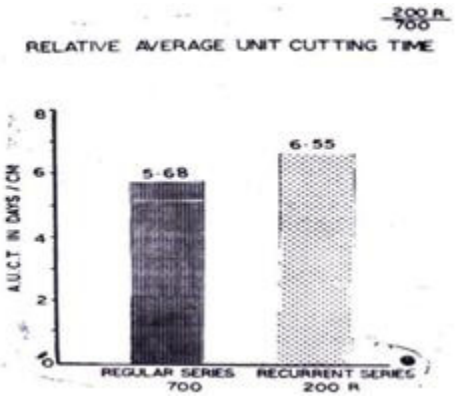

Figure-2 Relative average unit cutting time of regular and recurrent patients.

Source: Management of Bhagandara (Fistula-in-Ano) with *Ksharasutra*, Central Council for Research in Ayurveda & Siddha (CCRAS), Year:1989

Further studies on 395 patients have been conducted in the Council's peripheral Research Institutes and 386 (97.72%) patients responded to the procedure[2].

Ingredients of Kshara Sutra

Snuhi (*Euphorbia nerrifolia*)

Haridra (*Curcuma longa*)

Apamarg (*Achyranchus aspera*)

References

1. Management of Bhagandara (Fistula-in-Ano) with *Ksharasutra*, Central Council for Research in Ayurveda & Siddha (CCRAS), Year:1989.

2. CCRAS Research an Overview, Central Council for Research in Ayurveda & Siddha (CCRAS).

8. AYUSH BALARASAYANA

For Promotion of Health in Children

Background

Malnutrition is the underlying contributing factor in about 45% of all child deaths under the age of 5. It makes children more vulnerable to severe diseases. From the end of the neonatal period and through the first 5 years of life, the main causes of death are preterm birth complications, intrapartum-related complications, diarrhoea, pneumonia and malaria. According to WHO, the mortality rate of children under 5 is very alarming. 5.9 million Children under the age of five, died in 2015, at the approximate rate of 16,000 every day.

Ayurveda, the ancient science of life provides utmost focus on promotion & maintenance of health. The susceptibility of young children towards various infections or diseases is mainly due to their poor immunity. The Rasayana drugs provide longevity, optimum strength of physique, improves memory and intelligence.

Considering the general ailments affecting the infants and children, the ***AYUSH BALARASAYANA*** has been scientifically developed by the Central Council for Research in Ayurvedic Sciences for promotion of health in children and patented through National Research and Development Corporation, New Delhi. (Patent No:196916)

Drug Profile

A. Balarasayana for Health Promotion in Children

Sl. No.	Ingredient	Botanical /English Name	Part used
1.	Shatavari	*Asparagus racemosus* Willd.	Root
2.	Amalaki	*Emblica officinalis* Gaertn	Fruit
3.	Guduchi	*Tinospora cordifolia* (Willd.) Miers	Stem
4.	Bhumyamalaki	*Phyllanthus fraternus* G. L. Webster	Whole Plant
5.	Bala	*Sida cordifolia* L.	Root
6.	Mandukparni	*Centella asiatica* (L.) Urb.	Whole plant
6.	Mukta Shukti Bhasma	*Calcined shell of pearl oyster (Ostrea edulis)*	Shell

Clinical efficacy

Clinical studies conducted by CCRAS, New Delhi at its various peripheral centres to establish the efficacy of Balarasayana showed significant improvement in immunity. Also significant improvement in duration

and episodes of excess cry, diarrhoea and vomiting was observed. Highly significant improvement in episodes of cough/cold and fevers was also observed when compared to placebo.[1]

Recommended Dose

Balarasayana: 1 tablet (250mg) twice a day up to 5 years of age

2 tablets (250mg) twice a day for more than 5 years of age

Some important ingredients:

Shatavari (*Asparagus racemosus*)

Bala (*Sida cordifolia*)

Amalaki (*Emblica officinalis*)

Guduchi (*Tinospora cordifolia*)

References

1. Family Welfare Research Programme, Central Council for Research in Ayurveda & Siddha (CCRAS) Annual Report 2000-2001.

9. AYUSH GHUTTI

For Prevention of Diarrhoea and Fever in Children

Background

Infant mortality rate amounts very high in tropical countries like India due to infantile diarrhoea. In spite of enormous expenditure incurred to improve health standards of the masses, diarrhoea still poses the same threat especially in rural areas. Although it is not a deadly disease as such yet due to ignorance, lack of medical facilities and late treatment ,children suffer heavily and by the time they reach some proper medical institution the cases turn complicated to the extent of irreversible state.[1] Considering the gravity of the disease, the ***AYUSH GHUTTI*** has been scientifically developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) to prevent diarrhoea and fever in children. This is useful for development of proper digestion and assimilation as well as prevents the said disease conditions in childhood. The drug is patented through National Research and Development Corporation, New Delhi.(Patent No:193336)

Drug Profile

❖ **AYUSH - Ghutti (Prevention of Diarrhoea and Fever)**

Sl. No.	Ingredient	Botanical Name	Part used
1.	Dadima	*Punica granatum* L.	Fruit rind
2.	Amra	*Mangifera indica* L.	Seed Kernel
3.	Kamala	*Nelumbo nucifera* Gaertn.	Seed Kernel
4.	Haritaki	*Terminalia chebula* Retz.	Fruit
5.	Sunthi	*Zingiber officinale* Rosc.	Rhizome
6.	Bilwa	*Aegle marmelos* (L.) Correa	Fruit pulp
7.	Jahar Mohara pisti (Serpentine stone)		Calx

Clinical Efficacy

Clinical studies to establish the efficacy of AYUSH Ghutti were carried out at RSSCA, Varanasi. AYUSH Ghutti was tried in 50 cases each in trial and control group. Significant improvement was noted in the episodes and duration of diarrhoea and excess cry. Significant improvement in C_3 and C_4 levels (enhancement of immunity) was also reported.[2]

Dosage Schedule

❖ **Ayush – Ghutti:** 1 – 3 ml twice a day

Some Important Ingredients:

Dadima (*Punica granatum*)

Haritaki (*Terminalia chebula*)

Bilva (*Aegle marmelos*)

Amra (*Mangifera indica*)

References

1. Ancient Science of Life, Vol No. III No. 3 January 1984, Pages 136 – 139.

2. Family Welfare Research Programme, Central Council for Research in Ayurveda & Siddha (CCRAS), Annual Report 2000-2001.

10. AYURVEDIC FORMULATIONS
For Antenatal Care

Background

Pregnancy and child birth is a joyful event in every woman's life. The growing foetus is totally dependent on its own mother in every aspect. Thus a proper antenatal care would result in a good maternal and foetal outcome. Any negligence towards her health may lead to untoward effects and thus cause maternal & foetal complications or even could be fatal.

Ayurveda has described *"Garbhini Paricharya" i.e*. antenatal care right from conception up to the birth of the baby. In Ayurveda, antenatal care comprises of Aahar (dietary regimens), Vihara (life style) and Aushadhi (medicines). In view of the potential of Ayurveda in promoting the health of pregnant women and foetus, it is high time to mainstream Ayurvedic management. The Central Council for Research in Ayurvedic Sciences, New Delhi has developed certain formulations viz. AYUSH AG Tablet, AYUSH PG Tablet, AYUSH GG Tablet and AYUSH AD candy for antenatal care to promote the health of pregnant women and foetus and to minimize the complications associated with pregnancy and mortality rate of the mother and foetus.

Drug Profile: [1]

1. AYUSH AG Tablet for Promotion of general health of woman and fetal growth

Sl. No.	Ingredient	Botanical Name	Part used
1.	Ashwagandha	*Withania somnifera* (L.) Dunal	Root
2.	Shatavari	*Asparagus racemosus* Willd.	Tuber
3.	Amalaki	*Emblica officinalis* Gaertn.	Fruit
4.	Mandur bhasma	*Calcined iron rust*	
5.	Mukta shukti Bhasma	*Calcined shell of oyster pearl*	

2. AYUSH GG tablet for Edema during pregnancy

Sl. No.	Ingredient	Botanical Name	Part used
1.	Gokshura	*Tribulus terrestris* L.	Fruit

3. AYUSH PG tablet for Pregnancy Induced Hypertension (PIH)

Sl. No.	Ingredient	Botanical Name	Part used
1.	Gokshura	*Tribulus terrestris* L.	Fruit
2.	Punarnava	*Boerhavia diffusa* L.	Whole plant

4. AYUSH AD tablet for prevention of Nausea and Vomiting during pregnancy

Sl. No.	Ingredient	Botanical Name	Part used
1.	Amalaki	*Emblica officinalis* Gaertn.	(Juice/powder of fruit)
2.	Draksha	*Vitis vinifera* L.	Fruit
3.	Ela	*Elettaria cardamomum* Maton	Seed

Safety/Toxicity profile:

1. AYUSH AG Tablet

Acute Toxicity Study: No mortality in mice was reported at graded doses of Ayush-AG (100, 200, 500, 1000 and 2000/Kg, P.O).

Sub-Acute Toxicity Study: Sub-Acute studies in 40 albino rats revealed that no significant changes in the haematology, blood biochemistry and weight of the vital organs in comparison to the control at the graded dose level of 200, 800 and 1600 mg/Kg continuous up to 15 days were observed.

2. AYUSH PG tablet

Acute Toxicity Study: No mortality in mice was reported at graded doses of Ayush-PG (100, 200, 500, 1000 and 2000/Kg, P.O).

Sub-Acute Toxicity Study:

Sub-Acute studies in 40 albino rats revealed that no significant changes in the haematology, blood biochemistry and weight of the vital organs in comparison to the control at the graded dose level of 100, 500 and 1000 mg/Kg continuous up to 15 days.

Clinical efficacy

Clinical studies to ascertain the efficacy of above four coded Ayurvedic formulations were carried out by Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Govt. of India with technical support from Indian Council of Medical Research (ICMR), Government of India in selected areas of two districts *viz.* Mandi & Kangra at Himachal Pradesh. Total 2465 participants were enrolled in the study. But data of 1746 participants was analyzed. It is observed that the mean of Hb% at baseline (1st trimester) was 9.78 ± 0.79 and 10.11± 0.77 at the end of treatment which is statistically significant

($p<0.001$). Further, significant improvement in various outcome indicators such as minimal complications during pregnancy, achievement of full term pregnancy and no still birth and neonatal death were observed in the study. It is interesting to note that birth weight of most of the baby was comparable to standard i.e. $\geq$ 2.5 kg, which indicated the effect of interventions on neonatal health.

Dosage Schedule:

A. **AYUSH PG (Pregnancy Induced Hypertension):** 1 tablet (500 mg) BD for 7 to 15 days with water

B. **AYUSH AD (Prevention of Nausea and Vomiting during pregnancy):** To be kept in mouth SOS but not more than 8 in a day.

C. **AYUSH AG Tablet (Promotion of general health of woman and fetal growth):** 1 tablet (500 mg) TDS, from 3rd month onwards of pregnancy up to post delivery – 3 months with water.

D. **AYUSH GG tablet:** 1 tablet (500 mg) BD during 6th to 8th month of pregnancy.

Some Important Ingredients

Amalaki (*Embica officinalis*)

Ashwagandha (*Withania somnifera*)

Gokshuru (*Tribulus terrestris*)

Punarnava (*Boerrhavia diffusa*)

Ela (*Elettaria cardamomum*)

Shatavari (*Asparagus racemosus*)

References

1. Feasibility of Introducing Indian Systems of Medicine (Ayurveda and Siddha) In the National Reproductive Child Health (RCH) Services at the Primary Health Care (PHC) level – Hand book for service providers.

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