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A.C.C. R.U. PARMAR NOTARY WAGHODIA.

NOTARY * NOTARIAL * RAVJIBHAI U. PARMAR Area : Ta. Waghodia, Dist. Vadodara. Reg. No. 953/2009 * GOVT. OF GUJARAT (INDIA)

NOTARY * NOTARIAL * Name : RAVJIBHAI U. PARMAR Area : Ta. Waghodia, Dist. Vadodara. Reg. No. 953/2009 * GOVT. OF GUJARAT (INDIA)

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Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

Memorandum of Understanding

This Memorandum of Understanding (MOU) is made and executed at Mumbai on this 27th Day of August 2021, between Shree Dhootapapeshwar Limited, a Company incorporated under the Companies Act, 1956, having its registered office at 135, Nanubhai Desai Road, Khetwadi, Mumbai – 400004, hereinafter referred to and called as "SPONSOR",

And

1. Parul Institute of Ayurved, Faculty of Ayurved, Parul University, At & Po - Limda, Taluka- Waghodia, District - Vadodara, Gujarat, Pin code – 391760,

2. Parul Institute of Ayurved and Research, Faculty of Ayurved, Parul University, At & Po - Ishwarpura, Taluka- Waghodia, District - Vadodara, Gujarat, Pin code – 391760,

Hereinafter referred to and called as "INSTITUTE" and has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurved and Ayurvedic Drugs.

WHEREAS, the SPONSOR is an Ayurved company involved in research, development, manufacture and sale of medicines for use in humans.

WHEREAS, the SPONSOR contacted the INSTITUTE to provide formulation development & pharmacological study support.

WHEREAS, the SPONSOR and INSTITUTE are concerned with the diagnosis, treatment and prevention of disease and/or clinical research for the improvement of healthcare;

The Parties represent and warrant that they each have the authority to enter into this MOU. In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into this Collaborative Research Project MOU.

PROTOCOLS

The scope and nature of the Projects to be performed will be in accordance with the protocol agreed between the SPONSOR and INSTITUTE. "Protocol" means the document signed by the Authorised Representative of the INSTITUTE, detailing all aspects of the collaborative research project. This protocol fully details the study activities and responsibilities to be undertaken.

OBLIGATIONS

INSTITUTE and the SPONSOR agree to provide the aforestated Protocols as per **ANNEXURE I (IA & IB)** accompanied by services referred above at the onset for the following research projects of the SPONSOR:

IA. Clinical evaluation on the effect of Abhraloha in the management of Iron Deficiency Anemia.

IB. Clinical trial on role of Asthiposhak Tablets in Premenstrual Syndrome (PMS).

INSTITUTE shall prepare final report in writing and publication of the manuscript based on the data generated.

The SPONSOR shall be responsible for providing the funds required for the Projects as per **ANNEXURE II (IIA & IIB)** as mutually agreed between the parties.

PAYMENT

Total cost of the Projects would be as agreed upon by both the parties. Payment shall be made by the SPONSOR to the INSTITUTE in the favour of: 1. Parul University (IEC Fee - Parul Institute of Ayurved), 2. Parul Institute of Ayurved Research (IEC Fee - Parul Institute of Ayurved and Research) & 3. R and D Centre Unit of Parul University by cheque or DD or NEFT payable at Mumbai, against the invoice raised by the INSTITUTE.

CONFIDENTIAL INFORMATION

In consideration of the mutual promises and MOU contained herein, the sufficiency of which are hereby acknowledged by both parties, it is hereby agreed as follows:

a. The Parties agree to adhere to the principles of confidentiality during the term of this MOU as well after the conclusion of the same.

b. The INSTITUTE further undertakes to treat as strictly confidential and not to disclose to any third party, any Confidential Information of the SPONSOR.

c. The INSTITUTE undertakes not to make use of any Confidential Information of the SPONSOR, other than in accordance with this MOU, without the prior written consent of the SPONSOR.

d. In consideration of this potential access to confidential materials, INSTITUTE agrees that INSTITUTE including its employees, students and associates shall hold and keep secret all such information about the SPONSOR or the SPONSOR's Client List.

PUBLICATIONS & PRESENTATIONS

It is the intent of the parties that no publication shall contain any of confidential information disclosed by SPONSOR without SPONSOR's prior written permission.

No data shall be published in any scientific or non-scientific journal, newspaper or any other mass-media source in or out of India without prior written consent from SPONSOR.

ASSIGNMENT TO OTHER PARTIES

The parties hereto shall not transfer or assign any of their rights and obligations under this MOU to any other party without obtaining prior consent in writing from the SPONSOR.

TERM / DURATION OF MOU

This MOU shall be initially valid for a period of one year from the date of signing of this MOU and the confidentiality clause agreed to between the parties shall survive after the cessation of duration or termination of MOU. The Parties may extend the term of this MOU for additional periods as desired under mutually agreeable terms and conditions which shall be reduced to writing and signed by the Parties.

INTELLECTUAL PROPERTY AND COMMERCIAL RIGHTS

Intellectual property rights for the Project such as title to all inventions, discovery, development or other intellectual property, including not limited to copyrights, patents, shall reside with the SPONSOR. The INSTITUTE shall not hold any intellectual, commercial, or marketing rights of the Projects. These shall lie solely with the SPONSOR alone.

OBLIGATIONS OF THE INSTITUTE

i. The INSTITUTE accepts and signs the terms and conditions for the study provided by the SPONSOR.

ii. The INSTITUTE shall be responsible for all commitments from the INSTITUTE, communicated to the SPONSOR, in writing.

iii. The documentation and interpretation shall be in tune with the requirements of the project.

iv. The project coordinator/s and the Principal Investigator are responsible for secrecy and confidentiality of the process and materials used in the project. This MOU also acts as Non- Disclosure" arrangement of the project details for perpetual period.

TERMINATION

This MOU commences on the Effective Date and shall continue in force for one year but may be terminated:

i) If the INSTITUTE defaults on any material term of this MOU,

ii) Adherence to the protocol is poor or data recording is chronically inaccurate or incomplete.

However, The SPONSOR shall be at liberty to terminate the MOU by giving one month advanced written notice to the INSTITUTE, without assigning any reason.

The INSTITUTE may terminate this MOU prior to completion of the Project by written notification upon SPONSOR's material default of its/their obligations hereunder; provided that the INSTITUTE shall allow the SPONSOR thirty (30) days from the date of notification to cure such default.

In event of termination of this MOU at the instance of the INSTITUTE or due to INSTITUTE's defaulting of any material term of this MOU or non-adherence of the protocol, the SPONSOR shall not liable to pay any compensation or damage to the INSTITUTE. However, if the SPONSOR on its own accord terminates the MOU for other reasons not attributable to the performance of the INSTITUTE, the SPONSOR agrees to compensate the INSTITUTE on proportionate basis after evaluating the projects.

At close-out of the project/s following termination or expiration of this MOU the Parties shall upon request immediately deliver to the other Party all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes. Termination of this MOU will be without prejudice to the accrued rights and liabilities of the Parties under this MOU.

MISCELLANEOUS

This MOU shall be binding upon the parties, their legal representatives, successors and assignees; may not be amended except by written instrument signed by the parties. Nothing shall be construed as creating a joint venture, partnership or contract of employment between the Parties.

ARBITRATION, APPLICABLE LAW AND JURISDICTION

i) Any disputes between the parties shall be resolved by mutual discussions. Unresolved disputes, if any, shall be subjected to Arbitration under the Arbitration and Conciliation Act, 1996 wherein each Party can appoint one Arbitrator and the two Arbitrators will thereupon decide Presiding Arbitrator. The venue of arbitration shall be Mumbai. The decision of the arbitrator shall be binding on both parties.

ii) This MOU shall be governed by the Laws of India and subject to the jurisdiction of Courts in Mumbai.

iii) This MOU supersedes all other representations, understandings or communication whether written or verbal, with respect to the subject matter hereof.

In witness whereof, the parties hereto have executed this MOU by their duly authorized representatives.

Read and Understood:

SPONSOR

Ranjit Puranik
Managing Director
Shree Dhootapapeshwar Limited
135 Nanubhai Desai Road. Khetwadi
Mumbai – 400004.

INSTITUTE

Dr. Hemant Toshikhane
Dean & Principal, Parul Institute of Ayurved
Faculty of Ayurved,Parul University,
At & Po - Limda,
Taluka- Waghodia, District - Vadodara,
Gujarat, Pincode – 391760

Dr. Bhagawan G Kulkarni
Principal, Parul Institute of Ayurved and Research,
Parul University, AP Iswarpura, Tal – Waghodia,
Vadodara, Gujarat 391760

Witnesses:

1. Dr Mukesh B Chawda
   Senior Manager - Medical Services
   Solumiks Herbaceuticals Limited
   135 Nanubhai Desai Road
   Khetwadi, Mumbai - 400 004.

2. Mr Vijay Zagde
   Manager - Accounts
   Solumiks Herbaceuticals Limited
   135 Nanubhai Desai Road
   Khetwadi, Mumbai - 400 004.

3. Dr. Shailesh Vinayak Deshpande
   Professor, Department of Kayachikitsa,
   Parul Institute of Ayurved, Parul University,
   AP Limda, Tal – Waghodia,
   Vadodara, Gujarat 391760

4. Dr. Akshar Ashok Kulkarni,
   Associate Professor, Department of Kriya Sharir,
   Parul Institute of Ayurved and Research,
   AP Ishwarpura, Tal – Waghodia, Vadodara
   Gujarat 391760

NOTARY
Name: RAVJIBHAI U. PARMAR
Area: Waghodia,
Dist. Vadodara.
Reg. No. 953/2009
GOVT. OF GUJARAT (INDIA)

ATTESTED
RAVJIBHAI U. PARMAR
NOTARY (Govt. of Gujarat)

Annexure IA

Clinical Study Protocol

Protocol title: Evaluation of efficacy and tolerability of Abhraloha tablets in iron deficiency anaemia – Phase IV study

Name and address of the sponsor: Shree Dhootapapeshwar Limited,
135 Nanubhai Desai Road, Khetwadi,
Mumbai - 400 004

Principal Investigator (PI)

1) **Dr. Naresh Kore, Professor**
Department of Kayachikitsa, Parul Intitute of Ayurved & Research, Parul University
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Co-investigator(s)

1) **Dr. Manu Rajgopal, Assosciate Professor,**
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2) **Dr. Shriniwas Jadhav, Assistant Professor,**
Department of Prasutitantra & Strirog, Parul Intitute of Ayurved, Parul University.
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9945070999
3) **Dr. Nisha Munishwar, Assistant Professor,**
Department of Kayachikitsa, Parul Intitute of Ayurved and Research, Parul University.
nisha.munishwar@paruluniversity.ac.in
9130642840

Trial site(s):

- Site 1: Parul Institute of Ayurved, Parul University, AP Limda, Tal Waghodia, Vadodara, Gujarat 390019
- Site 2: Parul Institute of Ayurved and Research, Parul University, AP Ishwarpura, Tal Waghodia, Vadodara, Gujarat 390019

Clinical laboratory:

Site 1: Central Laboratory, Parul Ayurved Hospital, Parul University, AP Limda, Tal Waghodia, Vadodara, Gujarat 390019

Site 2: Central Laboratory, Parul Institute of Ayurved and Research, Parul University, AP Ishwarpura, Tal Waghodia, Vadodara, Gujarat 390019

Background Information

Anemia is a condition in which number of RBC becomes insufficient consequently decreased ability of blood to carry oxygen to meet physiological needs of cell. The World Health Organization (WHO) describes iron-deficiency anemia as "the most common and widespread nutritional deficiency in

the world." Prevalence of Anaemia is increasing in India and assessing the severity of the problem, it has been even included in the thrust area of health sectors governed by WHO and Ministry of AYUSH, Govt of India. Haemoglobin concentration lower than 12g/dL in women and 13g/dL in men is considered as Anemia. Prevalence of anemia is more in women and children. About 30 % world populations are anemic All over India, 70% population are anemic. In Gujarat and Vadodara, prevalence rate is 55.3% and 49.2% respectively.

Objectives:

Primary Objective

- To evaluate the efficacy of Abhraloha in Iron Deficiency Anemia on the basis of haemoglobin percentage.

Secondary Objective:

- To evaluate the efficacy of Abhraloha in Iron Deficiency Anemia on the basis of haemogram.
- To evaluate the efficacy of Abhraloha in Iron Deficiency Anemia on the basis of subjective parameters.
- To evaluate the tolerability of Abhraloha in Iron Deficiency Anemia on the basis of adverse events.

Study Design: A multi-centric, prospective, Phase IV study study.
Dose of drug: 2 tablets two times a day with lukewarm water after food for 2 months
Total duration of study is 12 months.

Treatment duration is 2 months. There will be total 5 follow-ups during study which will be scheduled on every 15+-5 days.

Subjective criteria:

- *Shrama* (fatigue)
- *Vaivarnata* (pallor)
- *Daurbalyata* (weakness)
- *Shotha* (edema)

Hridayaspandana (palpitation)
Shwasa (dyspnoea)
Kopana or *Adhirata* (irritability)

Grading of above clinical features	
Grade	**Score**
No clinical feature/symptom	0 □
Mild clinical feature/symptom	1 □
Moderate clinical feature/symptom	2 □
Severe clinical feature/symptom	3 □

Diagnostic criteria: Haemoglobin between 7 to 10 gm%

Selection Criteria:

- Every patient coming in OPD of respective hospitals will be screened for diagnostic criteria. Subjects fulfilling the diagnostic criteria will be included in trial.

Inclusion Criteria:

- Patients ready to give informed consent.
- Patients of either gender between 18 to 50 years.
- Patients fulfilling diagnostic criteria.

Exclusion Criteria:

- Anemia other than Iron deficiency.
- IDA Thalassemia, Myelodysplastic syndrome, Co-existing infection, Inflammation etc.
- IDA serious Hepatic, Renal, Pulmonary disease, malignancy etc.
- Patients receiving treatment with any other hematinic drug or multivitamins will be excluded from study.
- Pregnant and Lactating Woman
- Past history of hypersensitivity to any of the ingredients of study medicine.

Withdrawal criteria:

- Patient not giving follow-up on 2 consecutive scheduled visit.
- Patient suffers from any adverse event during study period which is detrimental for study.
- If patients haemoglobin not increasing by 1 gm% after taking Abhraloha for 1 month.

Plan of study:

1. After informed consent process every patient between the age group of 18 to 50 years will be made to undergo Haemoglobin % investigation.
2. Patients fulfilling the diagnostic criteria of Iron deficiency anemia will be selected. Further blood sample will be taken for peripheral smear and complete blood count.
3. Detailed history of the patient will be taken and later subjected for physical examination and it will be recorded in specially formed case report form.
4. Tab. Albendazole 400 mg will be given as a single dose for deworming a day before starting study medicine.
5. Tab Abhraloha will be given to patient for 15days. Patient will be called for follow up every 15+-5 days till completion of 2 months.
6. Data will be collected, analyzed and final conclusion will be drawn after completion of study.

Criteria of Assessment:

EFFECT OF THERAPY ON	ASSESSMENT DURATION
1) Haemoglobin %	Monthly
2) Peripheral Smear	Monthly
3) Haemogram	Before and after treatment

4)	Subjective parameters	At each follow up

Study End Points:

- Primary end point : Mean change in Hb %
- Secondary end point: Safety assessed by incidence of adverse events and any abnormal laboratory parameters during the study duration.

Treatment of Subjects:

2 tablets of Abhraloha will be given to the patients orally for the duration of three months thrice in a day with lukewarm water after food. The follow-up will be scheduled on every 15+-5 days.

Concomitant Medications:

- Medications or treatments received by patient for treatment of condition other than Iron deficiency anemia will be documented in case report form.

Statistics:

Statistical analysis will be done by applying appropriate tests.
Chi-square test will be applied to assess overall efficacy of Abhraloha

Ethics Description of ethical considerations relating to the trial: Ethical clearance will be taken from both institutions that is Parul institute of Ayurveda and Parul institute of Ayurveda and Research. CTRI registration will be done for the study.

Data Handling and Record Keeping: Data of the study will be maintained for 5 years at the study site after completion of the trial.

Insurance Financing: Study will be covered under clinical trial liability insurance scheme. The sponsorer bares the responsibilities of providing copy of insurance policy that is available with the sponsorer and that covers the proposed trial.

Publication Policy: The outcome of the study will be published in SCOPUS/PUBMED Indexed Journal and authorship will be shared among sponsorer, principle investigator and Co-investigators.Publication cost will be borne by the sponsorer.

Annexure IB

Open labeled Interventional clinical trial to evaluate effect of Asthiposhak Vati Tablet in the management of Premenstrual Syndrome (PMS)

Site 1-

Principal Investigator: DrKomal Patel, PSH, PU, Vadodara

Investigator – Dr. ManjushaKarkare, Prof. &H.O.D, Dept of PTSR, PIA, PU, Vadodara.

Co -Investigator: Dr. Asokan V

Site 2-

Principal Investigator: DrKomal Patel, PSH, PU, Vadodara

Investigator: Dr. Mauli Vaishnav, Assistant Professor, PIAR

Open labelled, Interventional Clinical trial to evaluate effect of AsthiposhakVati Tablet in the management of Premenstrual Syndrome (PMS)

The methodology intended for the study is as per the Consolidated Standards of Reporting Trials (CONSORT) statement 2010.The clinical trial was designed to assess the efficacy of Proprietary Ayurveda medicine *"AsthiposhakVati"* Tabletsin Pre-Menstrual Syndrome.

Introduction: Premenstrual syndrome is recognized as a psycho-neuro-endocrine disorder of unknown etiology. In the current era, an American gynaecologist, T. Frank, characterized the syndrome in 1931, but the term PMS was first coined in 1953. Although many women experience some discomfort, these premenstrual changes do not disrupt their daily routine. Premenstrual syndrome (PMS) encompasses a variety of emotional and physical symptoms that occur from several days to weeks before the onset of menstrual flow. They include debilitating mood and behavioural changes, in the week preceding menstruation. These symptoms if left untreated may lead to PMDD-Pre-Menstrual Dysphoric Disease which is a more severe form of manifestation of the symptoms related to PMS and may have disastrous effects in the form of suicidal thoughts, panic disorders, lack of interest in daily activities and relationships. This may have grave consequences on the socio-economic aspect of life thereby reducing the quality of life of the patient.

Various hypotheses are postulated to understand the etiopathogenesis of the PMS and PMDD as:

- Diminished progesterone levels
- Decreased synthesis of serotonin
- Withdrawal of endorphins from the brain during luteal phase
- Reduced Gama amino butyric acid levels

Ayurveda aims at holistic approach in the management of any disease, and so here the proprietary medicine *AsthiposhakVati* tablet is selected for the management of PMS, in the reproductive group which may have a positive effect on Calcium metabolism and thus may alter the pathology of PMS. The Tridosha Shamana effect of the adjuvants of the formulation may also aid in breaking the pathology of PMS at psychosomatic level.

Aim: the clinical trial aims to evaluate the efficacy of *AsthiposhakVati* tablet in the management of Pre-Menstrual Syndrome (PMS).

Objective:

PrimaryObjective: Is to evaluate the clinical efficacy of *AsthiposhakVati*Tablet in the management of PMS.

SecondaryObjective:

- ✓Is to evaluate the add on benefits of the intervention in management of Calcium deficiency related symptoms in the subjects of PMS.
- ✓To assess the improvement in the quality of life in young adult females.

Null Hypothesis:

Proprietary Ayurveda medicine *AsthiposhakVati* Tablet is not effective in the management of PMS.

Alternate Hypothesis:

Proprietary Ayurveda medicine *AsthiposhakVati* Tablet is effective in the management of PMS.

Study Design:

Open labelled, Interventional, Multi-centric, Phase IV,Clinical trial to evaluate effect of*AsthiposhakVati*Tabletin the management of PMS with appropriate arrangements for withdrawals.

Intervention: Asthiposhakvati

Dosage: 2 Tab. Twice daily after food.

Anupana: Sukhoshnajala/ Milk

Duration: 2 Months

Settings:

Women with PMS will be surveyed screened and diagnosed with standard diagnostic parameters and selected from Out-patient Department of PrasutiTantra and StreeRoga, Parul Ayurveda Hospital, Vadodara as well as ParulSevashram Hospital and Parul Hospital for Ayurveda and Research, Ishwerpura.

Source/s of monitory and material support:

- **Funding and Legal Support**: SDL Pvt. Ltd. Mumbai
- **Infrastructure, HR, Technical and Settings**: ParulAyurveda Hospital,ParulSevashram Hospital, Parul University, Vadodara, Gujarat.

Inclusion Criteria:

1. Subjects irrespective of their marital status aged between 18–35years.
2. Women with regular cycle with symptoms of pre- menstrual syndrome, at around 25th day onwards of menstrual cycle, with symptoms extending not beyond 5th day of subsequent menstrual cycle, having a minimum PMTS score >/=10 and VAS score.>/=1
3. Be able and willing, in the view of the investigator, to comply with all study procedures

Exclusion criteria:

1. Subjects aged above 35years
2. Unmarried or married subjects with irregular cycles more than 60 days interval
3. Pregnant women
4. Subjects on any type of OC Pills, hormone containing medication since past 6 months, IUCD, ovulation induction or menstrual regularizers-since past 6 months
5. Subjects with chronic debilitating ailments and on cortico-steroid therapy.
6. Women with history of PID, endometriosis and debilitating pathological conditions of the pelvic organs, systemic diseases like diabetes mellitus, bronchial asthma, tuberculosis, thyroid dysfunction, with organic lesion (benign or malignant growth of reproductive tract), any degree of uterine prolapse and hypo-plastic uterus.
7. Women with congenital anomalies of genital organs.
8. Subjects with history of or diagnosed cases of psychosomatic ailments, Cognitive disorders, psychosis or neurosis, personality disorders.
9. Women taking any concomitant medicine for PMS will be excluded from the study.

Subjects fulfilling the criteria of diagnosis and inclusion will be incorporated in this trail and subjected to thorough screening, history taking and physical examination.

Laboratory Investigations:

The following investigations will be carried out on all subjects Before trial and after trial in order to rule out other systemic illness and to assess the impact of the intervention.

- ✓ Routine haematological: CBC, RBS, Serum Calcium level
- ✓ Urine Routine and microscopy
- ✓ Ultra-Sonography: TVS / TAS USG- Abdomen and Pelvis
- ✓ Serum calcium levels

Details of History andExamination will be recorded in a specially designed Case Proforma.

TargetSample Size (n): Minimum 30

Drug review

*AsthiposhakVati*tablet is proprietary Ayurvedic medicine manufactured by SDL Pvt. Ltd. Mumbai. It is used in the premenstrual syndromes, Peri-menopausal and post-menopausal health ailments of women due to degenerative disorders related to bone and integumentary systems. It relieves the mood swings, abdominal cramps and body aches during PMS. It is a comprehensive formula in the management of premenstrual syndrome.*AsthiposhakVati* is also useful in menopause related disorders osteoporosis, osteo arthritis, calcium deficiency during pregnancy and lactation, premature greying of hair, which is a good source of calcium, anti-inflammation, when patient has body aches and muscular pain.

Benefits ofAsthiposhakVati

- ✓ Balances the Tridosha functions in body
- ✓ Decreases uterine spasm
- ✓ Relieves the pain during menstruation
- ✓ Ease the menstrual flow
- ✓ Reduces the stress and mood swings
- ✓ Supplements the natural calcium
- ✓ Reduces the hairloss
- ✓ Premature Greying of Hairs
- ✓ Anxiety related to PMS

Indication

- ✓ Premenstrual syndrome

- ✓ Debility, Mood swings
- ✓ Hairloss
- ✓ Calcium deficiency
- ✓ Joint pains
- ✓ Body aches
- ✓ Water retention symptom like swelling, Puffiness

Each coated tablet contains extracts of

Sl.No	Drug	Bot. Name	Proportion	Parts used
1.	KukkutandaTwakBhasma	Egg Shell Calx	100mg	Shell
2.	Asthisrunkhala	*Cissusquadrangularis*	100mg	Stem
3.	Arjuna	*Terminaliaarjuna*	50 mg	Bark
4.	SuddhaLaksha	*Lacciferlacca*	50mg	Gum resin
5.	Amalaki	*EmbelicaOfficinalis*	50mg	Fruit pulp
6.	Ashwagandha	*Withaniasomnifera*	50mg	Root
7.	Guduchi	*Tinosporacordifolia*	50mg	Stem
8.	SuddhaGuggulu	*Commiphoramukul*	50 mg	Gum Resin
9.	Bala	*Sidacordifolia*	50mg	Root
10.	BaboolaKwatha	Decoction of *Acacia arabica*	QS	Bark

Dosage: 2 Tab. Twice daily after food.

Anupana: Sukhoshnajala/ Milk

Duration: 2 Months

Side effects

- Stomach upset
- Nausea
- Acute toxicity

Ethical Clearance: Ethical clearance will be obtained from Institutional Ethics Committee of Parul Institute of Ayurved, Parul University, before enrolment of the first subject.

Registration: The trial will be registered with Clinical Trial Registry of India prospectively (CTRI; www.ctri.nic.in).

Informed Consent: An informed written consent will be obtained from all enrolled subjects. The consent form will be prepared in bilingual form in accordance with the guidelines of WHO Research Ethics Review Committee (ERC). This consent form has two components:

- Patient information Sheet and
- Certificate of Consent (Signed by the subject, will be attached with the research proforma)

Outcome Measurements:/Criteria of Assessment:

Patients will be assessed for relief using the following scales which have been mentioned in the annexure.

1. PMS VAS scale
2. PMS observer rating scale
3. PMSm self rating scale

Primary Outcomes:

- Improvement in the clinical features and relief of PMS
- Relief in pain in pre-menstrual period
- Improvements in low back ache, constipation
- Improvement in mood swings and other related disorders

Time Points: The outcomes will be measured after screening at Base Line (BT) and at the end of 2 months (AT).

Withdrawal Criteria: Subjects who develop any other serious disorders or adverse events due to interventions in the study will be withdrawn from the trial and referred to competent centres for management.

Rescue Medications: Subjects developing any serious events interim to the study will be advised suitable rescue medications. For minor complaints regular medicines from the institutional hospital will be advised.

The total effect of the therapy will be assessed considering to the overall improvement in signs and symptoms. For this purpose, following categories will be maintained.

Criteria for the assessment of overall effect of the therapies:

The 3 scales mentioned above and included in the Annexure will be used for the purpose of assessing relief.

Statistical Design:

The data generated will be analysed using suitable statistical tests

Levels of Significance: p values of

≤ 0.001 Statistically Highly significant

≥ 0.002 to ≤ 0.04 Statistically Significant

≥ 0.05 Statistically Non significant

Price Chart:

Sl.No.	Particulars	Price /Tests
1	CBC	Rs.200 x 2 =400/Subject
2	S.Calcium	Rs.200x2=400/subject
2	Urine Routine	Rs.100 x 2 =200/ subject
3	USG	Rs.500 x2=1000/ subject
Grand Total		**Rs.2000.00/Subject**

Legal Notification: We solicit a written undertaking from manufacturers for the safety profile of the trial drug on humans.

References:

1.DCdutta's textbook of Gynecology, Hiralalkonar, 6th edition pg no. 182,183

2www.medicinenet.com/script Premenstrual syndrome (PMS), Melissa Conrad Stoppler: medicine net inc.,1996-2017.

3Bharati Sharma, SubhashAharma et all; Ayurvedic concept of Premenstrual syndrome with special reference to PittavrittaVyanaVayu; IJPAR-Vol5, Issue 6;June 2017, page 96-100

4. AshaSwarup, Umadevi K et all; Evaluation of Evecare in the management of dysmenorrhoea and premenstrual syndrome;Obs and GynaeTodat (1998)(III),6, 369

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ANNEXURE IIA

Budget for Clinical evaluation on the effect of Abhraloha in the management of Iron Deficiency Anemia

No.	Expenditure Head	Total Expenditure (Rs.)
1	EC Review Fees.	10000.00
2	Investigator Charges	30000.00
3	Co-Investigator Charges	30000.00
4	Research Associate Charges	10000.00
5	Lab Investigations	108000.00
6	Institutional Charges	15000.00
	Total	**203000.00**
	Installment 1 (25% at Study Initiation)	**60000.00**
	Installment 2 (25% on receipt of Interim Report)	**50000.00**
	Installment 3 (Balance 50% after receipt of Final Report)	**93000.00**

ANNEXURE IIB

Budget for Asthiposhak Tablet Clinical Trial

No.	Expenditure Head	Total Expenditure (Rs.)
1	EC Review Fees.	10000.00
2	Investigator Charges	30000.00
3	Co-Investigator Charges	30000.00
4	Research Associate Charges	10000.00
5	Lab Investigations	36000.00
6	Institutional Charges	15000.00
	Total	**131000.00**
	Installment 1 (25% at Study Initiation)	**42000.00**
	Installment 2 (25% on receipt of Interim Report)	**31000.00**
	Installment 3 (Balance 50% after receipt of Final Report)	**58000.00**