

Formulation and Evaluation of Polyherbal Dark Compound containing Ashwagandha, Lodhra, Shatavari, Amla Extract for the Management of Dysmenorrhea

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Abstract: Dysmenorrhea affects a significant number of women, leading to pain and discomfort during menstruation. This study aimed to develop a functional dark chocolate formulation incorporating herbal extracts known for their benefits in women's reproductive health. Ashwagandha (*Withania somnifera*) was included for its anti-inflammatory and adaptogenic effects, Shatavari (*Asparagus racemosus*) for hormonal support, Lodhra (*Symplocos racemosa*) for its uterine tonic properties, and Amla (*Emblica officinalis*) for its antioxidant action. The extracts were obtained via Soxhlet extraction and incorporated into both dark and white compound chocolate bases. The dark compound was evaluated for organoleptic properties, weight variation, DSC, viscosity, stability, and presence of fat and sugar bloom.

The final formulation showed good stability, acceptable sensory attributes, and no significant degradation over time. The study demonstrates a novel, consumer-friendly approach to herbal therapy for dysmenorrhea, combining traditional Ayurvedic herbs with modern food delivery systems.

Keywords - Dysmenorrhoea, Ashwagandha, Lodhra, Shatavari, Amla, Menstrual Health, Dark compound

INTRODUCTION

The term dysmenorrhea is a compound of the ancient Greek words "Dys" (meaning unpleasant or painful) and "menorrhoea" (meaning menstruation) ⁽¹⁾. In most cases, symptoms subside after three days. Most often, the lower abdomen or pelvis hurts. It is a gynaecological licit disorder that affects 45–95 percent of women of various ages ⁽²⁾. The World Health Organisation conducted a comprehensive assessment in 2006 and found that between 17 and 81% of women had dysmenorrhea. Only 12 to 14% of cases had severe dysmenorrhea diagnosed ⁽³⁾

TREATMENT

Young women typically favour self-care for pain management. This can involve heat therapy, physical activity, psychological techniques, or the use of analgesic drugs like paracetamol and Ibuprofen ^(4,5). Pharmacological treatments for pain include NSAIDs, analgesics, selective COX-2 inhibitors, and oral contraceptives; however, they are not especially designed to treat dysmenorrhea. These drugs provide pain relief by acting via several methods. NSAID side effects include tiredness, headaches, and acid reflux ^(6,7). Morning sickness, vomiting, headaches, chest soreness, and weight fluctuations are just a few of the negative effects of oral contraceptives ⁽⁸⁾

Herbal Treatment for Dysmenorrhea

Menstrual pain and related symptoms can be effectively treated with herbal medications. Many dietary supplements have antispasmodic, anti-inflammatory, and nutritional properties that function in different ways. The mechanism of action of herbs for dysmenorrhea treatment is to stop prostaglandin production. Several herbs work by lowering inflammation and muscular spasms or by blocking the formation of prostaglandins when used to treat dysmenorrhea ^(9,10). Ayurvedic Herbs such as Ashwagandha, Shatavari, Lodhra, and Amla have been revered for their therapeutic potential in managing gynaecological disorders.

Introduction of Drug

1) Ashwagandha (*Withania Somnifera*): In Ayurvedic and indigenous medicine, ashwagandha is a significant herb that has been utilised as an antioxidant, antistress, anti-inflammatory,

adaptogen, hormone-modulating, and immunomodulatory⁽¹¹⁾. Ashwagandha is known for its adaptogenic properties and has been shown to reduce cortisol levels, thereby helping the body manage stress effectively.

Chemical components: *Withania somnifera* contains 35 synthesised compounds, the most abundant of which is withanine. It has alkaloids and withanolides, such as withaferin A, alkaloids, somniferine, somniferinine, withananine, pseudo-withanine, and tropine⁽¹²⁾

Botanical Name: *Withania somnifera*

Family: Solanaceae

Part Used: Root



Fig. 1. Ashwagandha Roots

2) Shatavari: The *racemosus asparagus* plant has been the subject of numerous studies to determine its medicinal and therapeutic use, like reproductive health, anti-inflammatory and anti-oxidant, and immunomodulatory. Shatavari is also called “Queen of Herbs”.

Reproductive Effect: It is used to treat reproductive problems in women, such as irregular menstrual cycles, endometriosis, dysmenorrhea, uterine bleeding, amenorrhoea, sexual weakness, dysfunction, menopause, and pelvic inflammatory diseases like sexual dysfunction. It has been used as a uterine tonic for PMS since ancient times; as a result, it causes uterine prolapse and strengthens, nourishes, and cleanses the uterus. It improves the uterine wall's ability to contract during foetal development and eradicates infertility, so Balances the hormone levels, preventing miscarriages and promoting lactation.

Chemical Constituents: Saponins, Alkaloids, Flavonoids. Because *A. racemosus* contains saponins that prevent the oxytocic action on the uterine musculature, it maintains unrestricted uterine

motility, confirming its usefulness in treating dysmenorrhea, which includes painful periods without significant pelvic anatomy⁽¹³⁾

Botanical Name: *Asparagus racemosus*

Family: Liliaceae

Part Used: Root



Fig.2. Shatavari Roots

3. Lodhra: It is an evergreen member of the *Symplocaceae* family. Lodhra is used in Ayurvedic medicine. This popular herbal remedy is primarily used to treat gynaecological conditions. It helps reduce uterine inflammation and menorrhoea, and leucorrhea by relaxing the uterine tissue. Its decoction is used to treat uterine diseases.

Menstrual cramps can be relieved by the antispasmodic, anti-inflammatory, and mildly oestrogenic properties of this herb. This also aids in the alleviation of PMS symptoms such as bloating, nausea, breast tenderness, and mood swings. It is known to be a herb that naturally regulates the menstrual cycle⁽¹⁴⁾

Botanical Name: *Symplocos racemosa Roxb*

Family: Symplocaceae

Part Used: Bark



Fig.3. Lodhra Bark

4. Amla: Amla is a fantastic cholesterol-lowering and detoxifying substance. Its anti-inflammatory and free radical scavenging properties may aid in re-establishing the body's hormonal equilibrium⁽¹⁵⁾. Quercetin, phyllaemblic compounds, gallic acid,

tannins, flavonoids, pectin, vitamin C, and a variety of polyphenolic compounds are all abundant in the fruit. Numerous phytochemical constituents, such as tannins, alkaloids, flavonoids, and terpenoids, have been demonstrated to have beneficial biological properties. The fruit has been used traditionally, and numerous pharmacological studies have shown that it has anti-inflammatory, immune system support, Analgesic, and antioxidant properties ⁽¹⁶⁾

Botanical Name : *Emblica officinalis*

Family: Euphorbiaceae

Part Used: Fruit



Fig.4. Amla Fruit

NEED FOR HERBAL-BASED CHOCOLATE FORMULATION

Dark compound is the food that people love the most, while medicine is a substance that people detest. To prevent various disorders, the goal of the current study was to create medicated chocolate, or chocolate that contains drugs. As a result, we need to make the chocolate with ashwagandha and shatavari, lodhra, and amla extract to achieve the intended pharmacological effect.

Method for Preparation of Dark Compound:

Collection and Authentication: The fresh and dried Ashwagandha (Roots), Shatavari (Roots), Lodhra (Bark), Amla (Dried fruit) were collected, identified, and authenticated by MANAS AYURVEDA, Babasaheb Ghatate square, Civil Lines, Nagpur -01.

Method of Extraction of Ashwagandha:

The traditional extraction technique, Soxhlet extraction, was carried out for 3-4 days using a classical Soxhlet apparatus and precisely weighed 10g of drug powder that had been screened through a mesh number 22. The extracting solvent used for the extraction was 500 millilitres of methanol. Finally, the extract was vacuum-evaporated ⁽¹⁷⁾

Method of Extraction of Shatavari:

The roots were cleaned, allowed to dry in the shade, then chopped into tiny pieces and ground into a

coarse powder using a mechanical grinding device. For later use, the powdered substance was kept in an airtight container. A Soxhlet extractor was used to extract 10g of air-dried powdered material for 35 hours using 100% methanol. The result was a waxy, brownish residue that was solvent-free. Tests for polyphenols, flavonoids, tannins, saponins, and glycosides were all positive for the extract. Before being used, the sticky concentrated mass was dissolved in distilled water and stored in a refrigerator at 4° C ⁽¹⁸⁾

Method of Extraction of Lodhra:

S. racemosa bark was cut into tiny pieces and allowed to dry at room temperature in the shade. After being ground into a powder, the dried bark was run through a coarse sieve. Using 50 mL of 95% (V/V) ethanol, 10g of dried, powdered *Simplices racemose* bark was extracted over the course of three to four days in a Soxhlet extractor until it was completely extracted. To obtain a dark brown residue, the ethanolic extract was concentrated at 40°C. Initial phytochemical analyses revealed the presence of alkaloids, terpenoids, glycosides, carbohydrates, flavonoids, saponins, and phytosterols ⁽¹⁹⁾

Method of extraction of Amla:

10 grams of dried *Emblica* Amla fruit powder (*officinalis*) was extracted using 99% ethanol. Employing a Soxhlet device at 60 degrees Celsius for 3-4 days ⁽²⁰⁾

Method of Formulation of Herbal Dark Compound:

MATERIALS: Ashwagandha (Roots) extract, Shatavari (Roots) extract, Lodhra (Bark) extract, Amla (Fruit) extract. Chocolate base (Morde) (White & Dark Compound), vanilla essence, and Butter purchased from the local market.

Preparation of Dark Compound Formulation:

1. Collect Ashwagandha (Roots), Shatavari (Roots), Lodhra (Bark), Amla (Fruit) plant, and wash them with water to remove dirt.
2. Shield dried it naturally for 4-5 days.
3. Reduce the size into powder form by using a mortar and pestle.
4. Use the Material for extraction method.
5. Take Chocolate Base, melt it in a water bath, then add plant extract and other ingredients and mix well.
6. Transfer the mixture into the chocolate mold and freeze it for 8 to 10 hours ⁽²⁰⁾

FORMULATION TABLE

Table No.1: Formulation table

Sr. No	Ingredients	Quantity Taken		
		Batch 1	Batch 2	Batch 3
1.	Dark Compound	40 gm	43 gm	45 gm
2.	White Compound	40 gm	43gm	45gm
3.	Ashwagandha Extract	5gm	3.5gm	2.5 gm
4.	Shatavari Extract	5 gm	3.5gm	2.5 gm
5.	Lodhra Extract	5 gm	3.5gm	2.5gm
6.	Amla Extract	5gm	3.5 gm	2.5gm
7.	Vanilla Essence (Flavouring Agent)	1-2 drops	1-2 drops	1-2 drops

Evaluation of Herbal Dark Compound:

1) Organoleptic Properties:

1. Colour
2. Odour
3. Taste
4. Texture

2) Stability Studies: To determine the stability of the prepared formulation, the Dark compound was packed in aluminium foil paper and its organoleptic properties (colour, odour, taste, mouth feel, and appearance) were assessed over one month at 25/75°C (°C/RH) and 2-8°C⁽²¹⁾.

3) Moisture content determination: A desiccator was used to determine the moisture content. This test was conducted to determine how much moisture was still in the dry chocolate. The freshly made chocolate mixture was precisely weighed and stored in a desiccator with anhydrous silica gel. The formulations were removed after 24 hours, weighed, and the percentage of moisture absorption was computed using the formula

$$\% \text{Moisture} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial Weight}}$$

4) Viscosity: Using a Brookfield rotational viscometer, the viscosity was measured after the dark compound base was heated to 50 degrees Celsius and the spindle was rotated at 50 revolutions per second.

5) Weight Variation: Each of the six dark compound formulations was weighed separately and collectively. The weight of all the dark compounds was added up to determine the average weight. The average weight and the individual weights were contrasted. The weight variation's percentage difference ought to fall within the acceptable bounds. The following formula was used to determine the percent deviation:

$$[(\text{Individual weight} - \text{Average weight}) / \text{Average weight}] \times 100 \text{ is the percentage deviation}^{(22)}$$

6) Blooming test⁽²³⁾

There are two types of blooming tests of the Dark Compound

- (1) Fat bloom
- (2) Sugar bloom

7) Differential Scanning Calorimetry: The drug-excipient interaction study was carried out in the thermodynamic laboratory of the Department of Chemistry, Institute of Pharmaceutical Education & Research, Borgaon (Meghe) Wardha (M.S).

RESULT & DISCUSSION

1) Organoleptic Properties:

Sr. No.	Parameters	Observations
1.	Colour	Brown
2.	Odour	Chocolaty
3.	Taste	Sweet
4.	Texture	Smooth and

Table No.2

2) Stability Studies:

Parameter	Storage Condition	Storage Condition	At the time of Preparation	After one month
Colour, Odour, taste, Mouth feels, appearance	40 -45°C	2-8 °C	Brown, chocolaty, slightly bitter, smooth, glossy	No change

Table No.3



Fig.5. Stability After One Month

3) Moisture content Determination:

$$\% \text{ Moisture} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100$$

$$= \frac{8.04 - 7.7}{8.04} \times 100$$

$$= 4.23 \%$$

4) Viscosity:

Sr. No	Formulation Code	Viscosity of Formulation
1.	F1	58,263cps
2.	F2	61,561cps
3.	F3	60,151cps

Table no.4

5) Weight Variation;

Average weight of six chocolate formulations:

$$\frac{W1+W2+W3+W4+W5+W6}{6}$$

Average weight of six chocolate formulation: $\frac{8 + 8.04 + 8.02 + 8 + 8.03 + 8.01}{6} = 8.01$

$$\frac{8 + 8.04 + 8.02 + 8 + 8.03 + 8.01}{6} = 8.01$$

The percent deviation was calculated by using the following formula

Percentage deviation of W1 formulation:

$$= \frac{[(\text{Individual Weight} - \text{Average weight}) / \text{Average weight}] \times 100}{}$$

6) Blomming Test :

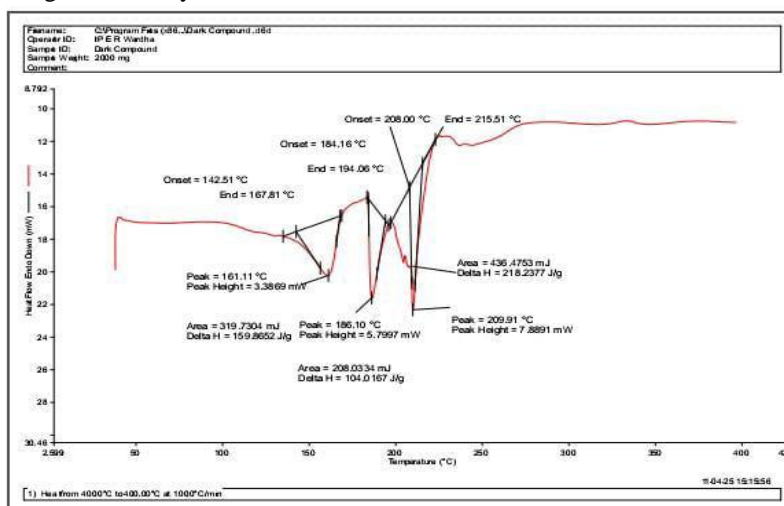


Batch II – Sugar Bloom.



Batch III – No sugar Bloom

7) Differential Scanning Calorimetry:



CONCLUSION

The formulated dark chocolate compound enriched with extracts of Ashwagandha, Shatavari, Lodhra, and Amla demonstrated good physical, sensory, and stability characteristics. The use of these herbs, known for their roles in reducing inflammation, balancing hormones, and supporting uterine health, makes the formulation a promising natural approach for the prevention and management of dysmenorrhea. The incorporation into a palatable chocolate base enhances patient acceptability and offers a novel method of herbal delivery. Further clinical evaluation is recommended to validate its therapeutic potential and support its application as a functional food for women's health. The herbs that are being used are safe to take and have no negative effects when swallowed.

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