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CrampEase: A Herbal Medicated Chocolate for Menstrual Relief

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Abstract: *The development of medicated chocolate as a functional food offers a promising approach to delivering therapeutic agents in a palatable and patient-friendly form. This study focuses on formulating a chocolate-based delivery system incorporating aqueous extracts of Vitex negundo, Cinnamomum zeylanicum, Glycyrrhiza glabra, and Zingiber officinale, known for their traditional use in alleviating menstrual cramps and associated discomfort. The formulation process involved the selection of suitable chocolate base and standardization of herbal extract concentrations to ensure uniformity, stability, and therapeutic efficacy. Physicochemical evaluations, including texture analysis, melting behaviour, extract release profile, and sensory acceptability, were conducted. The resulting medicated chocolate demonstrated desirable taste, acceptable release characteristics, and retained the bioactivity of the phytoconstituents. This innovative formulation provides a convenient and appealing alternative for the management of dysmenorrhea, potentially improving compliance and offering additional health benefits through its natural ingredients.*

Keywords: Antispasmodic, Phytotherapy, Confectionery, Muscle relaxant

I. INTRODUCTION

The menstrual cycle in women is regulated by endocrine, autocrine, and paracrine factors that control ovarian follicular development, ovulation, luteinization, luteolysis, and endometrial remodelling. While fundamental reproductive processes are shared between women and large domestic animals, differences exist in cycle characteristics, regulatory mechanisms, and research priorities. For instance, cycle irregularities and lack of ovulation are common in post pubertal adolescent women but would be unacceptable in breeding animals. Additionally, while reduced fertility during reproductive ageing is a major research focus in women, it is less relevant in domestic animals, which are typically not bred later in life.[1]

Primary dysmenorrhea (PDM), characterized by menstrual pain without pelvic abnormality, is the most common gynaecological disorder in reproductive-age individuals. PDM, experience cramping pain in the lower abdomen, which begins with menstruation and lasts for 24–72 hours. Between 20% and 90% of female adolescents have reported experiencing PDM, with 15% suffering from severe pain.[2]

The abnormal uterine activity in PDM is believed to result from excessive production of prostaglandins and leukotrienes, which mediate hyperalgesia and inflammatory pain while also causing vasoconstriction, ischemia, and myometrial contractions. Evidence suggests the presence of central sensitization in PDM, as indicated by hyperalgesia, particularly in deep tissues, throughout the menstrual cycle. Furthermore, during menstruation, hyperalgesia extends to non-referred pain areas.[3]

Primary dysmenorrhea is a common gynaecological condition characterized by painful menstruation without any visible pelvic abnormalities. It is widely recognized as the most prevalent menstrual disorder among young women. Budoff describes it as a “complex of symptoms” that primarily involves lower abdominal pain, which can extend to the lower back and upper thighs. In addition to pain, individuals may experience nausea, vomiting, headache, nervousness, fatigue, diarrhoea, and, in rare cases, dizziness or syncope. The onset of symptoms typically occurs a few hours before

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or at the beginning of menstruation and can persist for several hours, sometimes lasting up to 48 hours. This condition generally emerges 6 to 12 months after menarche, coinciding with the establishment of regular ovulatory cycles.[4]

The prevalence of dysmenorrhea tends to increase with both chronologic age and gynaecologic age during adolescence. Widholm reported that the incidence of "invariable" or "occasional" dysmenorrhea was 36.2% during the first gynaecologic year, increasing to 64.7% by the fifth gynaecologic year. Following adolescence, the incidence of dysmenorrhea appears to decrease, a trend that is presumed to be associated with the occurrence of pregnancy. However, the precise relationship between pregnancy and the reduction in dysmenorrhea remains unclear. During adolescence, the prevalence of dysmenorrhea reaches its peak, and it constitutes the most significant cause of lost working hours and school absenteeism among young women, thereby posing a considerable burden from both an individual health and a broader public health perspective.[5]

The development of new and relatively specific pharmacologic interventions for dysmenorrhea prompts an important question: has the availability of effective treatments been adequately communicated to adolescents? Historically, before research that elucidated the biochemical basis of dysmenorrhea, the understanding of the disorder was limited, and treatment options were poorly defined. In the current context, it remains essential to assess whether young women are now better informed regarding the aetiology and management of dysmenorrhea or if they, like previous generations, continue to view menstrual pain as an unavoidable condition that must be endured.

In patients who present with symptoms and physical examination findings typical of primary dysmenorrhea, empiric therapy is appropriate. There are multiple treatment options available, many of which have reasonable efficacy and safety profiles. Therefore, there is no universal, "one-size-fits-all" algorithm for the treatment of dysmenorrhea.

When choosing an initial therapy, considerations such as the patient's desire for contraception, cost, ease of use, contraindications, potential side effects, and the preferences of the patient (and possibly her family) should guide the decision.

Effective treatment requires a discussion of the risks, benefits, and alternatives of each option, with a particular focus on identifying a therapy that aligns with the patient's goals, lifestyle, and any existing medical conditions. Often, treatment begins with options that have the highest likelihood of improving symptoms. However, in some cases, less effective options may better suit the patient's needs, and combining more than one therapy can enhance overall efficacy.

Hormonal contraception and NSAIDs are generally considered first-line therapy for primary dysmenorrhea. For patients who desire contraception, it is reasonable to begin treatment with hormonal medication. Both combined oral contraceptives and progesterone-only options that reduce or eliminate menstruation are effective in alleviating symptoms of primary dysmenorrhea.

The selection of a hormonal agent should consider the patient's preference for route of administration, contraceptive effectiveness, and potential for abnormal bleeding. Additionally, personal medical history plays an important role in determining the appropriate hormonal option. For example, patients with a history of venous thromboembolism or migraine with aura should avoid oestrogen-containing therapies but may benefit from progesterone-only methods.[6]

Numerous herbs possess smooth muscle relaxant properties, making them clinically valuable for managing a broad spectrum of conditions due to the widespread presence of smooth muscle across various organ systems. Medicinal plants, in particular, are a significant source of anti-dysmenorrhoeal agents. Both mono-herbal and poly-herbal formulations have long been employed in the treatment of various disorders. It is estimated that over 700 such preparations—available as decoctions, tinctures, tablets, and capsules and derived from more than 100 different plants—are currently in clinical use. Anti-dysmenorrhoeal drugs are those that help alleviate heavy menstrual bleeding and uterine cramping.[7] Several herbal remedies have demonstrated the ability to modulate uterine muscle activity, offering natural alternatives for menstrual health management including ginger (zingiber officinale), vitex (vitex leaf), liquorice (glycyrrhiza glabra), cinnamon (Cinnamomum zelyanicum).

Ideal characteristics of chocolate for menstrual cramps:

1. It needs to be rich in flavour, with a smooth and creamy texture.
2. It needs to be made from high-quality cocoa, ensuring a balanced cocoa content for the best taste and mouthfeel.
3. It needs to be easily meltable, offering a pleasurable sensory experience when consumed.

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4. It needs to be long-lasting in shelf life.
5. It needs to be economical, offering good value while maintaining quality.
6. It needs to be effective in delivering the therapeutic benefits of herbal extracts.
7. It needs to be formulated to enhance the absorption and stability of the active herbal compounds.[8]

II. AIM AND OBJECTIVE

✓ **AIM:**

- To reduce the menstrual cramps by using the natural ingredients specially vitex by formulating the medicated chocolate with natural ingredients base.

✓ **OBJECTIVE:**

- To formulate herbal medicated chocolate by using antispasmodic herbs for effective relief from menstrual cramps.
- To evaluate the formulations physical properties and stability, while aiming to minimize side effects and adverse reactions commonly associated with synthetic antispasmodics.

III. PHYTOCHEMISTRY OF HERBS USED IN FORMULATION

1.Ginger:

Fig.1- Ginger

- **Biological source** - Ginger is derived from the dried rhizome of Zingiber officinale.
- **Family**- Zingiberaceae
- **Chemical constituents**- Gingerols, Shogaols, Zingerone, Essential Oils, Phenolic Compounds.
- **Medicinal uses** –
  - ✓ Ginger helps alleviate menstrual cramps by reducing inflammation and providing analgesic effects.
  - ✓ Ginger is effective in relieving nausea and vomiting, especially during pregnancy, providing relief from morning sickness.
  - ✓ It may help in managing symptoms related to hormonal fluctuations, such as mood swings and irritability during menstruation or menopause.

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- ✓ Ginger's anti-inflammatory properties may aid in managing symptoms of conditions like endometriosis and ovarian cysts, reducing pelvic pain and discomfort.[9]

2. Vitex:

Fig .2- Vitex

- **Biological source**- Vitex is derived from the dried leaves of Vitex Negundo Linn.
- **Family**- Lamiaceae
- **Chemical constituents**- Casticin, Chrysosplenol, Vitexicarpin, Negundoside, Vitetrifolin, Limonene.
- **Medicinal uses**-
  - ✓ Used traditionally to regulate menstrual cycles, especially in cases of irregular menstruation or dysmenorrhea.
  - ✓ Used to relieve premenstrual discomfort, mood swings, and bloating.
  - ✓ Used in some traditions to ease menopausal symptoms like hot flashes, mood swings, and insomnia due to its hormone-modulating and calming properties.
  - ✓ Additional uses are insecticidal and repellant, reduce fever, and promote faster healing of wounds and ulcers.[10]

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3. Liquorice:

Fig.3- Liquorice

- **Biological source-** Liquorice is derived from the dried roots of Glycyrrhiza glabra.
- **Family-** Fabaceae
- **Chemical constituents-** Glycyrrhizin (a saponin glycoside), Liquiritin, isoliquiritin, flavonoids, glucose, sucrose, starch, and asparagine.
- **Medicinal uses-**
  - ✓ Liquorice's estrogen-modulating effects may assist in regulating menstrual cycles and alleviating symptoms associated with hormonal imbalances.
  - ✓ The phytoestrogens in liquorice can help mitigate menopausal symptoms like hot flashes and mood swings by balancing estrogen levels.
  - ✓ Liquorice may support hormonal balance in women with PCOS, potentially reducing symptoms such as hirsutism and irregular menstruation.
  - ✓ Additionally used in cough syrups, throat lozenges, gastric and duodenal ulcers, bronchitis, sore throat and as a flavouring agent.[11]

4. Cinnamon:

Fig.4- Cinnamon

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- **Biological source**- Cinnamon is derived from the dried inner bark of Cinnamomum Zelyanicum.
- **Family**- Lauraceae
- **Chemical constituents** - Cinnamaldehyde, Eugenol, Cinnamic acid, Coumarin, Linalool.
- **Medicinal uses-**
  - ✓ It has antispasmodic and anti-inflammatory properties that help relieve cramps and discomfort during menstruation.
  - ✓ Used to treat infections such as vaginal yeast infections and other microbial imbalances in women's reproductive health.
  - ✓ Ease mood swings, anxiety, and irritability associated with menopause.
  - ✓ Additional uses are improving insulin sensitivity, reducing blood pressure, and preventing the oxidation of LDL (bad) cholesterol.[12]

TABLE I: INGREDIENTS AND THEIR ROLES

Sr. No.	Ingredients	Role
1.	Vitex agnus-casticin (Chasteberry)	Antispasmodic properties
2.	Ginger (Zingiber officinale)	Reduces gastrointestinal spasms
3.	Cinnamon (Cinnamomum verum)	Smooth muscle relaxant
4.	Liquorice (Glycyrrhiza glabra)	Soothing and spasmolytic
5.	Cocoa butter	Base and fat component
6.	Cocoa powder	Chocolate flavour and antioxidant
7.	Lecithin (soy or sunflower)	Emulsifier to blend fat and water phases

IV. MATERIALS AND METHOD

All the ingredients were obtained from Vidya Niketan College of Pharmacy, Lakhewadi laboratory except vitex, cocoa butter and cocoa powder. The vitex was obtained from lakhewadi rural area, mainly from farm and rest of two ingredients were purchased from market.

METHODS OF PREPARATION OF MEDIATED CHOCOLATE

Preformulation Procedure

1. Preparation of Herbal Powders

Crude herbal materials (Vitex, Ginger, Cinnamon, and Liquorice) were dried (if necessary) and powdered using a laboratory grinder. The powders were passed through a 60-mesh sieve to achieve uniform particle size and stored in airtight containers.

Step 1: Drying and Powdering of Herbal Ingredients

- Dry Vitex, Ginger, Cinnamon, and Liquorice roots (if not already dried).
- Grind to a **fine powder** using a laboratory grinder.
- Pass through **sieve #60** to ensure uniform particle size.

Step 2: Weighing - Accurately weigh the powders (or extracts) based on your formulation concentration (e.g., 5% w/w total herbal content).

Step 3: Preparation of Herbal Extract

All the crude herbal materials were weighed accurately and add into the 50ml distilled water.

↓

Decoction for 30 minutes

↓

Cool and store the herbal extract in air tight container at specific temperature

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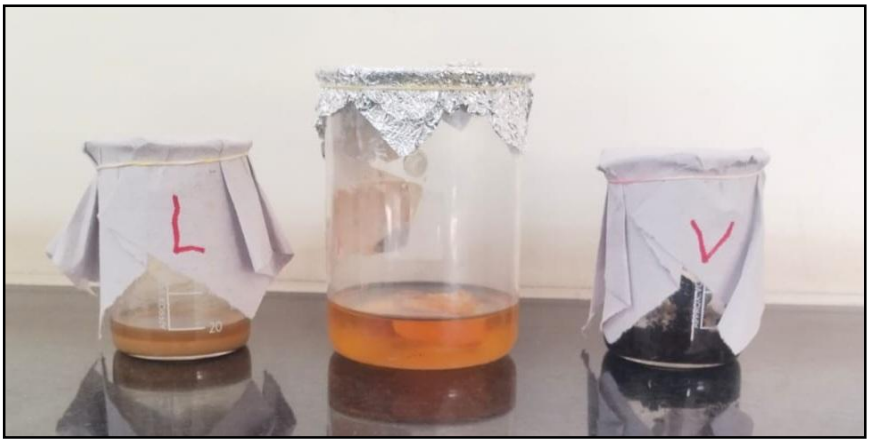

Fig.5- Extraction of Ingredients

- **Feasibility of Equipment's and Instruments:**
  - Laboratory grinder
  - Sieve (60 mesh)
  - Weighing balance (digital)
  - Water bat
  - Stainless steel beaker
  - Glass rod/spatula
  - Chocolate Molds
  - Refrigerator (4–8°C)
  - Homogenizer or magnetic stirrer

- **Formulation Procedure**

1. Chocolate Base Preparation

Fig.6- Chocolate Base

Cocoa butter was melted using a water bath at 40–45°C. Cocoa powder was then added gradually to the melted butter and stirred until a uniform mixture was obtained. Lecithin (~0.5% w/w) was added to improve emulsification and texture.

Step I: Melting the Base

- Melt **cocoa butter** in a water bath at **40–45°C**.
- Do not overheat to avoid degrading the active ingredients.

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Step II: Mixing Cocoa Components

- Once melted, add **cocoa powder** and stir until smooth and uniform.
- Add **lecithin** (~0.3–0.5% of total weight) as an emulsifier.

Cocoa butter was melted using a water bath at 40–45°C. Cocoa powder was then added gradually to the melted butter and stirred until a uniform mixture was obtained. Lecithin (~0.5% w/w) was added to improve emulsification and texture.

2. Incorporation of Herbal Drugs

Measured quantities of powdered herbal ingredients (5–10% w/w total) were slowly added to the melted chocolate base while stirring continuously to ensure even distribution. Homogenization was performed for 5 minutes using a magnetic stirrer to ensure uniformity.

3. Moulding and Solidification

The prepared mixture was poured into pre-labelled chocolate moulds. Air bubbles were removed by gently tapping the moulds. The chocolates were cooled at room temperature for 10–15 minutes and then transferred to a refrigerator at 4–8°C for 3-4 hours to solidify.

4.Cooling and Solidification

Cool at room temperature for 10–15 minutes. Then refrigerate at **4–8°C** for 1–2 hours until fully solid.

5. Packaging and Storage

The solidified medicated chocolates were demoulded and packed in aluminium foil and stored in airtight containers under cool and dry conditions for further evaluation. Once solidified, demould and store in airtight, light-resistant containers. Label appropriately with composition, dose, and storage conditions.

V. EVALUATION TEST

1) **General Appearance:**
   - **a)** The general appearance of a chocolate formulation plays a critical role in both consumer perception and manufacturing quality. It is primarily determined by evaluating the visual identity—such as colour, surface finish, uniformity, and any visible inclusions or defects. Additionally, the overall elegance or aesthetic appeal of the product is a key factor influencing consumer acceptance.
   - **b)** A visually appealing chocolate product suggests high quality and can enhance marketability. From a manufacturing standpoint, consistent appearance also reflects proper formulation, mixing, tempering, and moulding processes. Therefore, assessing the general appearance is not only important for attracting consumers but also for identifying any process-related issues during production that may affect batch uniformity or product stability.[13]

2) **Bloom Test:**
   (1) **Fat bloom** –
      (a) It is a common surface defect observed in medicated chocolate formulations, characterized by the appearance of a thin, whitish layer of fat crystals. This layer forms due to the migration and recrystallization of fats within the chocolate matrix [14]. As a result, the surface loses its characteristic glossy appearance and develops a soft, unappealing film, which diminishes the visual appeal and palatability of the product [15]. Fat bloom is often triggered by temperature fluctuations or improper storage conditions that accelerate fat movement and crystallization. To minimize the occurrence of this phenomenon, it is crucial to store the chocolate under stable and appropriate temperature conditions, which can effectively slow down the processes leading to fat bloom [14].

   (2) **Sugar Bloom-**
      (a) Sugar bloom is another common phenomenon that affects the appearance of chocolate products, including medicated formulations. Unlike fat bloom, sugar bloom occurs due to condensation, which usually takes

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place when chocolate is removed from a refrigerator and exposed to warmer air. As the temperature difference between the cold chocolate and the surrounding environment increases, moisture in the air condenses onto the surface of the chocolate. This moisture dissolves the sugar present in the chocolate, creating a liquid solution on the surface. When this moisture evaporates, the sugar recrystallizes in a rough and uneven pattern, resulting in the formation of irregular crystals on the surface. To avoid sugar bloom, it is essential to prevent condensation by storing the chocolate at a consistent temperature and keeping it away from high humidity or rapid temperature changes. Proper packaging and careful handling during transportation can also help reduce the risk of sugar bloom, preserving the product's appearance and texture. [15,16]

(b) Sugar bloom test and Fat bloom test of medicated chocolate was determined.

3) pH Determination:

(1) Digital PH Meter-

1. The pH of the formulation was assessed using a calibrated digital pH meter equipped with a glass electrode. For analysis, 2 grams of the prepared chocolate sample were accurately weighed and dissolved in 100 millilitres of phosphate buffer solution. The resulting mixture was then subjected to pH measurement under controlled conditions.

(2) pH Indicator Strip-

(a) To determine the pH of the chocolate formulation, a sample weighing 2 grams was dispersed in 100 mL of phosphate buffer and mixed thoroughly to obtain a uniform solution. A pH indicator strip was carefully dipped into the prepared mixture and held for a few seconds to ensure full contact with the liquid. Upon removal, the strip's colour was quickly compared to a standard colour chart, revealing a pH value of around 6. This suggests that the formulation maintains a mildly acidic to near-neutral pH environment.

(b) The pH of the medicated chocolate was determined by using the Digital pH Meter and pH Indicator Strip.

4) Melting Point Determination:

(1) Prepare the sample –

1. Crush the chocolate in very fine powder. Add this crushed chocolate into the test tube.

(2) Setup the Apparatus -

(a) Attach a thermometer vertically so that it deeps into the test tube without touching the bottom.
(b) Insert the thermometer – test tube assembly into the water bath.
(c) Use a Bunsen burner to gently heat the water bath and observe the melting point.
(d) Record the temperature at which the chocolate starts to melting and note the temperature when the entire chocolate sample melted and becomes a liquid.

(e) The melting point of the medicated chocolate was determined.

5) Hardness test:

i) Using a Hardness Tester (Hardness apparatus), the hardness of the chocolate was determined.

6) Stability Study:

i) Stability Studies was done according to short term stability study. The formulation was packed in aluminium foil and kept in air tight container, kept in a stability chamber at room temperature and refrigerated condition for one month. The formulation and physical stability were assessed by monitoring any change in general appearance and drug content of the medicated chocolate.

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VI. RESULT AND DISCUSSION

TABLE IIIII: GENERAL APPEARANCE

Sr No.	Parameters	Observation
1.	Colour	Brown
2.	Odour	Pleasant Chocolate Aroma
3.	Taste	Sweet and Cocoa – rich Flavour
4.	Texture	Smooth and Glossy

TABLE IVVVI: BLOOM TEST

Test	Result
Fat bloom	No
Sugar bloom	No

❖ **pH Determination:**

Using Digital PH Meter and pH indicator strip, the pH of the chocolate formulation was determined to be **6.31**.

- **Digital pH Meter**

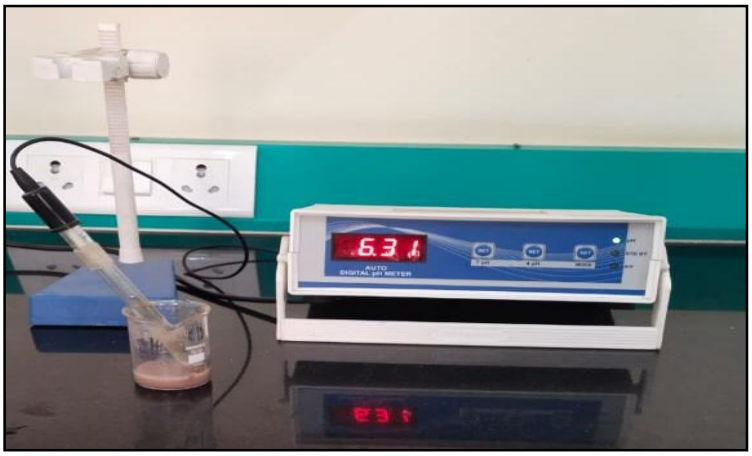

Fig.7 Digital Ph meter

- **pH Indicator Strip**

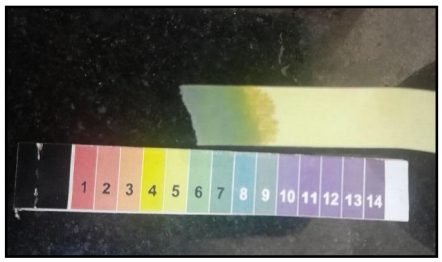

Fig.8 Ph indicator strip

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- **Melting Point Determination:**
  - Melting Point of the medicated Chocolate where the chocolate starts melting was determined to be- 34^0 C.

Fig.9 Initial melting point

  - The Melting point of the medicated chocolate where the chocolate completely melts and was determined to be 50 ^{0} C.

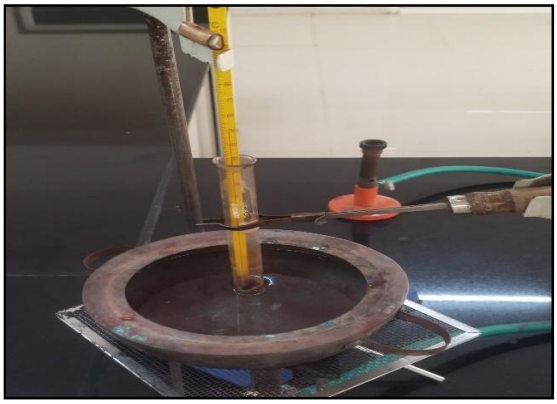

Fig .10 Final melting point

- **Stability Study:**
  - ✓ The general appearance of the chocolate formulation was observed at the conclusion of one month. The observations are listed in the table.

TABLE VIIV: STABILITY STUDY

Parameter	At the time of preparation	After one month
Colour	Brown	No changes
Odour	Pleasant chocolate aroma	No changes
Taste	Sweet	No changes
Texture	Smooth and glossy	No changes

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VII. CONCLUSION

- The herbal ingredients used may help in reducing menstrual pain naturally, with fewer chances of side effects compared to synthetic antispasmodic drugs. The chocolate dosage form is easy to consume, especially for young females and those who dislike conventional tablets or syrups. Overall, the study concludes that this herbal medicated chocolate can be a safe, effective, and patient-friendly alternative for managing menstrual cramps.
- In conclusion, the herbal antispasmodic chocolate shows potential as an effective and innovative approach for managing menstrual discomfort, especially in individuals preferring natural therapies.

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