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Formulation And Evaluation Of Herbal Lozenges

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ABSTRACT

Menstrual cramps, or dysmenorrhea, affect a significant proportion of women and often interfere with daily activities. The current study aims to formulate and evaluate herbal lozenges as a convenient and natural remedy for the management of menstrual cramps. Selected medicinal herbs known for their antispasmodic, analgesic, and anti-inflammatory properties—such as Zingiber officinale (ginger), Saraca Ashoka Bark Extract, Clove, Cinnamon, Cardamom, Turmeric, Jaggery, and Crystal Menthol were incorporated into a palatable lozenge formulation. The lozenges were prepared using the heating and molding technique with appropriate excipients, including sweeteners and binding agents. The final formulations were evaluated for physical parameters such as hardness, friability, weight uniformity, and disintegration time, along with phytochemical screening and microbial load testing. The results demonstrated that the lozenges were pharmaceutically acceptable and stable, with a pleasant taste and adequate release profile. Preliminary feedback from volunteers suggested a reduction in menstrual discomfort. This study highlights the potential of herbal lozenges as a non-invasive, easy-to-administer alternative for menstrual cramp relief.

KEYWORDS: Herbal lozenges, Menstrual pain, Herb, Medicament

INTRODUCTION

Menstruation – Definition

In a life cycle, a woman's body is vulnerable to a variety of changes. The cycle of these changes occur in women every month, positively for pregnancy is called the menstrual cycle. When an ovum is unfertilized, the uterus lining sheds and leads to a haemorrhage, called menstruation.

Menarche:

In a girl, menstruation starts from the age of 10 to 15 when she attains puberty and this beginning is known as menarche. The ending of menstruation is known as menopause which takes place at the age range of 50.

The first day of bleeding is marked as the first day of a menstrual cycle and the period from one menstrual cycle to another can vary from 28 to 30 days.

Dysmenorrhoea is also known as menstrual cramps .it is derived from the Greek words dys, meaning difficult/painful/ abnormal; meno, month; and rrhea, to flow. In women's reproductive years, dysmenorrhoea is one of the most common gynaecological conditions that affect the quality of life. Dysmenorrhea can be classified as primary or secondary. Primary dysmenorrhea is recurrent lower abdominal pain that happens during the menstrual cycle and is not associated with other diseases or underlying pathology. It is a diagnosis of exclusion. In contrast, secondary dysmenorrhea is associated with suspected or clinically identifiable pathology. Dysmenorrhea is a common complaint among menstruating patients during their reproductive years. Dysmenorrhea may be associated with significant negative emotional, psychological, and functional health impacts. Symptoms caused by dysmenorrhoea caused by high levels of prostaglandins (pain and inflammation hormone), nausea or dizziness, loose stools (diarrhoea), irritability, headaches and Menstrual cramps without an endometriosis, uterine fibroids, pelvic inflammatory disease (underlying health condition) that mainly occurs during the first few days and just before a woman's menstrual period. There are various risk factors which are associated with the period of primary dysmenorrhoea are poor sleep, hygiene, alcohol, cigarette smoking, caffeine consumption, a family history of dysmenorrhoea, lack of exercise, obesity, stressful lifestyle, dietary habits, and long menstrual cycles. [1,2] During menstruation, the uterus undergoes rhythmic contractions to expel its lining, and these contractions are triggered by the release of prostaglandins, which act as chemical messengers. While mild cramping may be considered a normal part of the menstrual cycle, a significant number of individuals experience severe and incapacitating menstrual cramps that can significantly impact their daily lives. The prevalence of dysmenorrhea varies across different populations, with some studies reporting rates as high as 90% among adolescent girls and young women. Prostaglandins, specifically prostaglandin F_{2α}, play a central role in promoting uterine contractions during menstruation. As the uterine muscle contracts, blood flow to the endometrial tissue is compromised, leading to the release of inflammatory mediators and pain signals. The management of menstrual cramps primarily focuses on relieving pain and reducing inflammation [3]

SYMPTOMS – Menstrual cramps usually refers to a dull , throbbing , cramping pain in the lower abdomen , just above the pelvic bone .

Other Symptoms May Include:

- Pain in the lower back and thighs
- Nausea and Vomiting
- Sweating
- Faintness and Dizziness
- Diarrhea or loose stools
- Constipation
- Bloating and Headaches.

Prevention:

People can also try certain lifestyle measures to reduce cramping. These include:

- ✓ Exercising Regularly
- ✓ Trying to reduce stress – for example practicing meditation, mindfulness, or Yoga

Home Remedies:

Some natural remedies that may provide relief are:

- ✓ Applying a heat pad to the lower abdomen
- ✓ Practicing relaxation and mindfulness techniques
- ✓ Engaging in physical exercise, such as jogging or yoga
- ✓ Taking a warm bath or shower
- ✓ Having a massage [4]

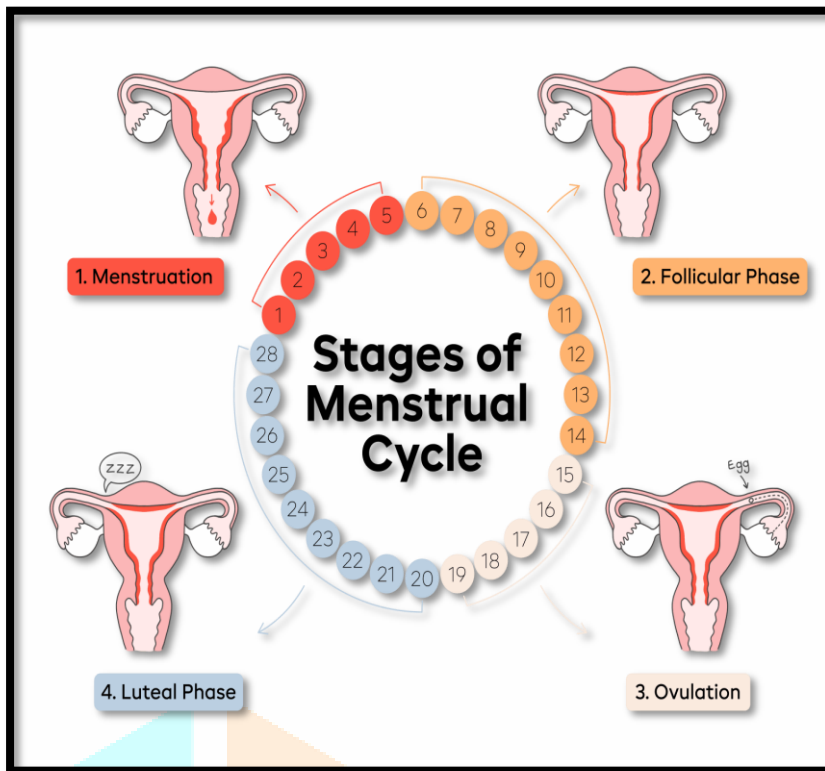
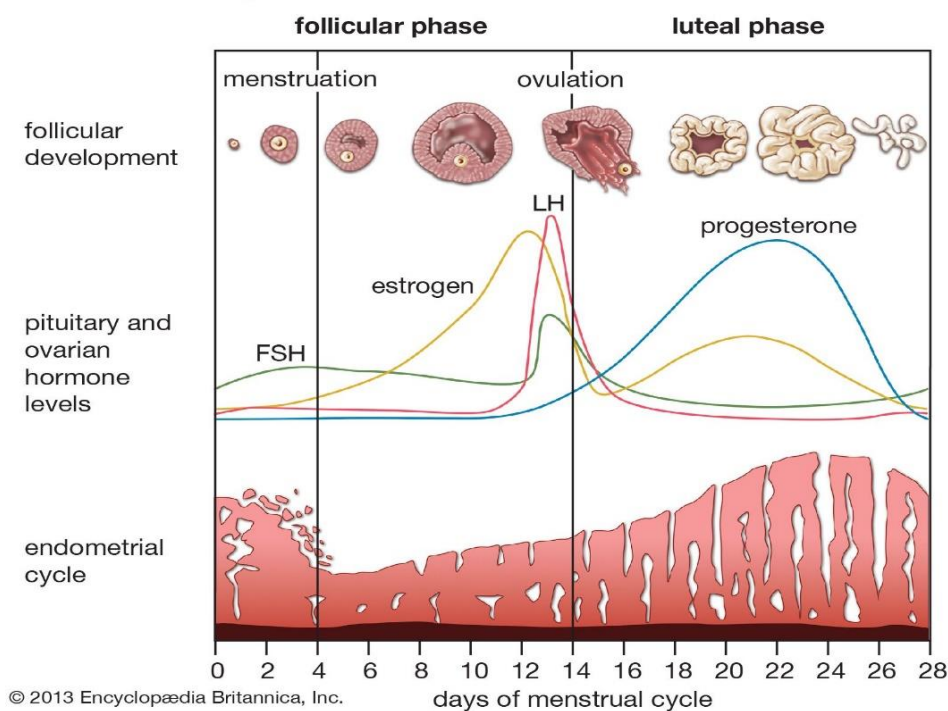


Fig No.1: Stages of Menstrual Cycle

Pathophysiology:

The menstrual cycle



- Not otherwise classified

Pathophysiology of menstruation cramps (Dysmenorrhea)

Menstrual cramps (also called dysmenorrhea) happen due to the contraction of the uterus as it sheds its lining during menstruation.

Main Cause: Prostaglandins

- The uterine lining (endometrium) releases prostaglandins, which are hormone-like substances.
- Prostaglandins trigger uterine muscle contractions to help expel the lining.
- Higher levels of prostaglandins lead to stronger, more painful contractions.

Treatment Options for Primary Dysmenorrhea:

➤ Lifestyle Modifications:

- Heat Therapy:** Applying a heating pad or hot water bottle to the lower abdomen can help relieve cramps.
- Exercise:** Regular physical activity, including aerobic exercise and yoga, can reduce menstrual pain.
- Dietary Changes:** Reducing caffeine and salt intake, and increasing water consumption, may help alleviate symptoms.
- Stress Management:** Techniques like meditation or deep breathing can help manage stress and pain.

➤ Medications:

- NSAIDs:** NSAIDs like ibuprofen and naproxen are effective in reducing prostaglandin production, which can cause pain.
- Hormonal Contraceptives:** Oral contraceptives, patches, or vaginal rings containing estrogen and progesterone can help regulate menstrual cycles and reduce pain.
- Paracetamol (Tylenol):** Can be used as an alternative to NSAIDs, particularly for those who are intolerant of them.

Treatment Options for Secondary Dysmenorrhea:

➤ Lifestyle Modifications:

- Dietary Changes:** Following a healthy diet and reducing stress may help manage symptoms.
- Physical Activity:** Regular exercise can help manage pain and improve overall health.

➤ Medications:

- NSAIDs:** May be used to manage pain and inflammation associated with the underlying condition.
- Hormonal Contraceptives:** Can be used to regulate menstrual cycles and reduce pain, particularly in endometriosis.

- **Other Medications:** Depending on the underlying condition, other medications may be used, such as Gonadotropin-Releasing Hormone (GnRH) agonists, which are used to treat endometriosis.

Side effect of NSAIDs:

NSAIDs like ibuprofen and naproxen are commonly used for menstrual cramps, but they can cause side effects like stomach upset, headaches, and dizziness.

Side effect of paracetamol:

Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light colored stools, throwing up, or yellow skin or eyes.

DEFINITION:

Lozenges are solid dosage forms that are intended to be dissolved or disintegrated slowly in the mouth. They contain one or more active ingredients and are flavoured and sweetened so as to be pleasant tasting. It is generally used for their topical effect, but may also have ingredients that produce a systemic effect.

Ashoka Bark:

The bark of the Ashoka tree (*Saraca asoca*) has been traditionally used in Ayurvedic medicine to treat menstrual disorders, including cramps. The primary active ingredients in Ashoka bark that are believed to act against menstrual cramps include:

Chemical Constituents of Ashoka Bark:

- Tannins – Have astringent properties that may help reduce heavy bleeding and inflammation.
- Flavonoids – These are known for their anti-inflammatory and antioxidant properties, which may reduce uterine inflammation and pain.
- Glycosides – Some plant glycosides can influence hormonal balance and uterine function.
- Saponins – Can help in reducing inflammation and improving circulation.
- Phytoestrogens – Plant-derived compounds that mimic estrogen and may help regulate menstrual cycles and reduce cramps.

Drug Release Mechanism in Lozenges

A) Sucking Action Begins: When a lozenge is placed in the mouth, the patient sucks on it rather than chewing or swallowing it.

Saliva starts to dissolve the lozenge's base, which is usually made of sugar, sorbitol, or other water-soluble excipients.

B) Slow Dissolution of the Matrix:

The solid matrix of the lozenge gradually dissolves in saliva.

This slow erosion allows the drug to be released gradually over several minutes (typically 5–15 minutes or more).

C) Drug Diffusion in Saliva:

As the lozenge dissolves, the active pharmaceutical ingredient (API) is liberated into the saliva.

The drug is then carried to the oropharyngeal mucosa where it can:

Act locally (e.g., numbing, soothing, antimicrobial) Or be absorbed into systemic circulation through the buccal/sublingual mucosa (if designed for systemic effects).

Aim & Objective:

Aim: Formulation and Evaluation of Herbal lozenges (Menstrual Cramps).

Objective:

The objective of menstrual cramp lozenges is to provide a convenient, fast-acting, and discreet method of relieving menstrual pain, particularly cramps, without relying solely on traditional pharmaceuticals.

- Alleviate menstrual cramps by using active ingredients (e.g., natural muscle relaxants, anti-inflammatories, or analgesics).
- Offer an easy-to-use alternative to pills, topical creams, or heat therapy that can be used anytime, anywhere.
- Utilize oral mucosal absorption for quicker pain relief compared to swallowed tablets.
- Provide a pleasant-tasting, easy-to-carry lozenge that enhances user compliance and satisfaction.

MATERIAL AND METHODOLOGY:

EXTRACTION OF BARK MATERIAL

- Dry the solid sample of Saraca Ashoka bark to remove moisture.
- Grind the sample into a fine powder to increase surface area for better extraction.
- Weigh an appropriate amount of the powdered of S. ashoka
- Place it in the thimble and insert the thimble into the main chamber of the Soxhlet extractor.
- Fill the round-bottom flask with the Ethanol (150ml).
- Attach the Soxhlet extractor to the round-bottom flask.
- Place the thimble containing the sample in the extractor.
- Attach the condenser to the top of the Soxhlet extractor.
- Connect water inlet and outlet tubes to the condenser to allow continuous water flow.
- Heat the solvent in the round-bottom flask using a heating mantle.
- The solvent vaporizes and rises into the condenser.
- Condensed solvent drips into the thimble, immersing the sample.
- When the extractor fills to a certain level, it automatically siphons the solvent back into the flask.
- This cycle repeats many time to ensure thorough extraction.
- Stop heating after the desired extraction time.

- Allow the system to cool completely.
- Remove the thimble and extract and collect the sample



Fig.1- Extraction of Ashoka Bark by Soxhlet Appartaus

Table 1: List of Ingredients used in the Herbal Lozenges

S.NO.	COMMON NAME	BOTANICAL NAME	PLANT PART USED	PROPERTIES	QUANTITY TAKEN
1	Bark Extract 	Saraca asoca (Roxb.) Willd	Bark	Reduce Menstrual Cramp	10gm
2	Cardamom 	Elettaria cardamomum	Seeds	Digestive Aid	1gm

3	Clove 	Syzygium aromaticum	Bud	Warming Effect	1.5gm
4	Cinnamon 	Cinnamomum verum	Bark	Anti- inflammatory, Analgesic	1gm
5	Ginger 	Zingiber officinale	Rhizome	Antispasmodic, Anti- inflammatory	2gm
6	Turmeric 	Curcuma longa	Rhizome	Hormonal Regulation, Antioxidant	0.5gm
7	Jaggery 	Saccharum officinarum	-	Improves Digestion & Reduces Bloating	25gm
8	Crystal menthol 	Mentha arvensis	Crystals	Cooling and Counter irritant	0.5gm

FORMULA OF HERBAL LOZENGES:**Table 2: Raw materials to be included in the Herbal Lozenges.**

SR.NO	INGREDIENTS	QUANTITY
1	Bark extract	10gm
2	Cardamom	1 gm
3	Clove	1.5gm
4	Cinnamon	1 gm
5	Ginger	2gm
6	Turmeric	0.5gm
7	Jaggery	25gm
8	Crystal menthol	0.5gm

METHOD OF PREPARATION OF HERBAL LOZENGES:

- Measure the raw materials
- Rinse the raw material prior grinding (Saraca Ashoka +Clove +Cardamom + Cinnamon +Turmeric +Crystal Menthol +Ginger Powder)
- After grinding extract the juice with help of mesh.
- Mare and menstrum is obtained.
- Menstrum includes leaf extract is mixed thoroughly.
- Liquify jaggery at low flame.
- Menstrum is added to the vessel containing jaggery.
- Continuously stirr at low flame until the desire density is obtained.
- Cool the preparation for few minutes before adding Honey.
- A pour preparation into oval shaped moulds.
- let it dry for 1-2 days.

Raw Materials

Grinding Raw Material

Extract the Juice



a)



b)



c)

Menstrum is obtained

Jaggery is Added

Continuously stirr at low flame



d)



e)



f)

Poured into Moulds



g)



Fig.2: Melting of Herbal Lozenges



Fig 3: Final product of herbal lozenges

PHYTOCHEMICAL SCREENING:(7)

Through a series of qualitative tests, the presence of numerous types of secondary metabolites was identified. Using Dragendorff's and Mayer's reagents, alkaloids were found. Alkaline reagent assays and Shinoda's test were both used to identify flavonoids. Lead acetate and ferric chloride tests were used to identify phenolics. The Salkowski test was used to determine the terpenoids.



Fig.4: Extraction of Saraca Asoka

- **Screening of Alkaloids:**

In a test tube, place a small quantity of the extract. Drops of Dragendorff's reagent should be added.

Alkaloids can be detected by the precipitate's orange-red colour.

- **Screening of Flavonoids:**

In a test tube, place a small quantity of the extract.

Add a couple of drops of weak hydrochloric acid (HCl), then a dash of magnesium oxide.

Flavonoids are present when a red colour is formed or changes colour.

- **Screening of Phenols:**

In a test tube, place a small quantity of the extract.

Drops of 5% ferric chloride solution should be added.

The presence of phenols is indicated by the development of a blue or green colour.

- **Screening of Tannins:**

In a test tube, place a small quantity of the extract.

Drops of 10% lead acetate solution should be added.

Tannins are present when a white or cream-colored precipitate forms.

- **Screening of Terpenoids:**

In a test tube, place a small quantity of the extract.

Several drops of concentrated sulfuric acid (H₂SO₄) should be added.

Terpenoids are present when a red colour forms or when the colour changes.

- **Wagner test:**

Take a little Saraca Ashoka essence and put it in a test tube.

Wagner's reagent should be added in small amounts to the test tube containing the extract.

Alkaloids can be detected in peppermint extract by the formation of a reddish-brown precipitate.



Fig.5: Phytochemical screening of extract of bark of saraca Ashoka

Table 3: Phytochemical screening of extract of bark of saraca Ashoka

SR.NO	PHYTOCHEMICALS	METHANOL EXTRACT
1	Alkaloid	+
2	Flavonoid	+
3	Phenol	+
4	Tannins	+
5	Terpenoid	+
6	Wagner	+

MACROSCOPICAL EVALUATION:

On the basis of ocular observation. The formulations organoleptic qualities were determined.

Table 4: Microscopic Evaluation

Properties	Batch
Colour	Dark brown
Odour	Aromatic
Taste	Sweet
Softness	Soft
Chewability	Good
Shape	Round

EVALUATION PARAMETER OF LOZENGES:(5,6)**1.Weight Variation Test:**

$$\% \text{ Deviation} = \frac{(\text{Individual weight} - \text{Average weight}) \times 100}{\text{Average weight}}$$

Average weight

Table no: 5 Weight Variation

Sr. No	W1	% Deviation
1	3.13	18.91
2	3.13	18.91
3	3.15	18.39
4	3.15	18.39
5	3.15	18.39
6	3.17	17.87
7	3.17	17.87
8	3.16	18.13
9	3.18	17.61
10	3.17	17.87
Average	3.47	-

2. Hardness Test:

The hardness of lozenges was measured using a Monsanto Hardness Tester. The crushing strength of the lozenge with known weight and thickness of each batch was recorded in kg/cm² and the average hardness and the standard deviation is reported.

Table No: 6 Hardness of Lozenges

Sr.no	Hardness
1	4.1
2	4.0
3	4
4	4.3
5	4.1
6	4.4
7	4.4
8	4.1
9	5.0
10	5.3
Average	4.3

3.Thickness Test:

The thickness in millimetres (mm) was measured individually for pre weighed lozenges by using a vernier Calipers. The average thickness and standard deviation are reported. The thickness of a lozenge can vary without any change in its weight.

Table No: 7 Thickness of lozenges.

Sr.no	Thickness
1	7.5
2	7.5
3	7.4
4	7.4
5	7.4
6	7.5
7	7.3
8	7.3
9	8
10	7.9
Average	7.5

6. Friability:

Table No:8 % Friability

Sr.no	Initial weight	Final weight	% Friability
1	11.31	11.30	0.08%
2	7.24	7.20	0.5%
3	5.48	5.44	0.7%
4	6.13	6.10	0.4%
5	8.91	8.86	0.5%
6	8.42	8.35	0.8%
7	5.44	5.38	1.1%
8	7.24	7.20	0.5%
9	11.48	11.36	1.04%
10	9.20	9.10	1.08%

COMPARATIVE STUDY OF STREPSILS AND LOZENGES

7. Disintegration test

The disintegration test determines the time it takes for a solid dosage form to break down into smaller particles or dissolve completely when placed in a liquid medium. The disintegration test was conducted on 5 randomly selected herbal lozenges and 5 selected Strepsils according to USP30. The test was performed using a disintegration tester with a basket rack assembly that rotates at 30 rpm through the disintegration medium of phosphate buffer with pH 6.2 maintained at 37°C. The time taken for each lozenge to disintegrate completely was recorded. The average disintegration time of the lozenges from batch A was 7 minute. The average disintegration time of the lozenges from batch B was 10 minute. The results of the disintegration test indicate that both batches of herbal lozenges have a consistent disintegration.

Table no. 9 Disintegration test

Sr no	Disintegration time
1	10 min
2	13min
3	15min
4	13min
5	12min
6	10min
7	17min
8	15min
9	13min
10	10min

8. Moisture content:

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

Initial weight

Table no:10 Moisture content

Sr no	Initial weight	Final weight	% Moisture content
1	11.20	11	1.7
2	10.40	10.14	1.3
3	9.12	9	1.3
4	9	8.90	1.1
5	10.40	10.58	1.1
6	8.84	8.70	1.5

7	9.26	9.07	1.4
8	7.24	7.12	1.6
9	8.12	8.01	1.3
10	7	6.80	1.4

Moisture content determination is a critical parameter of lozenges quality. It influences lozenges manufacturing and packaging. The standard limits of moisture content should be in the range of 0.5 to 1.5%.

As per the result obtained that moisture content in the prepared lozenges was found in the range 0.5 to 1.5% which is within the standard limits.

9.PH OF LOZENGES

The pH of the herbal lozenges was measured using a calibrated pH meter following the manufacturer's instructions, and the results showed a mean pH of 6.2 ± 0.3 (n=10) on the pH scale.

RESULT

The evaluation of prepared lozenges hardness (n=5), friability (n=5), thickness (n=5), weight uniformity (n=5), and disintegration time (n=5) produced the following results .

CONCLUSION

In conclusion, the developed herbal lozenges represent a promising, convenient, and potentially effective alternative for managing menstrual cramps. Further comprehensive clinical trials with larger sample sizes are warranted to definitively establish their safety, efficacy, and optimal dosing regimen in human subjects. This research lays a strong foundation for the development of natural, patient-friendly solutions for menstrual discomfort, potentially improving the quality of life for individuals experiencing dysmenorrhea.

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