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Research Article

Formulation and Evaluation of Herbal Lozenges Containing (Trachyspermum ammi) for the Management of Menstrual Cramps (Dysmenorrhea)

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ABSTRACT

This study focused on devising and assessing herbal lozenges with Ajwain (*Trachyspermum ammi*) for treating menstrual cramps (dysmenorrhea). The lozenges contained (*Trachyspermum ammi*), ginger (*Zingiber officinale*), clove (*Syzygium aromaticum*), cinnamon (*Cinnamomum verum*), cardamom (*cardamom Elettaria*), turmeric (*Curcuma longa*), jaggery (*Saccharum officinarum*), and menthol (*Mentha arvensis*), chosen for their pain-relieving, muscle-relaxing, and inflammation-reducing effects. The formulated lozenges were assessed for physicochemical properties, phytochemical components, hardness test is found to be 9.5, friability test found to be 0.63, disintegration duration found to be 15min, moisture levels found to be 2.22%, and PH 6.2+/-0.3. The findings demonstrated satisfactory quality characteristics, strong stability, and possible effectiveness in alleviating menstrual pain.

KEYWORDS: Ajwain, Herbal Lozenges, Dysmenorrhea, Menstrual Cramps, Antispasmodic Activity

ARTICLE INFO: Received 23 July 2026; Review Complete 16 August 2026; Accepted 13 Sept. 2026; Available online 15 Oct. 2026



Cite this article as:

Changdev JR, Dnyandeo BR, Kapile CR, Vrunda D N, Pawar DI, Shriwant SR, Giri A M, Formulation and Evaluation of Herbal Lozenges Containing (*Trachyspermum ammi*) for the Management of Menstrual Cramps (Dysmenorrhea), Asian Journal of Pharmaceutical Research and Development. 2026; 14(5): 31-36 DOI: <http://dx.doi.org/10.22270/ajprd.v14i5.1864>

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INTRODUCTION:

Menstrual pain, referred to as dysmenorrhea, is one of the most prevalent gynecological issues faced by women during their periods. It is marked by discomfort in the lower abdomen, which can be linked to nausea, vomiting, tiredness, headaches, and pain in the lower back. Dysmenorrhea primarily arises from heightened prostaglandin production, leading to intense uterine contractions and decreased blood flow to uterine tissues, causing pain and distress. Primary dysmenorrhea is a common gynecological condition affecting adolescent girls and young women, often interfering with daily activities and reducing quality of life.

Menstrual cramps are typically managed with analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), which alleviate pain by blocking prostaglandin production. Nevertheless, long-term use of these drugs can lead to side effects including gastric irritation, nausea, ulceration, and issues related to the kidneys. As a result of these worries, there is growing interest in herbal remedies as safer options due to their therapeutic effectiveness, natural source, reduced toxicity, and fewer side effects.

Ajwain (*Trachyspermum ammi*) is a significant medicinal plant frequently utilized in traditional medicine for addressing digestive issues, pain, and inflammation. Ajwain seeds hold active phytoconstituents like thymol, carvacrol, and p-cymene, which exhibit antispasmodic, analgesic, anti-inflammatory, and muscle-relaxing effects. These medication effects assist in diminishing uterine muscle contractions and alleviating menstrual discomfort. Ajwain has garnered interest as a potential herbal treatment for managing dysmenorrhea because of its medicinal significance.

Lozenges are therapeutic dosage forms intended to dissolve gradually in the mouth, releasing active components slowly for extended effects. Herbal lozenges provide numerous benefits, such as simple administration, better patient adherence, improved taste, convenience, and regulated release of active ingredients. Adding herbal extracts to lozenges offers a convenient and preferred dosage option for patients looking for natural treatments.

This study concentrates on the development and assessment of herbal lozenges with ajwain for alleviating menstrual cramps. Different pharmaceutical assessment criteria,

including weight variation, hardness, friability, moisture content, disintegration time, and organoleptic properties, are evaluated to guarantee the formulation's quality, stability, and efficacy. The creation of herbal lozenges could offer a secure, affordable, and efficient option for managing menstrual discomfort.

Anovulatory cycles: Anovulatory cycles occur when ovulation does not take place, often due to hormonal disorders, resulting in low progesterone levels and improper endometrial maturation.

Causes of AUB include:

Polyps, Adenomyosis, Leiomyomas, and Malignancy /hyperplasia.

Pathophysiology of menstruation cramps (Dysmenorrhea)

Menstrual cramps (dysmenorrhea) occur when the uterus contracts to shed its lining during menstruation. These contractions are triggered by prostaglandins, and higher prostaglandin levels can cause stronger, more painful cramps.

Treatment Options for Primary Dysmenorrhea:

Lifestyle measures such as heat therapy, regular exercise, healthy diet, and stress management can help relieve menstrual cramps. Medications like NSAIDs, hormonal birth control, and paracetamol may reduce pain and improve symptom control.

Treatment Options for Secondary Dysmenorrhea:

A healthy diet, stress reduction, regular exercise, and medications such as NSAIDs, hormonal contraceptives, and GnRH agonists can help manage menstrual disorders and reduce pain depending on the underlying cause.

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.

Lozenges are flavored and sweetened medicated dosage forms that dissolve slowly in the mouth to provide prolonged local or systemic therapeutic effects.

Phytochemical Screening test

Table 1: Phytochemical Screening test

Test	Procedure	Observation
Vanillin-H ₂ SO ₄	TLC spot of oil + spray vanillin+ sulphuric acid + heat 110°C	Blue -Violet spot at RF
Alkaloids Dragendorffs test	Ethanol extract + dragendorffs reagent	Orange PPT
Flavonoids Shinoda test	Ethanol Extract+ mg turnings+ conc HCL	Pink/Red Color
Tannins Gelatin test	Extract + 1% gelatin+NaCl	White PPT
Fixed oil Spot test	Extract Spot on filter paper	Permanente greasy stain

METHOD OF PREPARATION OF HERBAL LOZENGES:

The lozenges were formulated by heating and congealing technique. Syrup base was prepared in beaker by dissolving the required amounts of jaggery in water and kept for heating on hotplate. Temperature was maintained at 105°C

Ajwain: Ajwain is traditionally used to relieve menstrual cramps due to its antispasmodic and anti-inflammatory effects, which help reduce pain.

Chemical Constituents of Ajwain: Ajwain contains active compounds like thymol, carvacrol, p-cymene, terpenes, and flavonoids that help relieve menstrual cramps by reducing pain, relaxing uterine muscles, and decreasing inflammation.

Drug Release Mechanism in Lozenges: Lozenges dissolve slowly in the mouth when sucked, allowing saliva to gradually break down the base and release the active ingredients. The medication is distributed in saliva over 5–15 minutes or longer, providing effective therapeutic action.

METHOD AND MATERIALS

Ajiwain seed: Scientific name: *Trachyspermum ammi*
Family: Apiaceae Common names: Ajwain, Carom seeds plant, Bishop's weed

Thymol (major active compound)

1. Carvacrol 2. P-Cymene 3.γ-terpinene 4.Flavonoids and tannins (minor components)

Extraction of *Trachyspermum ammi* Seed:

The dried Ajwain seeds were first ground into a fine powder to facilitate efficient extraction. A suitable quantity of the powdered Ajwain was then weighed and placed in a thimble inside the Soxhlet extractor. Ethanolic extract was added to the round-bottom flask, and the Soxhlet apparatus was assembled with the condenser attached. The water inlet and outlet tubes were connected to the condenser to provide continuous cooling during the extraction process. Upon heating, the ethanol vaporized, condensed in the condenser, and dripped onto the powdered sample, allowing the extraction of bioactive compounds. The solvent repeatedly siphoned back into the flask, ensuring thorough extraction through multiple cycles. After the desired extraction period, the apparatus was allowed to cool, and the extract was carefully removed and collected for further analysis.

till it become thick. The *Trachyspermum ammi* extract and all other herbal powder mixture were added manually and mixed thoroughly after 30 min with continue process of heating. The prepared mass was further transfer to moulds and moulds were kept aside for 10-15 min. Prepared lozenges were separated from mould and kept for air drying.

Formulation Table of lozenges

Table 2: Formulation of lozenges

Sr. No	Ingredients	F1	F2	F3	F4	F5	Properties
1	Ajwain	1.0g	1.5gm	2.0gm	2.5gm	3.0gm	Reduce menstrualcramps, antispasmodic
2	Cardamom	1 gm	1gm	1gm	1gm	1gm	Digestive aid
3	Clove	1.5gm	1.5gm	1.5gm	1.5gm	1.5gm	Warming effect
4	Cinnamon	1gm	1gm	1gm	1gm	1gm	Anti-inflammatory, analgesic
5	Ginger	2gm	2gm	2gm	2gm	2gm	Antispasmodic anti-inflammatory
6	Turmeric	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	Harmonal regulation Antioxidant
7	Jaggery	7.53gm	7.03gm	6.53gm	6.03gm	5.53gm	Improve digestive reduce Boating
8	Crystal menthol	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	Cooling and counter irritant
9	Honey	QS	QS	QS	QS	QS	Sweetening agent

Organoleptic Evaluation:

Appearance: Assess the colour, size, and shape of the lozenges. Furthermore, the uniformity of form, surface texture, and any spots must be assessed.

Taste: The sweetness, sourness, bitterness, and saltiness of the lozenges must be evaluated. Evaluating the mouthfeel and aftertaste is also crucial.

Odor: The strength, character, and agreeability of the herbal aroma from the lozenges must be assessed.

Texture: The stickiness, chewiness, and hardness of the lozenges must be assessed. Moreover, it is essential to check if the lozenges dissolve easily in the mouth

Tablet Evaluation:

Weight variation: Test: Individual weight of 20 lozenges measured and compared. Average weight was found within acceptable limits with minimum variation, indicating uniformity of formulation.

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.

Thickness: 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.

Disintegration Test: The disintegration test was performed on herbal lozenges using a disintegration tester in phosphate buffer (pH 6.2) at 37°C to measure the time taken for complete breakdown. Batch A showed an average disintegration time of 7 minutes, while Batch B took 10 minutes, indicating consistent disintegration in both batches.

Friability Test: The friability test was performed using a friabilator to determine the mechanical strength of lozenges by rotating the apparatus at 25 rpm for 4 minutes. The initial and final weights of lozenges were measured after de-dusting, and friability was calculated using the formula $\% \text{ Friability} = [(W1 - W2) / W1] \times 100$, where the acceptable limit should not exceed 1%.

Moisture Content

The dry clean weighing bottle at 105°C for 30 min. It was Cool in desiccator for 30 min & Weight (W1). The 20 tablets were crushed to fine powder, then Transfer 1.0-2.0g accurately to bottle. Weight (W2). Bottle & sample were placed in oven at 105°C for 2-3 hours. The lid was slightly open. Close lid, cool in desiccator for 30-45min to room temp. Weight bottle & dried sample. Weight (W3). It was Dried again for 1 hr, then cool the & weight till 2 consecutive weights differ by NMT 0.5 mg.

PH Determination

The PH meter was switch on before 30 min of use. The electrode was wash with distil water & blot gently with the tissue. Then the electrode was dip into 7.0 buffer solution at 25°C. Then the reading was noted.

Result and Discussion:

Phytochemical Screening Test

Table 3: Phytochemical Screening Test result

Test	Observation	Inference
Vanilin-H ₂ SO ₄	Blue spot at RF	Thymol Present
Alkaloids Dragendorffs test	Orange PPT	Present
Flavonoids Shinoda test	Pink Color	Present
Tannins Gelatin test	White PPT	Present
Fixed oil Spot test	Permanente greasy stain	Present

Organoleptic Evaluation

Table 4: Organoleptic Evaluation

Properties	Batch
Colour Dark brown	Dark brown
Taste	Sweet
Softness	Soft
Chewability	Good
Texture	Hard, rough

Tablet Evaluation

Weight Variation Test:

Individual weight of 10 lozenges measured and compared. Average weight was found within acceptable limits with minimum variation, indicating uniformity of formulation.

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

Table 5: Weight Variation Test

Sr. No.	F1	F2	F3	F4	F5
1	2.2	2.1	2.2	2.1	3.12
2	2.1	2.3	2.1	2.3	3.14
3	2.3	2.4	2.3	2.2	3.13
4	2	2.1	2.2	2.1	3.15
5	2.2	2.3	2	2.3	3.11
Average	2.16	2.24	2.16	2.2	3.1

Hardness Test: The hardness of lozenges measured using hardness tester. Hardness of all Lozenges were found in the range of 9.5 is sufficient hardness, preventing breakage during handling and storage.

Table 6: Hardness Test

Sr.No.	F1	F2	F3	F4	F5
1	8.2	8.2	8.3	8.2	9.2
2	8.1	8.3	8.1	8.2	9.5
3	8.3	8.1	8.2	8.4	9.8
4	8	8.2	8.4	8.1	9.4
5	8.4	8.4	8	8.2	9.6
Average	8.2	8.24	8.2	8.22	9.5

Thickness Test: The Thickness of lozenges Measured using Vernier calliper. Thickness All lozenges were found in the range of 5.08 showed uniform thickness, confirming proper moulding and formulation consistency.

Table 7: Thickness Test

Sr.No.	F1	F2	F3	F4	F5
1	4.1	4.1	4.1	4.1	5.1
2	4.2	4.2	4.0	4.2	5.0
3	4.1	4.0	4.2	4.1	5.2
4	4.0	4.1	4.1	4.0	5.1
5	4.2	4.2	4.0	4.2	5.0
Average	4.12	4.12	4.08	4.12	5.08

Friability: Determined using friabilator to check resistance to breakage. Low friability (<1%) indicated good mechanical strength.

Table 4: Friability

Batch	Initial weight	Final weight	Average
F1	3.15	3.13	0.63
F2	3.14	3.12	0.64
F3	3.16	3.14	0.63
F4	3.13	3.11	0.64
F5	3.15	3.13	0.63

Disintegration test: The required lozenges to dissolve slowly in mouth. Lozenges dissolved gradually within 15 minutes, suitable for prolonged action.

Table 4: Disintegration test

Sr. No	Disintegration time
F1	11min
F2	12 min
F3	13 min
F4	12 min
F5	15 min

Moisture content: The moisture content of the prepared herbal lozenges was found to be 2.22%, which is within the acceptable range for herbal lozenges. Proper moisture level helps maintain hardness, prevents microbial growth, and improves stability during storage. Therefore, the formulation showed good quality and suitability for use in menstrual cramp relief.

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

Table 4: Moisture content

Sr. No	Batch	Initial weight	Final weight	%Moisture
1	F1	3.15	3.01	4.44
2	F2	3.14	3.00	4.46
3	F3	3.16	3.02	4.43
4	F4	3.13	2.99	4.47
5	F5	3.15	3.01	2.22

PH Determination

The PH of the prepared herbal lozenges was found to be 6.2 $\pm$ 0.3, indicating suitability for oral administration.

Discussion

The present study aimed to formulate and evaluate herbal lozenges containing Ajwain (*trachyspermumammi*) for the management of menstrual cramps (dysmenorrhea). The formulated lozenges incorporated herbal ingredients such as ajwain, ginger, cinnamon, clove, turmeric, cardamom, jaggery and menthol, which are known for their analgesic, anti-spasmodic, anti-inflammatory, and smoothing properties.

The organoleptic evaluation revealed that the lozenges possessed a dark brown colour, pleasant sweet taste, good

chewability and acceptable texture. These characteristics and acceptability, especially in herbal formulation. Individual weight of 10 lozenges measured and compared. Average weight was found within acceptable limits with minimum variation, indicating uniformity of formulation. The hardness of lozenges measured using hardness tester. Hardness of all Lozenges were found in the range of 9.5 is sufficient hardness, preventing breakage during handling and storage. The Thickness of lozenges Measured using Vernier calliper. Thickness All lozenges were found in the range of 5.08 showed uniform thickness, confirming proper moulding and formulation consistency. Determined using friabilator to check resistance to breakage. Low friability (<1%) indicated good mechanical strength. Disintegration test the required lozenges to dissolve

slowly in mouth. Lozenges dissolved gradually within 15 minutes, suitable for prolonged action.

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CONCLUSION:

The formulated herbal lozenges containing Ajwain demonstrated satisfactory physicochemical properties, including acceptable hardness, friability, disintegration time, moisture content, and pH. The presence of herbal ingredients with analgesic, antispasmodic, and anti-inflammatory activities suggests potential usefulness in relieving menstrual cramps. Further clinical studies are required to confirm safety, efficacy, and optimal dosage in human subjects.

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