

Formulation and Evaluation of Hard Candy Lozenges Containing *Jasminum grandiflorum* L. for the Treatment of Mouth Ulcers

Sunil Kumar Pandey¹, Kirti Tomer², Archana Patidar³, Deepti Andheriya Modi⁴, Arpan Debnath^{5*}

¹ Assistant Professor, B.R.Nahata College of Pharmacy, Mandsaur university, Mandsaur, Madhya Pradesh.

² Assistant Professor, Modern Institute of Pharmaceutical sciences, Indore, Madhya Pradesh.

³ Associate professor, Shivajirao Kadam Institute of pharmaceutical education and research, Indore, Madhya Pradesh

⁴ Associate professor, Swami Vivekanand college of pharmacy, Indore, Madhya Pradesh.

^{5*} Corresponding Author, Assistant Professor, B.R.Nahata College of Pharmacy, Mandsaur university, Mandsaur, Madhya Pradesh

Abstract

This research focuses on the preparation and assessment of hard candy lozenges containing *Jasminum grandiflorum* leaf extract, which is a traditional anti-ulcer agent. Mouth ulcers are one of the common oral diseases that cause pain and discomfort. Lozenges are a novel dosage form, which is perfect for the local delivery of therapeutic agents in the mouth. The study was conducted to develop a stable, palatable, and effective formulation with the extract of *Jasminum grandiflorum*. Hard lozenges were effectively formulated and evaluated for physical properties, drug content, and in vitro dissolution. Findings proved promising potential with the herbal lozenges in the treatment of mouth ulcers and improved patient compliance.

Keywords: Lozenges, *Jasminum grandiflorum*, mouth ulcers, herbal formulation, anti-ulcer, hard candy, drug delivery

1. Introduction

Mouth ulcers are painful swellings on the mucosal rounding of the oral cavity due to a number of factors, such as stress, nutritional deficiencies, hormonal imbalances, and trauma [1]. They are not life-threatening but have a considerable effect on the quality of life. Topical anesthetics, corticosteroids, and antiseptics are already used and continue to be used in the market, yet the quality of compliance and reuse is poor.

Lozenges, or troches, or pastilles are a non-invasive method of drug administration that is patient-friendly and allows the drug to be released continuously in the mouth of the patient [2]. Lozenges of hard candy are particularly convenient in the case of the pediatric and geriatric groups because of convenience and the ability to hide the taste [3].

Jasminum grandiflorum L. (family Oleaceae), commonly known as jasmine, is recognized in traditional medicine for its anti-inflammatory and healing properties [4,5]. The current research examines how the incorporation of *Jasminum grandiflorum* leaf extract into lozenges to treat mouth ulcers can be done.

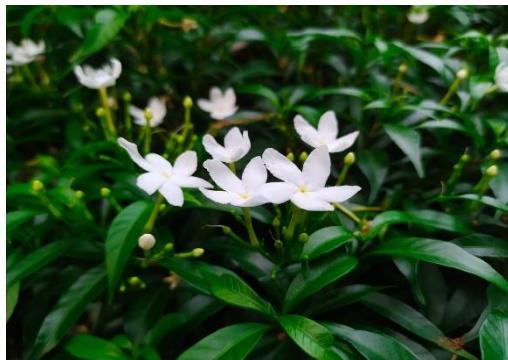


Fig 1: *Jasminum Gradiflorum* L.

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2. Materials and Methods

2.1 Plant Collection and Extraction

The *Jasminum grandiflorum* leaves were collected from Gadhinglaj, dried in shade, and then powdered. The 70% ethanol extract was made by macerating 40 g of powdered leaves in 400 ml of the 70% ethanol over a period of 4 hours using a mechanical shaker. The extract was dried under vacuum at 40°C, and the yeild of the dried extract was 24%.

2.2 Phytochemical Screening

The extract was analyzed for active phytoconstituents:

Alkaloids: Identified by Dragendorff's and Mayer's tests.

Dragendorff's Method: The Dragendorff method is a chemical test used to detect the existence of alkaloids, a class of naturally occurring organic compounds commonly present in plants. It uses a reagent known as Dragendorff's reagent that reacts with alkaloids to give a typical orange or reddish-brown precipitate [6].

Mayer's tests: The Mayer test is a chemical test, which is mainly used to detect the presence of alkaloids in a sample. It entails the introduction of Mayer reagent (potassium mercuric iodide solution) in the test solution. A positive result is obtained as a white or pale yellow precipitate [7].

Solubility: Soluble in ethanol and glycerol, sparingly soluble in water.

2.3 Formulation of Hard Candy Lozenges

A sugar syrup had been prepared by adding 100 g of sucrose with 45 ml of water, heating, and dissolving dextrose to 160°C. When cooled to 90°C, the drug extract (1.7 g), lemongrass oil (0.5-1 ml), and citric acid (0.5g) were incorporated. The mixture was put into molds and left to harden.

The prepared tablets were covered with aluminum foil and put in desiccators in order to avoid taking up moisture.

Using the formula below about 35 medium size lozenges were prepared.

INGREDIENTS	AMOUNT
Sugar (Sucrose)	100 gm
Active Drug	1.7 gm
Water	45 mL
Lemon Grass oil	0.5-1 mL
Citric acid	0.5 gm

Table 1: Formulation Table of Lozenges

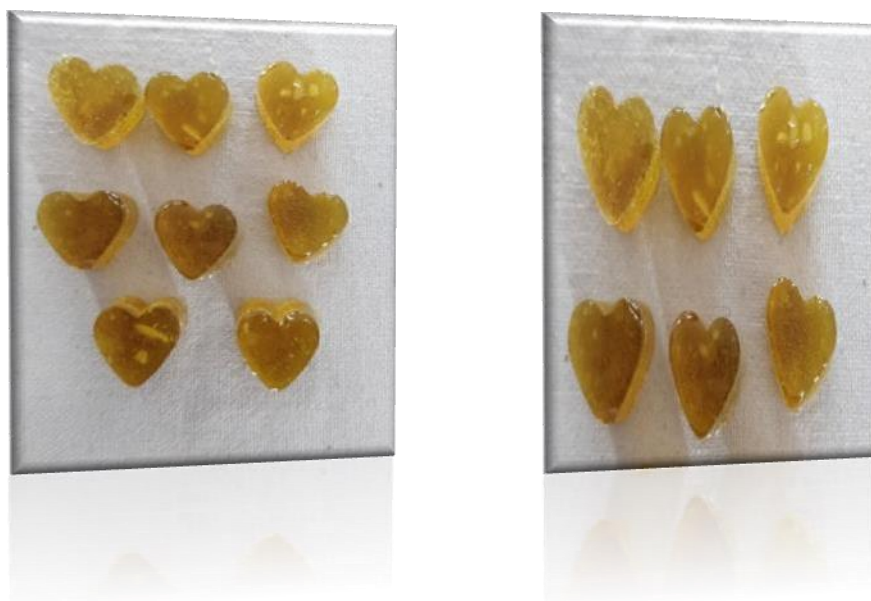


Fig 2: - Hard candy lozenges

2.4 Evaluation Parameters

Hardness: The Monsanto Hardness Tester was used to determine the hardness of the hard lozenges [8]. Mean and standard deviation were calculated and reported. It is expressed in kg/cm². The mean hardness of lozenges is obtained, and the standard deviation and observation value are indicated in the following table.

Stage	Process	Temperature	Key Parameters
1. Mixing	Combine sugar, corn syrup, water	20-25°C	Sugar 45%, Corn syrup 45%, Water 10%
2. Dissolution	Heat and stir until clear	100-110°C	Complete dissolution, continuous stirring
3. Cooking	Concentrate mixture	145-155°C	Target 97-99% solids, prevent crystallization
4. Cooling	Cool to working temperature	120-130°C	Prevent premature hardening
5. Additives	Add flavors, colors, acids	115-125°C	Quick mixing, uniform distribution
6. Forming	Shape into rope	90-110°C	Consistent diameter (10-15mm)
7. Cutting	Cut into individual pieces	80-100°C	Uniform weight (2-5g each)
8. Cooling	Cool lozenges	60°C → 25°C	Gradual cooling to prevent cracking
9. Conditioning	Equilibrate moisture	20-25°C, 24-48h	Final moisture <3%, RH 30-45%
10. Packaging	Wrap in moisture-proof material	20-25°C	Prevent moisture absorption

Table 2: Standard Manufacturing Process for Hard Candy Lozenges

Thickness and Diameter: The diameter and the thickness were recorded with the help of a Vernier caliper [9]. The dimensions of the hard candy lozenges are a very critical factor that goes into the production. Thickness and diameter were measured against the three lozenges picked at random out of the formulation.

Weight Variation: Twenty lozenges of the formulation were randomly picked and weighed along with the tablets, which were weighed separately. The batch passes the test of weight variation test when not more than two of the individual lozenge weight deviation is more than the weight of the average weight by the percentage as per IP.

Friability: Friability was determined by weighing 10 lozenges in a Roche friabilator and making the parameters set on the friabilator [10]. The equipment was rotated at 25 rpm (100 rotations), taking 4 minutes. After revolutions the lozenges were deducted and reweighed. The maximum mean weight loss samples are not exceeding 1.0%. The formula below was used to determine the percentage friability :-

$$\% F = \frac{W_0 - W}{W_0} \times 100$$

% F = Friability in percentage,

W₀ = Initial weight of lozenges

W = Final weight of lozenges after revolution

Drug Content: Ten lozenges in each batch were picked and weighed separately and crushed in a mortar. The drug was extracted using 50 ml of methanol. The spectrophotometric analysis was done to determine the drug content at 262 nm using blank lozenge extract as a reference.

In-Vitro dissolution release: In-vitro dissolution was conducted using the USP dissolution test apparatus type II (paddle type) with 100 rpm and 37 ±0.5°C. In vitro dissolution was performed using PH 6.8 buffer with 2% SLS as the dissolution medium. In each 60 min, samples of 5 ml were taken out of the flasks with lozenge in the dissolution apparatus and allowed to run at a specific time interval. In order to maintain sink conditions, the same volume of medium was replaced. Analysis of the samples was done through a UV-visible spectrophotometer at 262 nm and the percentage of drug released was calculated. This experiment was tripled and an average of the percentage release was obtained.

Storage:

These preparations are to be kept in a place where they are not exposed to heat and also not in the hands of children. They are to be shielded against excess moisture. Depending on the storage temperature needed for both the drug and base, room temperature or refrigerated temperature was typically indicated.

Packaging:

Hard candies are hygroscopic and are basically liable to absorption of atmospheric moisture [11]. Issues such as the hygroscopicity of the candy base, the storage conditions of the lozenges, the storage period of the same, and possible drug interactions were need to be taken into consideration.

To pack hard candy lozenges aluminum foil was used, and two to three times foil wrappings are done because the lozenges are not put directly in contact with the atmosphere [12]. These products were packed in closed containers so as to avoid uptake by moisture. Once packed in this aluminum foil, stored the wrapped lozenges in an airtight container and labeled them properly. Sealable plastic bags may also be used instead of airtight containers.

3. Results

3.1 Organoleptic Evaluation

Sr.no.	Parameter	Observation
1	Shape	Heart-shaped
2	Color	Yellowish-orange
3	Texture	Smooth
4	Taste	Sweet
5	Odor	Pleasant, characteristic

Table 3: Organoleptic Evaluation of Lozenges

3.2 Physical Evaluation

Sr.no.	Parameter	Result
1	Thickness	11 mm
2	Hardness	12 kg/cm ²
3	Weight	Pass ($\pm 7.5\%$)
Variation		
4	Friability	Pass (<1%)
5	Drug Content	80.11%

Table 4: Physical Evaluation of Lozenges

3.3 UV Spectrophotometer analysis:

Instrument used: Shimadzu 1800

Software used: UVprobe

Through the analysis using the ultraviolet spectroscopy, we obtain the purity of the drug. Also from UV spectroscopy we calculated the drug content of the formulation.

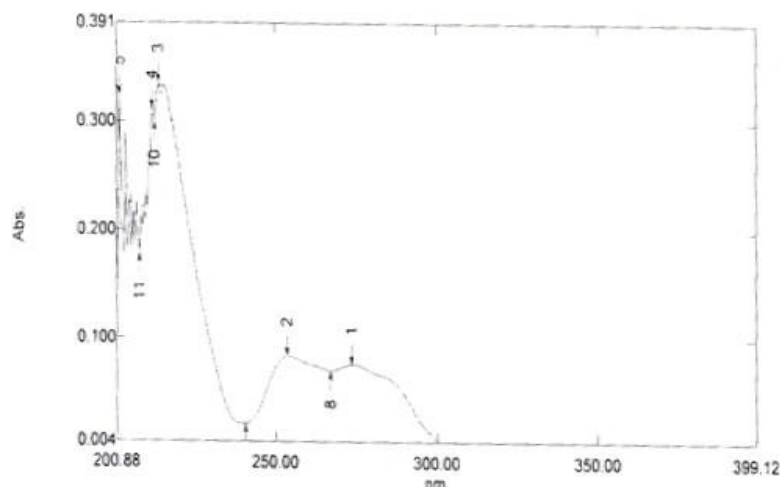


Fig 3: UV Spectra of Lozenges containing *jasmine grandiflorum* Lin.

Sr.no.	Wavelength (nm)	Absorbance
1	211	0.335
2	213	0.311

Table 5: Absorbance recorded through UV Spectroscopy

3.4 In Vitro Drug Release

The release of the drugs was observed over a period of 60 minutes, and cumulative release had a moderate and sustained release profile, indicating a good rate of lozenge disintegration and diffusion of the drug.

4. Discussion

Initial attempts of soft lozenges made with polyethylene glycol failed as they were not very consistent, probably because of improper gelling or thermal effects. On the contrary, the hard candy lozenges were very stable physically and acceptable to patients.

The presence of alkaloids, flavonoids, and glycosides confirmed in the phytochemical screening are known to have healing properties for the mucosal area and anti-inflammatory properties. Small friability and high hardness are signs of strong structural integrity that can be used in the packaging and handling.

Lozenges provided moderate and sustained drug release, which aligned with the objective of localized and extended exposure of the drug at the site of infection. The drug content (80.11%) was within acceptable pharmaceutical limits.

5. Conclusion

This current study was successfully able to illustrate the development of hard lozenges with the *Jasminum grandiflorum* L. extract to be used in treating mouth ulcers. The ready lozenges were promising in the case of organoleptic and physicochemical characteristics. The herbal preparation is an effective, non-invasive, patient-compliant herbal formulation to manage local oral ulcers, particularly in pediatric and geriatric patients. Clinical follow-up and therapeutic potency are suggested to be optimized by further clinical testing and isolation of particular bioactive compounds.

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