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Research Paper

Formulation and Evaluation of Agele Marmelos Lozenges

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ABSTRACT

The present study focuses on the formulation and evaluation of herbal lozenges containing Aegle marmelos extract, a medicinal plant known for its anti-diarrheal, antimicrobial, and anti-inflammatory properties. Lozenges were prepared using the wet granulation method, incorporating suitable excipients such as binders, sweeteners, and flavoring agents to enhance palatability and patient compliance. The formulated lozenges were evaluated for various physicochemical parameters including weight variation, hardness, friability, drug content uniformity, disintegration time, and in vitro dissolution profile. Results demonstrated that all batches met the pharmacopeial standards, with optimized formulations exhibiting satisfactory mechanical strength, acceptable organoleptic properties, and sustained release of the herbal extract. The study concludes that Aegle marmelos lozenges offer a promising natural remedy for gastrointestinal ailments with improved ease of administration and enhanced therapeutic efficacy. The present research work involves the formulation and evaluation of herbal lozenges containing Aegle marmelos extract, a well-known medicinal plant traditionally used in Ayurvedic medicine for the treatment of various gastrointestinal disorders, especially diarrhea and dysentery. The objective was to develop a convenient and palatable dosage form that delivers the therapeutic benefits of Aegle marmelos in a sustained and patient-friendly manner. Lozenges were prepared using the wet granulation technique, incorporating suitable excipients such as sucrose, glucose, and natural flavors to improve taste and texture, along with binders and lubricants to ensure proper tablet formation.

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Multiple formulations were developed and subjected to comprehensive evaluation, including physical characteristics like hardness, thickness, friability, and weight variation, as well as pharmaceutical tests such as disintegration time, content uniformity, and in vitro drug release. Among the prepared batches, the optimized formulation showed satisfactory organoleptic properties, adequate mechanical strength, uniform drug content, and a controlled release profile over a specified time period. The results indicated that the formulated lozenges can effectively deliver Aegle marmelos extract in a stable, easy-to-administer form with improved patient compliance. This study supports the potential use of herbal lozenges as a novel dosage form for delivering natural plant-based remedies with therapeutic benefits.

INTRODUCTION

Lozenges are small, often medicated tablets designed to dissolve slowly in the mouth, providing a localized effect in the throat or oral cavity. Typically composed of sugar, flavouring agents, and active pharmaceutical ingredients, lozenges are commonly used to soothe sore throats, relieve coughs, or deliver medication for oral health. [1] The formulation allows for prolonged contact with mucous membranes, enhancing the therapeutic effect of the ingredients, which can include soothing agents like menthol or herbal extracts. Lozenges come in various shapes and flavours, catering to different preferences and needs, and are an effective delivery method for both over-the-counter and prescription medications. Their ease of use and palatable nature make them a popular choice for individuals seeking relief from oral discomfort without the need for liquid medication. Lozenges serve several purposes, primarily aimed at providing relief for various oral and throat They are commonly used to soothe sore throats, reduce coughing, and alleviate dry mouth. [2] By the 19th century, lozenges gained prominence as a convenient form of medication, particularly with the development of sugarbased formulations. Pharmaceutical companies began to mass-produce lozenges, incorporating active ingredients for various therapeutic purposes. The Victorian era saw a rise in the popularity of medicinal lozenges, often marketed for their soothing properties. [3]

Importance of lozenges in medicine:

Lozenges hold significant importance in medicine due to their effective delivery system for localized treatment of oral and throat conditions. Their design allows for slow dissolution in the mouth, ensuring prolonged contact with mucous membranes, which enhances the therapeutic effects of the active ingredient. [4] This makes lozenges particularly useful for soothing sore throats, alleviating coughs, and providing relief from dry mouth. Additionally, they can incorporate a variety of medications, including local anaesthetics, antiseptics, and herbal remedies, making them versatile for treating infections or discomfort. [5] Their ease of use, palatable nature, and convenience-requiring no water or swallowing-make them an ideal choice for patients, especially children and the elderly, who may have difficulty with traditional medications. As a noninvasive option, lozenges contribute to patient compliance and comfort, highlighting their valuable role in modern therapeutic practices. [6]

Advantages of Lozenges:

- It is easy to administer to both pediatric and geriatric patients.
- It has a pleasant taste and will extend the time a quantity of drug remains in the oral cavity to elicit local activity.
- It very well may be given to those patients who experience issues in gulping.
- It can decrease dosing recurrence.
- No disintegration.
- Do not require water for intake.
- Less production times.

- Less production cost. [7]

Disadvantages of Lozenges

- Possible draining of drug from oral cavity to stomach along with saliva.
- The lozenges dosage form could be used as candy by children mistakenly.
- A hard candy lozenge is a high temperature required for their preparation.
- Heat stable drugs are suitable. [8]

Types of Lozenges

Therapeutic lozenges

Therapeutic lozenges are specialized formulations designed to provide targeted relief for various oral and throat ailments. They typically contain active pharmaceutical ingredients that offer soothing, analgesic, or antiseptic properties. Common ingredients include menthol, which provides a cooling sensation; honey and herbal extracts that soothe irritation; and local anaesthetics like benzocaine that numb pain. [9]

Nutritional lozenges

Nutritional lozenges are specialized dietary supplements designed to provide essential vitamins, minerals, and other nutrients in a convenient and palatable form. These lozenges cater to individuals seeking to enhance their nutritional intake without the need for traditional pills or liquids, making them particularly appealing to those who may have difficulty swallowing. Commonly enriched with vitamins such as Vitamin C, B vitamins, or minerals like zinc, nutritional. [10]

Herbal lozenges

Herbal lozenges are formulated with natural plant-based ingredients designed to provide soothing relief for various throat and oral conditions while promoting overall health. Typically containing extracts from herbs such as echinacea, licorice root, marshmallow root, and ginger, these lozenges capitalize on the therapeutic properties of their constituents.[16] For example, Echinacea is often used for its immune boosting effects, while licorice root is known for its antiinflammatory and soothing qualities. [11]

AIM AND OBJECTIVES:

AIM

"To explore the effectiveness of Aegle marmelos lozenges."

OBJECTIVES: -

➢ Lozenges are designed to provide various health benefits in the form of a small tablet that slowly dissolves in the mouth

➢ Provide natural relief for sore throat and cough symptoms

➢ Offer a soothing sensation through herbal ingredients like

➢ Deliver a convenient and portable solution for on-the-go relief.

➢ Promote overall wellness by using natural, plant-based ingredients.

➢ Ensure efficacy and safety through rigorous quality control and testing processes.

➢ Cater to specific preferences and needs by offering a variety of flavors and formulas.

➢ Educate consumers about the benefits of herbal remedies and their role in health practices. [12]

➢ Bael leaf lozenges are cost effective & safe.

Plant Profile:

Aegle Marmelos Powder:
English Name: Beal fruit, Bengal quince, Golden apple.

Tamil Name: Vilvam, Vilva-pazham, Bilvam
Telugu: Bilvamu.
Kingdom: Plantae.
Order: Sapindales.
Family: Rutaceae.
Sub family: Aurantioideae
Genus: Aegle.
Species: A. marmelos Habitat
Aegle marmelos treating fever, nausea, vomiting, swellings, dysentery, dyspepsia, seminal weakness, and intermittent fever. [13]

Fig 1: Agele Marmelos Extract Powder

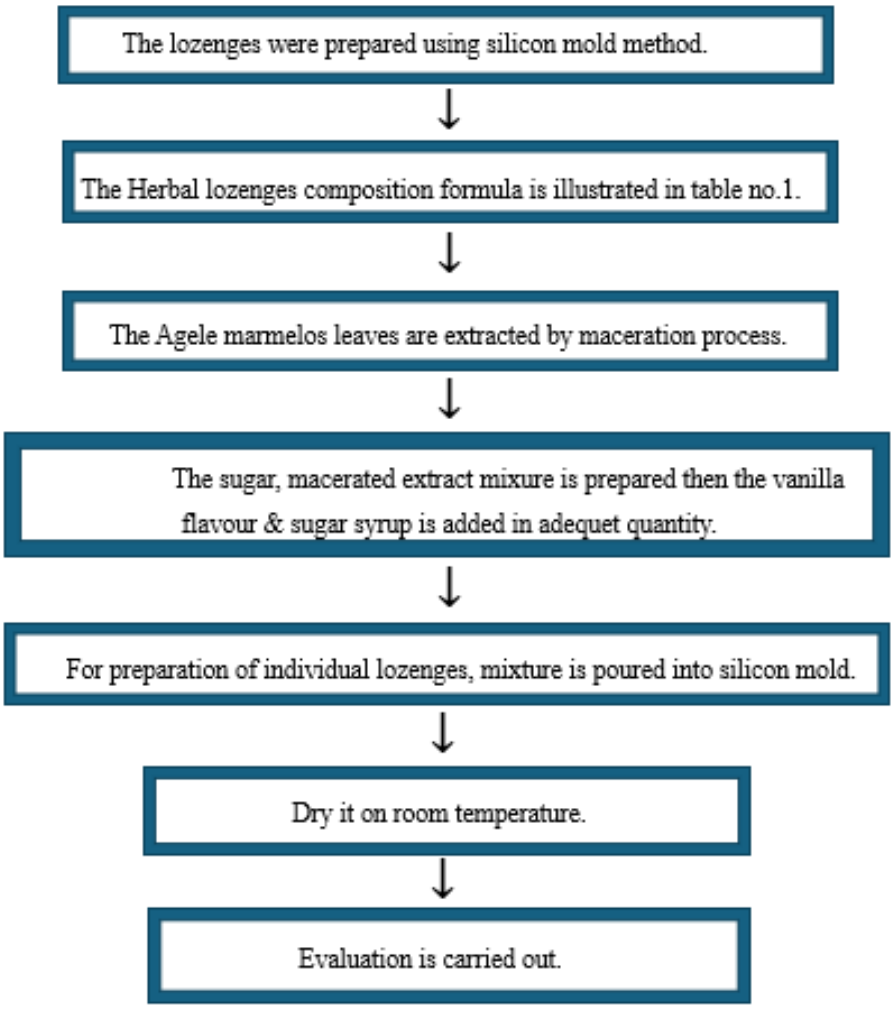
MATERIAL AND METHOD:

All ingredients were purchased from trusted supplier. All others are purchased from, Local Suppliers, Washim.

Table no 1: Formulation Table

Sr. No	Ingredients	F1	F2	F3	Function
1	Extract agele marmelos powder	9 gm	8 gm	7 gm	Anti-Diarrhoea,Anti-Inflammatory
2	Sugar	33.75 gm	33.66 gm	33.62 gm	Antioxidant
3	Sugar Syrup	1-2 drop	1-2 drop	1-2 drop	Preservative
4	Flavour	qs	qs	qs	Taste
				Total	42.75≈ 43 gm

Procedure:



Preparation Images

Fig no 2: - Collection

Fig no 3: - Mixing

Fig no 4: - Final Product

Evaluation of Formulation

Formulation developed was sampled and evaluated for different parameters such as organoleptic properties, weight variation, friability, hardness, dissolution test, disintegration test.

1. Organoleptic parameters-

The lozenges were found to be oval in shape with smooth texture. This oval shape was due to molds used for preparation. The taste of the lozenges was sweet and acrid in taste. The sweet taste could be attributed to the use of sugar as base and acrid tast due to Aegle Marmelos Macerated extract. [14]

2. Weight variation-

The USP weight variation test is done by weighing 20 lozenges individually and then by taking average comparing it as follows:

Weight variation = (average weight – initial weight) ÷ average weight. [15]

Fig no 5: - Weight Variation

3. Friability-

These is carried out for same as hardness testing. Friability testing is carried out by using Roche Friabilator operated at specific speed for specific time such 25 rpm for 4 min. [16]

Fig no 6: - Friability

4. Hardness-

The resistance of lozenges to shipping, storage conditions breakage, Transportation and handling, depending upon the hardness. hence it becomes necessary to measure hardness for checking its threshold capacity which can be measured by using Monsanto hardness tester in terms of kg/cmsq. [17]

Fig no 7: - Hardness

5. Dissolution time:

Dissolution time is an important parameter to evaluate in herbal lozenges as it can affect the release of active ingredients and the efficacy of the product. The dissolution time of herbal lozenges can be influenced by factors such as the size and shape of the lozenge, the type and number of excipients used, and the environmental conditions during storage. The dissolution time of herbal lozenges can be determined by placing a lozenge in a beaker of water at a specified temperature and measuring the time it takes for the lozenge to completely dissolve. The acceptable dissolution time for herbal lozenges depends on the specific product and its intended use. [17,18,19]

Fig no 8: - Dissolution Time

6. Disintegration time:

Ideally this test is not official for the formulation expected to be dissolved slowly in the mouth and hence the limits are not specific. Still the test was performed to find whether the lozenge dissolves in mouth and how much time it takes to dissolve completely so that the faster and localized onset of action can be obtained. The test was performed as per the procedure given in the monograph for uncoated tablets. [19]

Fig no 9: - Disintegration Time

7. Packaging:

Hard candies are hygroscopic and frequently prone to absorption of atmospheric moisture. Considerations must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time they are stored and the potential for drug interactions. These products should be stored in tight containers to prevent drying. This is especially true of the chewable lozenges that may dry out excessively and become difficult to chew.) If a disposable Mold with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bag. Packaging should be proper and attractive or colourful. [20]

RESULT AND DISCUSSION

Table no 2: Organoleptic Properties

Parameter	F1	F2	F3
Colour	Brown	Brown	Brown
Odour	Pleasant	Pleasant	Pleasant
Taste	Sweet & Slightly acrid	Sweet	Sweet
Shape	Round	Round	Round

Table no.3: Drug Excipients compatibility study

Sr. No	Drug + Exicipient	Ratio	Parameter	Condition (40^0C±2\75±5%RH	
1	API	1: 0	Appearance	Yes	Yes
2	API + Sucrose	1: 10	Appearance	Yes	Yes
3	API + Vanillin	1: 5	Appearance	Yes	Yes

Weight Variation Test:

20 lozenges are selected for weight variation test. Individual are average weight is calculated and further weight variation is determined.

Table no 4: Weight Variation Test

Sr. No	F1	F2	F3
1	3.16	3.14	3.12
2	3.29	3.27	3.26
3	3.60	3.59	3.57
4	3.45	3.44	3.43
5	3.72	3.70	3.71
6	3.75	3.73	3.74
7	3.15	3.12	3.14
8	3.21	3.20	3.22
9	3.45	3.43	3.46
10	3.05	3.03	3.06
11	3.29	3.27	3.26
12	3.75	3.74	3.73
13	3.16	3.14	3.13
14	3.45	3.43	3.42
15	3.15	3.14	3.13
16	3.60	3.58	3.56
17	3.72	3.70	3.69
18	3.45	3.43	3.42
19	3.05	3.04	3.03
20	3.21	3.19	3.17

Total Weight of Tablet = 67.66 ÷ 20 = 3.383

Average Weight = 3.383

Friability test is determined by using Roches Friabilator.

Friability Test

Table no 5: Friability Test

Sr. No	F1	F2	F3
1	≤ 1%	≤ 0.8%	≤ 0.7%

Initial Weight = 33.83

Final Weight = 33.49

Formula: -

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

$$= \leq 1\%$$

Hardness is checked by Monsanto tester.

Table no 6: Hardness Test

Sr. No	**F1**	**F2**	**F3**
1	4.7±0.5Kg/cm^2	4.6±0.5Kg/cm^2	4.5±0.5Kg/cm^2
2	4.5±0.5Kg/cm^2	4.4±0.5Kg/cm^2	4.3±0.5Kg/cm^2
3	4.8±0.5Kg/cm^2	4.7±0.5Kg/cm^2	4.6±0.5Kg/cm^2

Dissolution Test

This test is conducted by using Beaker apparatus. The results are shown in following table.

Table no 7: Dissolution Test

Sr. No	F1	F2	F3
1	8Min	7Min	6Min

This test is conducted by using disintegration test apparatus. The results are shown in following table.

Table no 8: Disintegration Test

Sr. No	F1	F2	F3
1	4±0.5 min	3±0.5 min	2±0.5 min

DISCUSSION

Lozenges have a rich history that dates back to ancient times. The concept of using hard, flavored tablets for medicinal purposes can be traced to the Egyptians, who created early forms of lozenges using honey and herbs. In medieval Europe, herbal lozenges became popular, often containing soothing ingredients like honey, licorice, and various spices to treat ailments such as coughs and throat irritations. Lozenges hold significant importance in medicine due to their effective delivery system for localized treatment of oral and throat conditions. Their design allows for slow dissolution in the mouth, ensuring prolonged contact with mucous membranes, which enhances the therapeutic effects of the active ingredients. Therapeutic lozenges are specialized formulations designed to provide targeted relief for various oral and throat ailments. They typically contain active pharmaceutical ingredients that offer soothing, analgesic, or antiseptic properties. Common ingredients include menthol, which provides a cooling sensation; honey and herbal extracts that soothe irritation; and local anaesthetics like benzocaine that numb pain.

CONCLUSION

The formulation and evaluation of lozenges is a complex process that requires careful consideration of various factors to ensure the development of safe, effective, and patient-acceptable products. Through this study, it is evident that lozenges offer flexible delivery options for various APIs, improving patient compliance, reducing side effects, and enhancing therapeutic outcomes. The optimization of formulation and manufacturing processes, coupled with rigorous evaluation and quality control testing, is crucial to ensure product quality and regulatory compliance. Future research directions, including novel APIs, excipients, and manufacturing technologies, will continue to expand the potential of lozenges in improving health outcomes. Ultimately, the successful development of lozenges relies on a multidisciplinary approach, integrating pharmaceutical science, engineering, and clinical expertise to create innovative, effective, and patient-centered products. Herbal lozenges show potential for addressing various health issues due to their natural ingredients, their efficacy and safety for specific diseases remain inconclusive. Further research is needed to determine their

effectiveness, appropriate dosage, and potential interactions with medications to use as an effective against variousdisease such as anti-diarrheal activity as well as anti-inflammatory and anti-Ulcer activity. Lozenges show promising potential for anti- diarrheal activity, offering convenience and potential targeted delivery. Future studies could explore novel ingredients, enhance taste, and conduct clinical trials to validate their effectiveness and safety, ultimately leading to practical applications in healthcare.

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