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Conceptualization and Refinement of Polyherbal Mouth Dissolving Lozenges

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ABSTRACT:
Lozenges are solid preparations containing one or more medicaments in a flavored and sweetened base that dissolve or disintegrate slowly in the mouth. They have been used to relieve oropharyngeal symptoms and treat local irritation or infection in the mouth. Lozenges have a promising future as a unique means of delivering medications into the mouth cavity for both local and systemic activity. Local anesthetics, antihistamines, antitussives, anti-inflammatories, antiseptics, decongestants, demulcents, and antibiotics are among the medications that can be made into lozenges. This study was conducted to evaluate the effectiveness of polyherbal lozenges for anti- inflammatory activity in the oral cavity. Lozenges were formulated by incorporating Psidium *Guava, Emblica officinalis, Piper betel*, and honey, using Jaggery as the candy base. Four batches were formulated by varying the concentration of the herbal ingredients (F1 to F4). The prepared formulations were evaluated by various parameters like Macroscopic evaluation, hardness, weight variation, friability, PH, and moisture content. Out of all the formulations, formulation F4 was found to have better activity.

Key words – Psidium Guava, Emblica Officinalis, Piper betel, honey, cumin powder, sodiumbicarboante, lemon, sugar, jaggery

AIM –To develop and formulate the Polyhebral mouth dissolving Lozenges.

I. OBJECTIVES

1. The effect of Poly hebral medicine on the oral cavity.
2. Instant relieve from the pain and soothing and cooling effect in themouth
3. To enhance anti-inflammatory and analgesic activity.
4. For the management of mouth ulcers.
5. To make safe and effective dosage form for pediatric and diabeticpatients
6. To improve oral hygiene.

II. INTRODUCTION

Herbal medicines are still the mainstay of about 75–80% of treatment in the worldwide population, especially in developing countries, for primary health care due to their better cultural acceptability, better compatibility with the human body, and fewer side effects. Herbal medicines include plants or their parts to treat injuries, diseases, or illnesses and are used for the prevention and treatment of diseases and ailmentsor to promote health and healing. It is a drug or preparation obtained from one or more plants and used for any purpose. Herbal medicines are the oldest type of health care known to mankind.

The World Health Organization (WHO) has defined herbal medicines as finished, labeled medicinal products that contain active ingredients, aerial or underground parts of the plants or other plant material, or a combination of these. Herbal formulations are widely accepted as therapeutic agents like anti- microbial, anti-diabetic, anti-aging, anti-arthritic, anti-depressant, anti-anxiety, anti-inflammatory, anti-HIV, treatment of cirrhosis, asthma, migraine, Alzheimer's disease, and improving memory. The WHO recently described traditional medicine (including herbal medications) as consisting of therapeutic techniques that were in use before the creation and propagation of modern medicine and are still in use today, frequently for hundreds of years. Traditional medications include organic materials, minerals, and medicinal plants. Only traditional medicines that use medicinal plant preparations as their main therapeutic component are classified as herbal drugs.

Many people prefer this herb as a safer means of treatment and less expensive than conventional medications, which is why so many people are returning to this traditional concept of medicine. Herbal medicine is also known as botanical medicine. Other aspects that contribute to

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their benefits include the type of habitat in which the plant was developed and how it was gathered an processed. The plant can be received either raw or as extracts, which have been macerated with water, alcohol, or other solvents to extract some of the compounds. Several chemicals are present in the end products, including fatty acids, sterols, alkaloids, flavonoids, glycosides, saponins, and others.

III. DESCRIPTION OF MATERIALSIN POLYHERBAL LOZENGES

MATERIALS USE

SL.NO	MATERIALS	SOURCE
1	Guava fruit	Organic market
2	Guava leaves	College
3	Betel leaves	Market
4	Amla fruit	Market
5	Lemon	Market
6	Honey	Farm house
7	Cumin powder	Market
8	Sodium bicarbonate	Lab
9	Sugar	Market
10	Jaggery	Market

TABLE NO.2: EQUIPMENT USE

SL.NO	EQUIPMENT	SOURCE
1	Beaker	Lab
2	Measuring cylinder	Lab
3	Porcelain dish	Lab
4	Mortar-Pestle	Lab
5	Thermometer	Lab
6	Pfizer hardness tester	Lab
7	Friability apparatus	Lab
8	PH meter	Lab
9	Disintegration apparatus	Lab
10	Vacuum oven	Lab

IV. Method of preparations

Collection of plant materials: Guava fruit, Amla, and Betel leaves were purchased from the organic market. Honey, cumin, lemon, and jaggery were procured from the local market. All ingredients were pure and analytical grade.

COMPARATIVE FORMULATION AND DEVELOPMENT

Table 3

SN	Ingredients	F1	F2	F3	F4	Optimized formula
1	Guava fruit	0.5gm	0.5gm	0.4gm	0.4gm	0.4gm
2	Guava leaves	0.5gm	_	_	_	_
3	Amla fruit steamed	0.6gm	0.5gm	0.4gm	0.4gm	0.4gm
4	Betel leaves steamed	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm

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5	Cumin seeds powder	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm
6	Honey	0.5gm	0.3gm	0.3gm	0.3gm	0.3gm
7	Lemon juice	1 drop	1 drop	1 drop	1 drop	1 drop
8	Sodium Bicarbonate	1 pinch	1 pinch	1 pinch	1 pinch	1 pinch
9	Sugar powder	_	2gm	1.0gm	_	_
10	Jaggery powder	2gm	_	1.5gm	2.5gm	2.5gm
	Total weight of the candy	**4gm**	**4gm**	**4gm**	**4gm**	**4gm**

METHOD OF PREPARATION OF LOZENGES

The lozenges were prepared by heating and congealing methods.

The herbs, guava, amla, and betel, were grated, steamed, and boiled in a container till they formed a soft mass. In another container, the required quantity of jaggery and sugar was added and heated to 150 °C till the color changed to golden brown (caramel formation).The above-prepared herbs were added to the jaggery solution along with honey, sodium bicarbonate, cumin powder, mixed uniformly, and heated with constant stirring for 10–15 minutes.The preparation was then poured into molds to get lozenges of the ideal size. The mold was allowed to cool, and later the hard lozenges were tossed over powdered sugar to avoid getting sticky in the humidity. Then it was wrappedand stored in an airtight container in a cool place.

Fig No.: Lozenges Preparation Process

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V. Evaluation:

Macroscopical evaluation The laboratory formulation was evaluated for acceptability based on visual observation of several organoleptic properties.

Macroscopical Evaluation

Table 4

SNO	TEST	F1	F2	F3	F4	OPTIMIZED
1	Colour	Brown	Light yellowish	Yellowish brown	Brown	Brown
2	Odour	Pleasant	Aromatic	Aromatic		
3	Taste	Acrid	Sweet	Sweet	Sweet	Sweet
4	Texture	Smooth	Smooth	Smooth	Smooth	Smooth

Hardness

The hardness of the lozenges is determined by Pfizer or Monsanto hardness tester. The resistance of lozenges to shipping or breakage under conditions of storage, and transportation.

Table No.5:

Batch	F1	F2	F3	F4
Hardness (kg/cm^2)	10.25± 0.007	10.12±0.004	12.15±0.019	12.30±0.005

Weight Variation test

Twenty lozenges were randomly selected and individually weighed using an electronic balance. The average weight and standard deviation of 20 tablets were calculated or the initial weight was compared with the calculated average weight.

Average weight = Weight of 20 Lozenges / 20

Weight variation = Individual Weight - Average Weight x 100% /Average Weight

Table No: 6 Weight Variation test

Batch	Average weight (gm)
F1	4.01 ±0.002
F2	4.02 ±0.005
F3	4.05±0.007
F4	4.02 ±0.004

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Friability

The friability of tablets was determined using the Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed and transferred into a friability. The friability was operated at 25 rpm for 4 minutes. The tablets were weighed again after taking out the tables and brushing the dust away. If tablets are found broken or cracked and the final value exceeds the limit test is considered failed. The value should be no more than 1%. If exceed repeat three time for overall estimation.The % friability was then calculated with the help of the following formula

Friability = (Initial Weight - Final Weight) X 100 / Initial Weight

Table 7: Friability test

Batch	F1	F2	F3	F4
%Friability	0.01±0.003	0.02±0.007	0.023±0.015	0.017±0.008

Figure no 1

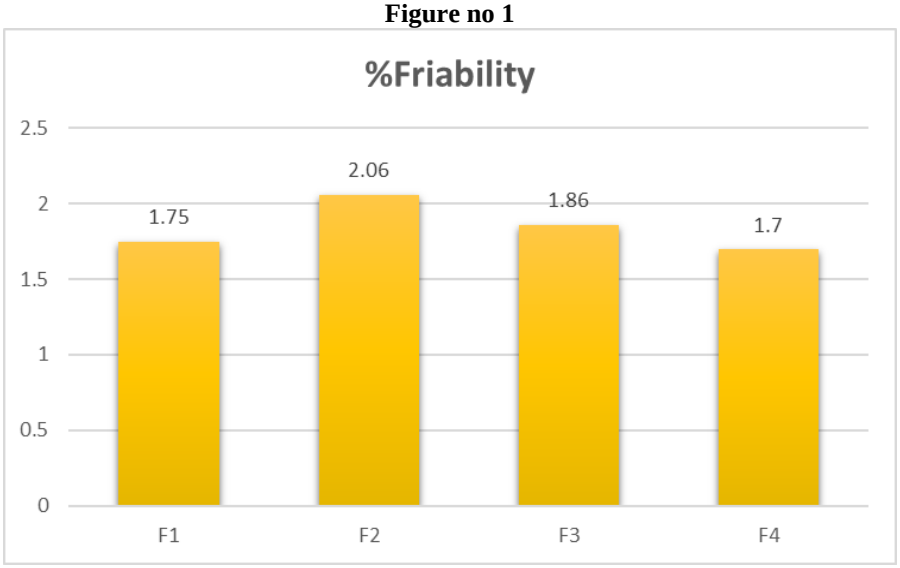

Figure No. 16: Friability Test

1. Measurement of pH

The acidity or alkalinity of lozenges was indicated by using a lab pH meter, a scale from 1.0 to 14.0. 1% W/Solution was prepared by dissolving 1 g candy in 100 ml distilled water and its pH was recorded.

Table no. 8: pH determination

Formulation	F1	F2	F3	F4
PH	8.5	8.0	7.8	7.5

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Figure no.2: Ph. Determination

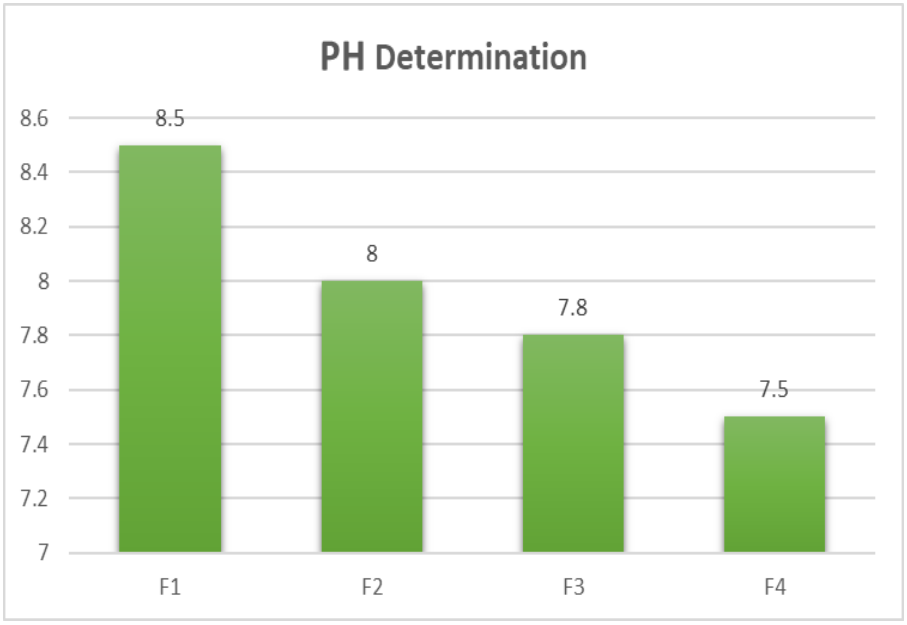

Figure no.3: Ph. Determination

2. Disintegration time-

It is the interval required for the complete disappearance of a lozenge or its particles from the tester net. The disintegration test of the prepared lozenges was performed according to USP30, using a disintegration tester through the disintegration mediumof phosphate buffer with pH 6.2 maintained at 37 ± 0.5°C.

Table no.9: Disintegration time

Formulation	**In vitro disintegration time (min)**
F1	15:65
F2	17:60
F3	16:50
F4	18:05

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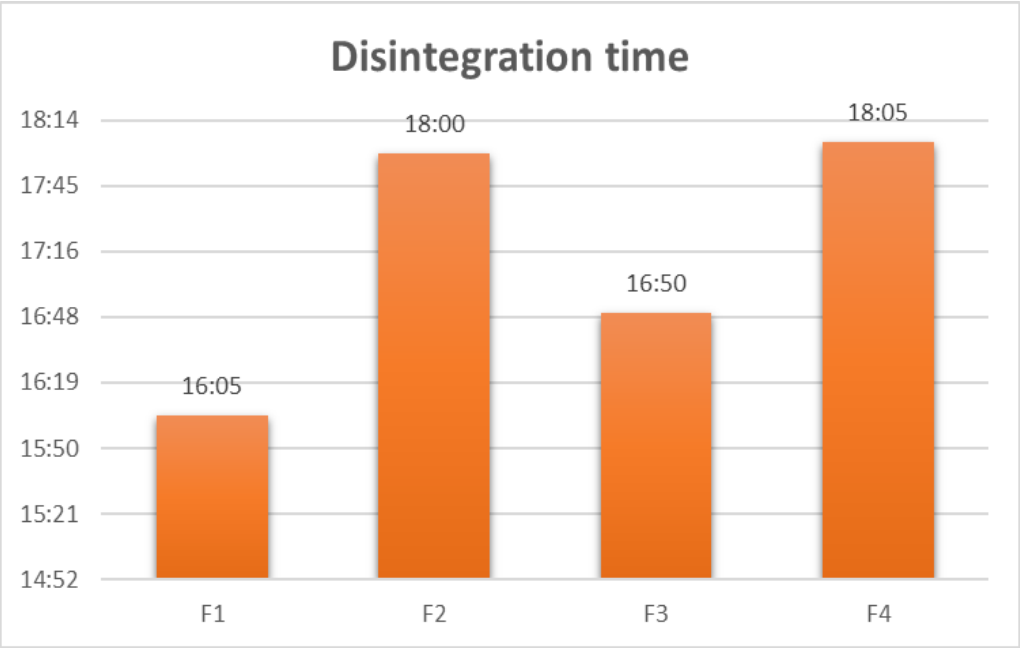
Figure no 3



3. Moisture content-

The prepared lozenges were crushed in a mortar (3 lozenges of each batch) and weighed. From each crush lozenge 1 gm of sample was weighed and placed on a butter paper and then placed in the desiccator for 24 hours. After that, the samples were removed and weighed again. The weight reduced was then calculated for the % moisture content by the following formula:

% Moisture Content = Initial weight - Final weight × 100/ Initialweight

Table no10.: Moisture content

Formulation	F1	F2	F3	F4
Percentage	0.89	0.82	0.75	0.68

VI. RESULTS AND DISCUSSION

Lozenges were prepared in an authentic and stable dosage form. Lozenges aredeveloped by altering the quantities of ingredients and replacing major bases with sugar or jaggery powder. To enhance the palatability, appearance, and physiochemical characteristics of the dosage form by adding guava fruit replaced by guava leaves, the betel leaves were adjusted and the formulation was optimized. This formulation is preferred organoleptically, especially by patients in the pediatric population.

The formulated lozenges were evaluated for macroscopic evaluation, hardness test, weight uniformity test, friability, PH determination, disintegration time, and moisture content.

The objective of the present study is to determine the effect of polyherbal lozenges on the management of mouth ulcers.

Using six distinct herbs, polyherbal lozenges were formulated. The development of the polyherbal lozenges involved a comprehensive analysis ofthe herbs as well as optimization of the formulation, dosage, and evaluation. The comparative formulation was developed in F1–F4. From the evaluation parameters, visual appearance was observed for 30 days at periodic intervals. F-4 lozenges had a pleasant odour and taste compared to F1-F-3.

Disintegration time was seen to be longer for F-4, which shows lozenges dissolve slowly and give effective therapeutic activity, and a lower percentageloss in weight was observed. Among all

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the formulations, F-4 had acceptable palatability, appearance, and better activity.

VII. CONCLUSION

The polyherbal lozenges were created through a systematic and thorough investigation of all the herbs included in the formula, followed by optimization of the polyherbal formulation dosage and evaluation of qualitative and quantitative parameters using precise, advanced analytical instruments. Herbal remedies are more acceptable in the belief that they are safer with lesser side effects than the synthetic medicines. This polyhebral lozenge plays an important role in maintaining oral hygiene and for the management of mouth ulcers. The lozenges showed analgesic and anti-inflammatory activity. This formulation is preferred organoleptically especially by patients in the pediatric population. For young patients medicated lozenges will be the mostsuitable dosage form. These will offer additional benefits for patience compliance, ease of use, and comfort for effective treatment, such as low dosage, quick start of action, short dosing schedule, and most effectiveness. This will provide a better novel dosage form.

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