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Formulation and Evaluation of Herbal Lozenges

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ABSTRACT
Lozenges are solid preparations consisting of sugar and gum, facilitating slow release of the medicament. It is used to medicate throat for the slow administration in cough remedies. They may possess anaesthetic or antiseptic properties. Lozenges provide a pleasant dosage form for patients who are unable to swallow other types of solid dosage forms. As they are formulated to taste good, they must be kept out of the reach of children, who may view them as candy. A throat lozenge (also known as a cough drop, sore throat sweet, troche, cachou, pastille or cough sweet) is a small, typically medicated tablet intended to be dissolved slowly in the mouth to temporarily stop cough, lubricate, and soothe irritated tissues of the throat (usually due to a sore throat or strep throat), possibly from the common cold or influenza. They provide a pleasant dosage form for patients who are unable to swallow other type of solid dosage forms. The present work was carried out to prepare and evaluate herbal lozenges by using betel, basil leaves extracts and honey, jaggery as their bases.

Keywords: Lozenge, Troches, Pastilles,

I. INTRODUCTION

The word “Lozenge” is derived from French word “Losenge"which means a diamond shaped geometry having four equal sides. Lozenges and pastilles have been developed since 20thcentury in pharmacy and is still und er commercial production. Lozenges are solid preparations that are intended to dissolve in mouth or pharynx. They may contain one or more medicaments in a flavored and sweetened base and are intended to treat local irritation, infection of mouth oropharynx and may also be used for systemic drug absorption. They can deliver drug into the oral cavity or to the mucosal surface. Lozenges are better innovative dosage forms placed in oral cavity. Lozenges historically have
been used for the relief of minor sore thro at pain and irritation and have been used extensively to deliver topical anesthetics and antibacterial. Today lozenge s contain
different category of medicament as follows: analgesics, anesthetics, antimicrobial antiseptics and antitussives.

Advantages
1.It can
be given to those patients who have difficulty in swallowing.
2.Easy to administer to geriatric and pediatric population.
3.It
extends the time of drug in the oral cavity to elicit a specific effect.
4.Easy to prepare, with minimum amount of eq uipment and time.
5.Do not require water intake form administration.
6.Systemic absorption of drugs can be possible through buccal cavity.
7.Taste of the drugs can be masked by sweete ners and flavors used in the formulation.
8.Technique is non invasive, as is the case with parenterals

Disadvantages
1.Some drugs may not
be suitable with aldehyde candy bases eg; benzocaine.
2.Children having above 6 years of age can us e lozenges safely.
3.The non ubiquitous distribution of drug within saliva for local therapy.
4.Possible draining of drug
from oral cavity to stomach along with saliva.
5.The
lozenge dosage form is that it mistakenly could be used as candy by children.
6.A hard candy lozenge is the high temperature

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II. METHODOLOGY

Lozenges were prepared by melting and mold technique. Jaggery was melted and mixed with the other ingredients to form a homogeneous mixture. Subsequently, the mixture was poured into the stainless-steel mold.

Table 1 (F1)

S. No	Ingredients	Quantity required
1	Basil leaves extract	1.5ml
2	Honey	6.7ml
3	Corn flour	q.s
4	Vegetable oil	1-2 drops

Table 2 (F2)

S. No	Ingredients	Quantity required
1	Betel leaves extract	1.5ml
2	Honey	6.7ml
3	Corn flour	q. s
4	Vegetable oil	1-2 drops

Table 3 (F3)

S. No	Ingredients	Quantity required
1	Myrobalan powder	1.5gms
2	Jaggery	6.7gms
3	Corn flour	q. s

The Process for preparation of Herbal formulation in the form of lozenges, where in the process comprises the following steps.

Step 1

Prepare the extraction of herbal leaves (Basil, Betel leaves) by grinding the leaves in the mixer. After this process the fluid containing pulp is obtained. Then separate the water content and pulp content from this above extraction.
The myrobalan is prepared into the powder form by using the mixer grinder.

Step 2

The preparation of the syrup content which consists the jaggery in the formulation 1, honey in the formulation 2, and in formulation 3 along with required amount of water respectively. The concentration of the liquid should be taken according to the base product and herbal extraction.

Step 3

The prepared extraction of the herbal leaves and myrobalan powder is introduced into the respective formulation. The liquid solution is stirring continuously throughout the process for mixing the herbal extracted product in the liquid solution.

Step 4

The concentrated products of the lozenges is obtained from the previous steps.
By using the moulds (the containers which are used to give the different shapes) the liquid lozenges are turns into the different solid shaped candies.

III. [7,8,9] EVALUATION TEST

1. Organoleptic evaluation

The formulation developed in the laboratory were evaluated for its acceptance based on visual observation for various organoleptic properties

2. Weight variation test

This test is based on the weight of each lozenge which are present in the group. Take 20 lozenges and weighed individually. Calculate average weight and compare the individual lozenges weight to the average weight.

3. Hardness

A lozenge requires a certain amount of strength or hardness and resistance to friability to with stand mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures the lozenges crushing strength.

4. Disintegration test

USP Disintegration apparatus is used to determine the disintegration time of lozenges. Disintegration time is noted in pH 6.8 phosphate buffer at 37°C.

5. Dissolution test

Dissolution is the process in which a substance forms a solution. Dissolution testing measures the extent and rate of solution formation form a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. This study is carried out by using USP II Dissolution type apparatus (paddle type). Dissolution study was carried out in 900 ml of

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buffer pH 6.4 by USP II paddle method at 100 rpm. Samples were withdrawn at 5 min time interval and replaced immediately with an equal volume of fresh buffer and were analyzed spectrophotometrically. Temperature 37°C ± 2°C maintained between dissolution studies.

6. Moisture Analysis

Gravimetric, Karl Fisher titration and Azeotropic distillation methods are used to determine the moisture content of lozenges. In gravimetric method, sample (1g) is weighed and placed in vacuum oven at 60-70°C for 12-16hrs. Final weight is subtracted from initial and the difference in moisture content is calculated. Karl Fischer titration involves calculating a sample to contain 10-250mg water in titration flask and titrated with Karl Fischer reagent. In azeotropic distillation method, 10- 12g candy is pulverized and placed in 500ml flask to which 150-200ml toluene is added. Flask is connected to a reflux condenser and is refluxed for 1-2hrs. Water collected gives the amount of water present in the sample.

IV. RESULTS

1. Organoleptic evaluation

This presents the organoleptic evaluation of the formulation in the following tables

Table 4 (F1)

S.No	PARAMETER	OBSERVATION
1	Color	Light green
2	Odor	Pleasant
3	Taste	Sweet
4	Texture	Smooth
5	Shape	Star

Table 5 (F2)

S.No	PARAMETER	OBSERVATION
1	Color	Green
2	Odor	Pleasant
3	Taste	Sweet
4	Texture	Smooth
5	Shape	Flower

Table 6 (F3)

S.No	PARAMETER	OBSERVATION
1	Color	Dark brown
2	Odor	Pleasant
3	Taste	Sweet
4	Texture	Smooth
5	Shape	Heart

2. Weight Variation

Table 7

Formulations	Weight variation
F1	721.94±0.05
F2	722.54±0.15
F3	725.90±0.14

3. HARDNESS

Table 8

Formulation	Hardness
F1	3.7±0.20
F2	3.9±0.15
F3	4.1±0.10

4. DISINTEGRATION TIME

Table 9

Formula	Disintegration time (sec)
F1	42±4
F2	36±1
F3	38±3

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5. DISSOLUTION STUDY

Table 10

Sampling time (minutes)	Drug release profile (% drug release)		
	F1	F2	F3
10	85±0.24	84±0.23	86±0.28
15	89±0.51	87±0.29	90±0.35
20	92±0.73	90±0.40	93±0.54
30	94±0.04	94±0.20	95±0.29

6. MOISTURE CONTENT

Table. 11

Formula	Moisture content(w/w)
F1	1.84±0.17
F2	1.73±0.05
F3	1.71±0.5

V. DISCUSSION

A simple technique of Herbal lozenges preparation was performed and three formulations were prepared in present study. Herbal Lozenges was formulated, evaluated and studied. It was prepared by using different quantities of basil leaves extract, honey, corn flour, vegetable oil, betel leaves extract, myrobalan, jaggery powder Three different formulations F1, F2, F3 were prepared and subjected to evaluation studies. The preparation was formulated and evaluated and was found to be satisfied with all the required characterization. It was found of all the three formulations, F1 showed better results.

VI. CONCLUSION

A systematic approach involving preparation and evaluation of Herbal lozenges using different formulation was attempted. The evaluation studies were conducted which projected the satisfactory results. The developed formulations can be used to medicate throat and also for cough remedies.

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