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FORMULATION & EVALUATION OF MULTI-PURPOSE HARD CANDY & SOFT GELATIN LOZENGES

Gaurav Vaman Pawar*, Prof. Nilesh Subhash Jadhav, Yogesh Govind Raut, Gitanjali Dattatray Rodge, Misba Jakir Patel, Sidhhant Gorakshnath Rasal

Department of Pharmaceutical Chemistry, S.V.N.H. College of B.Pharmacy, Shrishivajinagar (Rahuri Factory), Tal-Rahuri Dist-Ahmednagar, MS, India-413706.

***Corresponding Author: Gaurav Vaman Pawar**

Department of Pharmaceutical Chemistry, S.V.N.H. College of B.Pharmacy, Shrishivajinagar (Rahuri Factory), Tal-Rahuri Dist-Ahmednagar, MS, India-413706.

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ABSTRACT

Lozenges are popular over the counter medicinal products nowadays. In the current market there are many brands that have medicated products with traditional herbal drugs. In this research paper we will have to overview about formulation aspects and evaluation of medicated Lozenges having multiple purpose property. Also hard candy Lozenges are conventional dosage forms for the pediatric population. Lozenges containing Liquorice, Ginger, Ashwagandha, Tulsi have their particular pharmacological activity on the human body. Liquorice has antivirals, antibacterial, antidiabetic and anti-asthmatic action. Ginger has anti-emetics and antidiabetic activity. While Tulsi has antifungal and mosquito repellent activity. Ashwagandha is a real potent regenerative tonic (Rasayana of Ayurveda), due to its multiple pharmacological actions. Lozenges containing multiple herbal medications can be proven a good therapeutic dosage form especially in children. In this research article we will study about formulations of both Hard Candy and Soft Gelatin based Lozenges and their evaluations.

KEYWORDS: Hard Candy Lozenges, Soft Gelatin Lozenges, Ethanolic Extracts.

INTRODUCTION

Lozenges are solid preparations that contain one or more medicaments, usually in a flavored, sweetened base, that are intended to dissolve or disintegrate slowly in the mouth. They can be prepared by molding (Gelatin and/or fused sucrose and sorbitol base) or by compression of sugar-based tablets. Molded lozenges are sometimes referred to as pastilles, whereas compressed lozenges may be referred to as troches. They are used for patients who cannot swallow solid oral dosage forms well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bathe the throat tissues in a solution of the drug. Lozenges historically have been used for the relief of minor sore throat pain and irritation and have been used extensively to deliver topical anesthetics and antibacterial.[1][2]

Phytochemical screening of herbal extracts

For determination and confirmation of different phytoconstituents present in herbal extracts phytochemical screening was performed. Chemical reactions of phytoconstituents with different chemical reagents gives presence or absence of chemical compound present in herbal extract. Each compound has their characteristic pharmacological action.

Table 1: Phytochemical screening of plant extracts.[3][4][5][8]

Extracts	Alkaloid	Flavonoid	Phenols	Tannin	Saponin	Anthraquinone	Steroid	Ascorbic Acid	Glycoside	Reducing Sugar
Liquiorice	-	+	-	-	+	-	-	-	-	+
Ginger	+	-	-	-	+	-	-	+	+	+
Ashwagandha	+	-	+	-	+	-	+	-	+	-
Cumin	+	+	+	+	+	-	-	-	+	-

MATERIALS AND METHODS

Powdered crude drug of liquiorice, ginger, ashwagandha and cumin was purchased from commercial sources. All other excipients and chemicals was obtained from college laboratory

Methods of extracton

Soxhlet extraction method: Dried plant material coarsely grinded. Then extraction takes place in Soxhlet apparatus using 180 ml ethanol as a solvent at a temperature of 75^0C for six hours. Extractive value find out using following formula.

Alcohol Soluble % Extractive value= Dried extract weight/ Course powder weight x 100

A. Soft gelatin based lozenges

One of the most popular lozenges for pediatric use are chewable lozenges. These also called as 'gummy type' candy lozenges. These formulated using gelatin as a base and glycerin. Gelatin based lozenges also called as 'Pastilles'. They are prepared by pouring the melt into molds and then cooling. Last step of 'Dusting' of product with powdered sugar decrease the tackiness. Soft gelatin based lozenges are more popular among pediatric population due to their glossy appearance.[1]

Preparation of soft gelatin lozenges

For the preparation of soft lozenges; gelatin powder and glycerin was taken and melted at temperature of 110^0C with continuous stirring. When clear viscous solution of gelatin and glycerin was formed then temperature lowered down at 80^0C. With continuous stirring other ingredients plant extracts, methyl paraben, saccharin, coloring agents and small amount of water was added. Then viscous solution was poured into pre-lubricated molds. Then molds was kept in refrigerator for cooling, after 15-20 minutes soft, glossy lozenges are formed.[6]

Table 2: Composition of soft gelatin lozenges.[1]

Ingredients	Quantity			
	F1	F2	F3	F4
Liquiorice	100 mg	150 mg	200 mg	300 mg
Ginger	100 mg	200 mg	300 mg	200 mg
Ashwagandha	200 mg	250 mg	300 mg	250 mg
Cumin	100 mg	200 mg	300 mg	150 mg
Glycerin	2 ml	2.5 ml	2 ml	0.5 ml
Gelatin	1000 mg	1500 mg	1000 mg	400 mg
Methyl Paraben	20 mg	25 mg	10 mg	10 mg
Sodium Saccharin	20 mg	25 mg	25 mg	20 mg
Coloring Agent	Q.S	Q.S	Q.S	Q.S

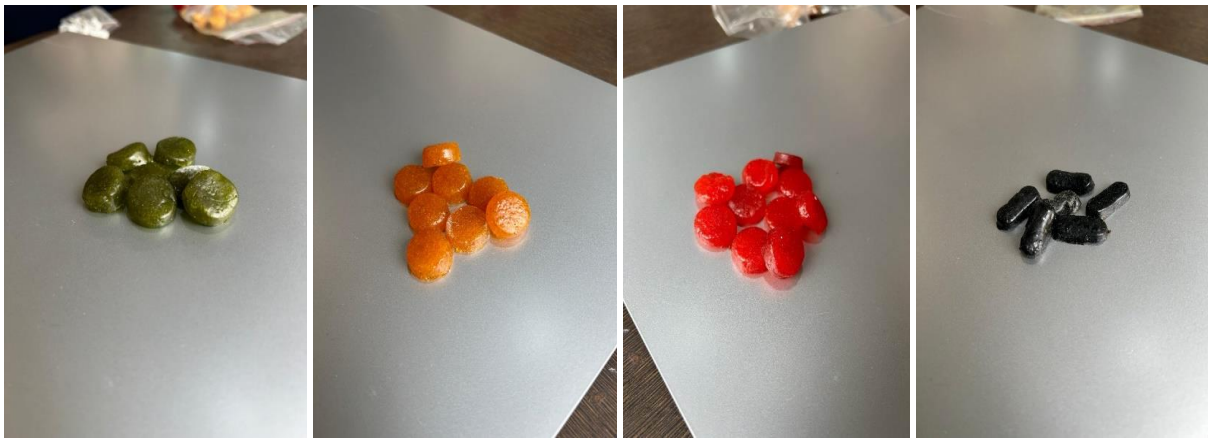

Fig. Soft gelatin lozenges batch F1, F2, F3 & F4.

Evaluation of soft gelatin lozenges

1) Organoleptic observations

The prepared gelatin based lozenges were observed organoleptically for color, taste, shape, texture, and clarity. The texture observation was conducted by mildly rubbing the surface and rubbing the tablets between two fingers.[7]

Table 3: Organoleptic evaluations of soft lozenges.

Parameters	Result			
	F1	F2	F3	F4
Color	Green	Orange	Red	Black
Shape	Spherical			Cylindrical

Texture	Smooth
Taste	Sweet

2) Diameter and Thickness

The diameter and thickness were measured by using Vernier caliper. The soft gelatin based lozenges dimensions are a very important factor in their manufacture. The three lozenges were selected randomly from the formulation, and then thickness and diameter were measured.[6]

Table 4: Evaluation of soft lozenges for Diameter and Thickness.

Evaluation parameter	Result (Mean ± SD) (n=10)			
	F1	F2	F3	F4
Diameter/Length	19 mm	19 mm	19 mm	20 mm
Thickness	4.8 mm	5.9 mm	5.5 mm	3.6 mm

3) Weight variation test

Ten lozenges from the formulation were randomly selected and weighed together the tablets were then weighed individually. The batch passes the test for weight variation test if not more than two of the individual lozenge weight deviates from the average weight by more than the percentage according to IP limits shown in table.[6]

Table 5: Weight Variation Limit According To IP.

Average Weight of Tablet (gm)	% Deviation
Less than 80	10
80-250	7.5
More than 250	5

Table 6: Average weight of soft lozenges.

Batch	Average Weight (n=10)
F1	2.52 gm
F2	2.85 gm
F3	2.60 gm
F4	1.24m

4) Mouth dissolving time

The time taken by the lozenges to dissolve completely was determined by USP disintegration apparatus, where lozenges placed into each tube of the apparatus and time taken for then lozenges to dissolve completely was noted by using 900ml phosphate buffer of pH 6.8 at 37^0C. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation.[6]

Table 7: Evaluation of soft lozenges for mouth dissolving time.

Evaluation parameter	Result			
	F1	F2	F3	F4
Mouth dissolving time	14.35 min	15.10 min	15.33 min	22.10 min

1) Anti-microbial activity

i. Preparation of agar plate

Agar plates was prepared by using nutrient agar, peptone, sodium chloride and distilled water. Agar solution was heated for homogenous mixing and allow to cool. Cooled agar solution poured into petri dish to form culture media.

ii. Inoculation and development of microbes

Microbial strain direct obtained from curd sample are spread on petri dish and petri dish allow to growth of microbes in incubator for 48 hours at a room temperature of 37^0C.

iii. Agar well diffusion method

After complete growth of microbes; small wells of 5-6 mm diameter was created in petri dish and sample of formulation was placed in the well. further observation takes place for zone of inhibition.

iv. Zone of Inhibition

Zone of inhibition of lozenges formulation for lactobacillus was found as given below:

Table 8: Zone of inhibition for soft lozenges.

Parameter	Result			
	F1	F2	F3	F4
Zone of Inhibition	5 mm ± 0.3 mm	6 mm ± 0.3 mm	7 mm ± 0.3 mm	6 mm ± 0.3 mm

B. Hard candy lozenges

Hard candy lozenges are the mixture of sugar and other carbohydrates in amorphous (no crystalline) or glassy condition. These are also called as solid syrup. Lozenges typically used for local medicament like throat diseases, mouth diseases etc. They mainly contains drugs like topical anesthetics and antibiotics. They are flavored and attractive in appearance.

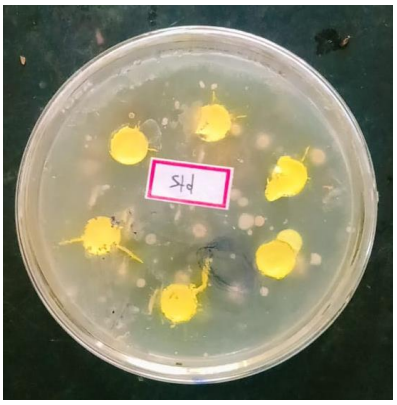

Fig. 5. Zone of Inhibition For Tetracycline Standard Solution

Fig. 6. Zone of Inhibition For Lozenges Formulation

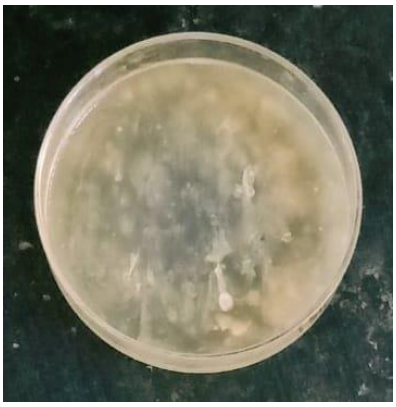

Fig. 7. Fully Growed Lactobacillus In Petri Dish.

Preparation of hard candy lozenges

A sugar syrup was made by mixing sugar and water. Powdered sugar was dissolved in a small amount of water and heated to 110°C until it formed a clear viscous syrup. The temperature was then lowered to 90°C, and the drug and other ingredients were added. The mixture was poured into molds to create lozenges. To protect them from moisture, the lozenges were wrapped in aluminum foil and stored in desiccators.[6]

Table 9: Composition of hard candy lozenges.

Ingredients	Quantity (mg)
Liquiorice	200 mg
Zinger	150 mg
Cumin	100 mg
Ashwagandha	200 mg
PEG	1000 mg
Sucrose	2000 mg
Mint oil	0.1 ml
Alcohol	0.5 ml
PVP	5%
Coloring Agent	Q.S

Fig. 8: Hard candy lozenges.

Evaluations of hard candy lozenges

1) Organoleptic observations

The prepared gelatin based lozenges were observed organoleptically for color, taste, shape, texture, and clarity. The texture observation was conducted by mildly rubbing the surface and rubbing the tablets between two fingers. [7]

Table 10: Organoleptic evaluations of hard lozenges.

Parameters	Result
Shape	Spherical
Color	Orange
Texture	Smooth
Taste	Sweet

2) Diameter and Thickness

The diameter and thickness were measured by using Vernier caliper. The soft gelatin based lozenges dimensions are a very important factor in their manufacture. The three lozenges were selected randomly from the formulation, and then thickness and diameter were measured.[6]

Table 11: Evaluation of hard lozenges for Diameter and Thickness.

Evaluation parameter	Result (Mean ± SD)
Diameter	18.9 mm
Thickness	7 mm

3) Hardness

The hardness of ten hard lozenges was determined by using Monsanto Hardness tester. Mean and standard deviation were computed and reported. It is expressed in kg/cm^2. The average hardness for lozenges is calculated and presented with standard deviation and observation reading mentioned in below table.[6]

Table 12: Evaluation of hard lozenges for hardness.

Evaluation parameter	Result (Mean ± SD) (n=3)
Hardness	5 ± 1 Kg/cm^2

4) Weight variation test

Ten lozenges from the formulation were randomly selected and weighed together the tablets were then weighed individually. The batch passes the test for weight variation test if not more than two of the individual lozenge weight deviates from the average weight by more than the percentage according to IP limits shown in table.[6]

Average Weight of Hard Candy Lozenges- 3.24 gm.

5) Friability

Friability was determined by using a Roche friabilator. 10 lozenges were weighed and placed in the Roche friabilator and all the parameters set on the friabilator. The apparatus was rotated at 25rpm (100 rotations) for 4 minutes. After revolutions the lozenges were deducted and weighed again. The maximum mean weight loss samples are not more than 1.0 %. The percentage friability was measured using the formula:[6]

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

and observation reading mentioned in below table:

Where,

% F = Friability in percentage,

W_0 = Initial weight of lozenges,

W = Final weight of lozenges after revolution.

Table 13: Evaluation of hard lozenges for friability.

Evaluation parameter	Result (Mean ± SD) (n=10)
Friability	0.964 ± 0.2% (Pass)

6) Mouth dissolving time

The time taken by the lozenges to dissolve completely was determined by USP disintegration apparatus, where lozenges placed into each tube of the apparatus and time taken for then lozenges to dissolve completely was noted by using 900ml phosphate buffer of pH 6.8 at 37^0C. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation.[6]

Table 14: Evaluation of hard lozenges for mouth dissolving time.

Evaluation parameter	Result
Mouth Dissolving Time	8.1 min

7) Anti-microbial activity

Anti-microbial activity studied as same as soft lozenges and zone of inhibition for hard lozenges was found to be: 4 mm ± 0.3 mm.

RESULT AND DISCUSSION

Formulated hard candy and soft gelatin lozenges has elegant appearance, smoothness and sweet taste. Hard candy lozenges are rough and hard while soft gelatin based lozenges are smooth and rubbery. Also candy base lozenges contain multiple herbal ingredients that have multiple therapeutic actions. Average weight of hard and soft lozenges was found to be 3.5gm and 2.5gm respectively. Both hard and soft lozenges are uniform in size and safe and having moth dissolving time of 8 and 15 minutes. According to antibacterial activity of all formulation F3 formulation shows highest antibacterial activity against Lactobacillus and have zone of inhibition of 7mm. Hence F3 formulation has highest antibacterial activity.

CONCLUSION

Both hard candy and soft lozenges can be formulated using base of gelatin and sugar respectively. Lozenges has elegant appearance and sweet hence popular among pediatric as well as adult population. Formulated F3 batch of soft lozenges have better antibacterial activity. They can be used in multiple condition like bacterial infection of mouth, emesis, gastrointestinal problems and respiratory problems.

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