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**DESIGN, CHARACTERIZATION AND EVALUATION OF HARD CANDY
LOZENGES AND SOFT JELLY LOZENGES OF *RAPHANUS SATIVUS* LEAF
EXTRACT**

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ABSTRACT

Objective: Medicinal properties of leaves of *Raphanus sativus* have been neglected from years, recent research has proven the anti-inflammatory activity of leaf extract, the current study aims in formulating and evaluating *Raphanus sativus* leaf extract into hard candy and soft jelly lozenges.

Methods: The hard candy lozenges are prepared in sucrose base using heat and congealing method. Soft jelly lozenges are prepared by using heat and congealing method using gelatin as gelling agent

Conclusion: Hard candy lozenges prepared by using HPMC K15, K100M are elegant, non friable and exhibited good hardness. Soft jelly lozenges formulations have shown increased viscosity and decreased syneresis with increase in the concentration of gelling agent.

Keywords: *Raphanus sativus*, Hard candy lozenges, Soft jelly lozenges, Heat and congealing method, Anti-inflammatory activity

INTRODUCTION

Lozenges are solid dosage forms 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 or pharynx and may also be used for systemic drug absorption. They can deliver drug multi directionally into the oral cavity or to the mucosal surface. Lozenges are better innovative dosage form placed in oral cavity. 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]. Today lozenges contain different category of medicament as follows: analgesics, anti-inflammatory agents anesthetics, antimicrobials, antiseptics, antitussives, astringents, decongestants, demulcents and other classes and combinations of drugs. Lozenges are available as over the counter medications in the form of caramel based soft lozenges, hard candy lozenges and compressed tablet lozenges containing drugs for sore throat, mouth infection and as mouth fresheners [2, 3].

Leaves and Roots of *Raphanus sativus* has been widely consumed in different parts of

the world. Radish roots are low in calories and are usually eaten raw; the young leaves can be cooked like spinach. The leaves, seeds and old roots are used in the treatment of asthma and other chest complaints [4]. The juice of the fresh leaves is diuretic and laxative [5]. However, earlier much research on leaves of *Raphanus sativus* is not done. Recent studies focused more on therapeutic properties of constituents present in leaves of *Raphanus sativus* indicating the leaves show anti-inflammatory properties. The components of *Raphanus sativus* leaves are known as phenolic compounds (caffeic, *p*-coumaric, ferulic, hydroxycinnamic, *p*-hydroxybenzoic, vanillic, salicylic, and gentisic acids) and glucosinolates (benzyl isothiocyanate). The expression of nuclear factor-kappa B (NF- κ B), the key regulator of the transcriptional activation of the inflammatory cytokine genes, was reduced by the *Raphanus sativus* leaves chloroform fraction, which suggests that leaves exhibits anti-inflammatory effects in LPS-stimulated macrophages via NF- κ B inactivation [6-8].

Anti-Inflammatory agents are most commonly used in dental procedures to reduce inflammation. In the current study an approach has been made to develop and formulate lozenges from leaf extract of

Raphanus sativus, which is proven to possess anti-inflammatory properties. These anti-inflammatory lozenges can be used for local infections in oral cavity followed with dental procedures.

MATERIALS AND METHODS

Leaves of *Raphanus sativus* was purchased from local market of hyderabad region, Food grade HPMC, used as binder is obtained from Sakshi chem. Sciences private limited, Nagpur, Food grade Mannitol, used as diluent is purchased from Mitushi biopharma, Ahmedabad. Sucrose used as base for lozenges and Menthol used as coolant and flavouring agent, Gelatin used as gelling agent in soft jellies, Sodium benzoate used as preservative in soft jellies are obtained as gift samples from Joginpally B.R Pharmacy College.

Preparation of *Raphanus sativus* leaf extract:

Freshly collected leaves of *Raphanus sativus* are washed thoroughly and shade dried for a period of 4-7 days, until the leaves got completely dried. The dried leaves are grinded into fine powder. The leaf powder is extracted by hot extraction method. 100 grams of leaf powder is weighed and mixed with 500 ml of water and boiled until the liquid reduces to half of its initial quantity.

Preparation of *Raphanus sativus* leaf extract syrup solution:

The extract obtained from above process is filtered and boiled by adding 800 grams of sucrose, until all the sucrose is melted and viscous solution is formed. This viscous extract is further used in preparation of hard and soft lozenges.

Preparation of Hard Candy Lozenges [9]:

Hard Candy lozenges of *Raphanus sativus* leaves are prepared by heat and congealing method. Formulations F1, F2, F3 are prepared by taking 50 ml each of *Raphanus sativus* leaf extract syrup solution and heated by adding different concentrations of HPMC k15 M polymer. Formulations F4, F5, F6 are prepared by taking 50 ml each of *Raphanus sativus* leaf extract syrup solution and heated by adding different concentrations of HPMC k100 M polymer. 50 grams of mannitol is added to all the formulations, and heated until thick viscous solution with string consistency is formed, menthol is added at the end as flavouring agent. The above mixture is poured into previously lubricated silicone moulds and left aside for cooling. After 30 minutes the formed hard lozenges are removed and evaluated. Formulation of *Raphanus sativus* leaf extract hard candy lozenges is given in **Table 1**.

Preparation of Soft Jelly Lozenges:

Soft Jelly lozenges of *Raphanus sativus* leaves are prepared by heating and

congealing method. Formulations FS1 to FS6 is prepared by taking different concentrations of gelatin powder and dissolved in 10ml of water and kept aside for 30 min resulting in swelling of gelatin powder. The resultant solution is added to 50 ml each of *Raphanus sativus* leaf extract syrup solution, 50 grams of mannitol powder and heated until viscous solution of definite consistency is formed. Sodium Benzoate is added as a preservative as gelatin is prone to microbial growth, Menthol is added as flavouring agent at the end, the viscous solutions containing different concentrations of polymers is poured into previously lubricated silicone moulds and kept in refrigerator in freezer zone for 2 hours. After 24 hours the formed soft jellies are removed and subjected to further evaluation. Formulation of *Raphanus sativus* leaf extract soft jelly lozenges is given in **Table 3**.

EVALUATION

Evaluation of Hard Candy Lozenges

The moulds used for preparing of lozenges are of different shapes and sizes, the prepared lozenges are evaluated for thickness, hardness, weight variation, friability.

Lozenge hardness:

Hardness of lozenge is defined as the force applied across the diameter of the tablet in order to break the lozenge. The resistance of

the lozenge to chipping, abrasion or breakage under condition of storage transport and handling before usage depends on its hardness. For each formulation, the hardness of 6 lozenges was determined using Pfizer hardness tester and the average was calculated and presented with standard deviation [7, 8].

Lozenge thickness:

Lozenges thickness is an important characteristic in reproducing appearance. Twenty Lozenges were taken and their thickness was recorded using Vernier callipers. The average thickness for Lozenges is calculated and presented with standard deviation [7, 8].

Weight variation test:

Twenty lozenges were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one lozenge was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity. The percent deviation was calculated using the following formula [7, 8, 10, 11].

$$\% \text{ Deviation} = (\text{Individual weight} - \text{Average weight} / \text{Average weight}) \times 100$$

Friability:

It is a measure of mechanical strength of tablets. Roche friabilator (Electro lab,

Mumbai, India) was used to determine the friability by following procedure. Pre-weighed lozenges (20 lozenges) were placed in the friabilator. The lozenges were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the lozenges were re-weighed, loss in the weight of lozenges is the measure of friability and is expressed in percentage [7, 8] as:

$$\% \text{ Friability} = [(W_1 - W_2) / W_1] \times 100$$

Where,

W_1 = Initial weight of 20 tablets

W_2 = Weight of the 20 tablets after testing

Evaluation of Soft Jelly lozenges

The moulds used for preparing of lozenges are of different shapes and sizes, the prepared lozenges are evaluated for Physical appearance, Stickiness and Grittiness, pH, Viscosity, Syneresis.

Physical Appearance: The medicated jelly was examined for physical appearance in terms of color, texture, clarity, and consistency. These tests are important regarding patients' compliance and acceptance [12].

Stickiness and Grittiness: Texture of medicated jelly in terms of stickiness and grittiness had been evaluated by visual inspections of the product after mildly rubbing the jelly sample between two fingers [12].

pH: pH of the final jelly have an influence on not only stability but also on the taste. The pH of the jelly was measured using Digital pH meter at room temperature. For this, 0.5 gm of jelly was dispersed in 50 ml of distilled water to make 1% solution, and the pH was noted [13, 14].

Viscosity: Viscosity of jelly was carried out using (LV) Brookfield viscometer. As the system is non-Newtonian spindle no. 63 was used. Viscosity was measured for fixed time 2 min at 50 rpm at room temperature ($25 \text{ }^\circ\text{C} \pm 5 \text{ }^\circ\text{C}$) [15].

Syneresis: Syneresis is a contraction of the gel upon storage and separation of water from the gel. It is more pronounced in the gels, where lower concentrations of gelling agents are employed. All jellies were observed for sign of syneresis at room temperature ($25 \text{ }^\circ\text{C} \pm 5 \text{ }^\circ\text{C}$) and $8 \text{ }^\circ\text{C} \pm 1 \text{ }^\circ\text{C}$ [16].

RESULTS AND DISCUSSION

EVALUATION OF HARD CANDY LOZENGES

Lozenge hardness:

The hardness of formulations F1 to F6 was found to be in the range of 5.3-6.6 kg/cubic.cm. As the concentration of polymer increases the hardness of the formulation has also been increased. . The

hardness values of for all formulations are given in **Table 2**.

Lozenge thickness:

The thickness of formulations F1 to F6 was found to be in the range of 0.7cm – 1.0cm. The thickness of all the formulations is pretty good for residence time inside the oral cavity. . The values of thickness for all formulations are given in **Table 2**.

Weight variation test:

The weight variation of formulation F1 was found to be in the range of 5.5-6.1gms, F2 was found to be in the range of 5.2-5.8gm, F3 was found to be in the range of 5.3-5.9gm, F4 was found to be in the range of 5.5-6.5gm, F5 was found to be in the range of 5.3-5.6gm, F6 was found to be in the range of 5.2-5.8gm. All the formulations have shown weight variation in acceptable limits. . The values of weight variation for all formulations are given in Table no 2

Friability:

The friability of formulations F1 to F6 was found to be in the range of 0.05- 0.07%. The friability of all the formulations was found to be within the limits. The values of friability for all formulations are given in **Table 2**.

EVALUATION OF SOFT JELLY LOZENGES

Physical Appearance: The soft jelly lozenges of all formulations are of different shapes and sizes depending on the cavities of mould used. The formed soft gels are glossy in appearance, light brown in colour with smooth texture.

Stickiness and Grittiness: The stickiness of soft gel lozenges decreased with increased concentration of gelatin. All the formulations are non gritty in nature.

Viscosity: The viscosities of all the formulations are found by using Brookfield viscometer. The viscosities of all the formulations are found to be in the range of 840 ± 30 cps to 1830 ± 25 cps. The viscosity of formed jellies increased with increase in the concentration of gelatin.

pH: The PH of the formulations FS1 to FS6 of soft jellies are found to be in the range of 6.65 ± 0.03 to 6.98 ± 0.06 .

Syneresis: The syneresis behavior of jelly formulations was reduced with increase in the concentration of gelatin.



Figure 1: Formulation of *Raphanus sativus* leaf extract Hard Candy lozenges F1 – F3



Figure 2: Formulation of *Raphanus sativus* leaf extract Hard Candy lozenges F4 – F6



Figure 3: Formulation of *Raphanus sativus* leaf extract Soft jelly lozenges

Table 1: Formulation of *Raphanus sativus* leaf extract Hard Candy Lozenges

S. No.	Ingredients	F1	F2	F3	F4	F5	F6
1.	<i>Raphanus sativus</i> leaf extract syrup solution	50 ml					
2.	Mannitol	50g	50g	50g	50g	50g	50g
3.	HPMC K15 M	4g	6g	8g	--	--	--
4.	HPMC K100 M	--	--	--	4g	6g	8g
5.	Menthol	0.5g	0.5g	0.5g	0.5g	0.5g	0.5g

Table 2: Evaluation parameters of *Raphanus sativus* leaf extract Hard Candy Lozenges

S. No.	Parameter	F1	F2	F3	F4	F5	F6
1.	THICKNESS	0.9cm	1cm	0.9cm	0.7cm	0.7cm	1cm
2.	DIAMETER	2.5cm	2.5cm	2.5cm	2.5cm	2.5cm	2.5cm
3.	WEIGHT VARIATION	5.5-6.1gm	5.2-5.8gm	5.3-5.9gm	5.5-6.5gm	5.3-5.6gm	5.2-5.8gm
4.	FRIABILITY	0.05%	0.07%	0.05%	0.06%	0.07%	0.06%
5.	HARDNESS (kg/cm ³)	5.3	5.5	6.2	5.6	6.2	6.6

Table 3 Formulation of *Raphanus sativus* leaf extract Soft Jelly Lozenges

S. No.	Ingredients	FS1	FS2	FS3	FS4	FS5	FS6
1.	<i>Raphanus sativus</i> leaf extract syrup solution	50 ml					
2.	Mannitol	50g	50g	50g	50g	50g	50g
3.	Gelatin	0.5g	1 g	1.5g	2.0g	2.5g	3.0g
4.	Sodium Benzoate	0.4g	0.4g	0.4g	0.4g	0.4g	0.4g
5.	Menthol	0.5g	0.5g	0.5g	0.5g	0.5g	0.5g

Table 4: Evaluation parameters of *Raphanus sativus* leaf extract Soft Jelly Lozenges

S. No.	Parameter	FS1	FS2	FS3	FS4	FS5	FS6
1.	Colour	Brown	Brown	Brown	Brown	Brown	Brown
2.	Stickiness	Sticky	Sticky	Sticky	Slightly sticky	Slightly sticky	Non Sticky
3.	Grittiness	Non gritty	Non gritty	Non gritty	Non gritty	Non gritty	Non gritty
4.	Viscosity(cps)	840 ± 30	950 ±25	1165 ± 20	1315 ±35	1610 ±20	1830 ± 25
5.	PH	6.65 ±0.03	6.70 ±0.04	6.68 ± 0.02	6.73 ± 0.05	6.87 ± 0.04	6.98 ± 0.06
6.	Syneresis	+++	+++	+++	++	++	--

CONCLUSION

Raphanus sativus leaf extract is prepared in sucrose base, the resultant mixture is made into hard candy and soft jelly lozenges, both HPMC K15, K100M have shown good evaluation results and can be used as binders in preparation of hard candy lozenges, the increase in concentration of polymer increased the hardness of the lozenges. Increase in concentration of gelling agent in soft jellies showed less syneresis and more

viscosity. Further studies can be carried out on *Raphanus sativus* leaf extract to formulate them as novel drug delivery systems to maximize the benefits of constituents in the leaf extract.

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CONFLICT OF INTREST

The authors declare no conflict of interest.

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