

FORMULATION AND EVALUATION OF MEDICATED LOZENGES FOR SORE THROAT

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ABSTRACT

Objective: The objective of the present work was to formulate and evaluate lozenges for a sore throat using Loratadine. Loratadine is a long-acting peripheral H₁-receptor antagonist which is mainly used as an antihistamine. Loratadine lozenges were prepared to prevent the itching and inflammation in sore throat.

Methods: Solid dispersion of Loratadine was prepared using β -cyclodextrin in the ratios of 1:1, 1:2, and 1:3 to enhance the solubility of Loratadine. The prepared solid dispersion of Loratadine was analyzed for solubility enhancement. Loratadine lozenges were then formulated with mannitol, sucrose, acacia, xanthan gum, liquid glucose by heat, and congealing technique. The prepared lozenges were evaluated for drug-excipient incompatibility study, diameter, thickness, weight variation, hardness, friability, *in vitro* release study, and drug content.

Results: The results of the Fourier transform infrared study showed that there was no interaction between the selected drug and excipients. *In vitro* drug release study of Loratadine lozenges were performed in pH 6.8 phosphate buffer, wherein >90% of the drug was released within 30 min for all the formulations. The lozenges were optimized based on *in vitro* release data. Formulation F7 of Loratadine lozenges exhibited 99.1% release in 30 min. Stability studies revealed that the formulation was stable.

Conclusion: From the present work, it was concluded that the Loratadine lozenges can be considered as a suitable delivery system for the treatment of sore throat.

Keywords: Lozenge, Loratadine, Heat and congealing method, Sore throat.

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INTRODUCTION

Among the various routes of administration, the oral route is the most favored route because of different points of interest including simplicity of ingestion, flexibility, and in particular patient compliance. The significant disadvantage of this route is for pediatric and geriatric patients who face difficulty in swallowing. Almost 35% of everyone, particularly the older patients and children, experience the ill effects of trouble in swallowing, which brings about a high rate of resistance and inadequate treatment. Swallowing problems are very common in children because of their poorly developed muscular and nervous systems. Other groups who may also experience problems in swallowing conventional oral dosage forms are the patients with tremors of extremities, intellectually sick, non-cousable patients, and patients with diminished fluid admission plans or patients suffering from nausea [1].

Sore throat or pharyngitis is inflammation of the throat which exhibits symptoms such as the runny nose, cough, headache, difficulty swallowing, swollen lymph nodes, and a hoarse voice. It is typically caused by a viral, bacterial, or fungal infection. The microscopic organism that most normally causes sore throat is streptococci. A sore throat can also occur by aggravation, smoking, air contamination, unnecessary shouting, and postnasal trickle brought about by hypersensitivities and breathing through the mouth [2].

To conquer these issues such as difficulty in swallowing and conditions such as sore throat, formulators have significantly devoted their push to build up a novel kind of tablet dosage form for the oral route, that is, one, which deteriorates and breaks up quickly in salivation without the requirement swallowing the dosage form as a whole. These tablets are lozenges that break down from 15 s to 2 min. The quicker the

medication breaks, the faster the assimilation and beginning of clinical impact [3].

Most lozenges can be bought over-the-counter and work by dissolving in the mouth gradually as you suck them, greasing up the throat coating, and decreasing the dryness and irritation and inflammation of the throat. Various brands of lozenges have different combinations of ingredients and various blends of fixings. They are used either for local or systematic action through the oral cavity. Lozenges are utilized for the delivery of analgesics, sedatives, antimicrobials, antihistamines, cleaning agents, antitussives, aromatics, astringents, corticosteroids, decongestants, demulcents and different classes, and combinations of medications [4].

Loratadine is a second-generation antihistamine used to manage symptoms of allergic rhinitis. It is sparingly soluble in water. It is utilized for the symptomatic relief of runny nose, itchy or watery eyes, wheezing, throat irritation, inflammation, and ceaseless urticarial [5].

Henceforth, an attempt was made in the present study for the preparation of lozenges of Loratadine for the treatment of sore throat.

MATERIALS AND METHODS**Material**

Loratadine was obtained as a gift sample from Strides Private Limited, Bengaluru. β -cyclodextrin was a gift sample from Vittalwadi, Hyderabad. Mannitol and liquid glucose were procured from SD Fine-Chem Ltd., Mumbai, India. Acacia was procured from HiMedia laboratories Pvt. Ltd., Mumbai. Microcrystalline cellulose was procured from Madras Pharmaceuticals, Chennai. Xanthan gum was procured from LOBA Chemie Pvt. Ltd., Mumbai. All the chemicals are of analytical grade only.

Methods

Determination of melting point

The drug was filled in one side open thin-walled capillary tube. The capillary tube was placed in the melting point apparatus provided with a thermometer. The temperature at which solid melted was noted.

Determination of absorption maxima (λ_{max})

Loratadine (10 $\mu\text{g/ml}$) was prepared and scanned in double-beam UV spectrophotometer at 200–400 nm [6]. Calibration curve of Loratadine was prepared in pH 6.8 buffer at the λ_{max} obtained.

Fourier-transform infrared (FTIR) spectroscopy

FTIR spectroscopy was estimated by utilizing Shimadzu FTIR spectrophotometer to detect the interaction between the excipients and Loratadine. The excipients and drug were finely ground with potassium bromide to set up the pellets at 600 psi and spectra were examined in the range of 400 and 4000 cm^{-1} [7].

Preparation of solid dispersion of loratadine

Loratadine solid dispersion was prepared to increase the solubility of the drug. It was prepared by the melting method. In this method, Loratadine and β -cyclodextrin were taken in the ratios of 1:1, 1:2, and 1:3 and warmed in a china dish until softened. The liquefied blend was then hardened quickly in an ice bath under vigorous stirring. The mass obtained was grounded and sieved. The sample gathered was utilized for further investigation [8].

Solubility analysis

For this solvency study, 100 mg of solid dispersions of various proportions (1:1, 1:2, and 1:3) were transferred to the conical flask with 100 ml of pH 6.8 buffers. Conical flasks were stoppered and then set in a rotational shaker for 24 h. After 24 h, 1 ml of sample was taken and transferred to a 10 ml volumetric flask and made up with a pH 6.8 buffer solution. The absorbance was estimated at 250 nm using a UV-visible spectrophotometer [9].

Preparation of loratadine lozenges

Loratadine lozenges were prepared by heat and congealing method. In this method, sugar syrup was prepared by blending sugar and water. Sugar was dissolved in a little amount of water and warmed it to 110°C till sugar breaks down totally forming clear thick syrup. The sugar syrup was warmed to 160°C till the color changes to brilliant yellow. The temperature was decreased to 90°C, solid dispersion of Loratadine and other excipients was then included. The entire preparation was then filled in the cavities of molds. The lozenges formed were enclosed by aluminum foil and kept in desiccators to prevent moisture uptake [10].

Evaluation of loratadine lozenges

Determination of organoleptic properties

Organoleptic properties were examined by visual inspection of lozenges for appearance, color, and shape.

Weight variation

Ten lozenges were randomly selected from each batch and individually weighed. The average weight and standard deviation of 10 lozenges were calculated. The batch passes the test for weight variation test if not more than 2 of the individual lozenges weight deviates from the average weight.

Thickness uniformity

Six lozenges were selected randomly from each batch and thickness was measured using Vernier calipers.

Hardness

Hardness or crushing strength (F_0) is the force required to break a lozenge in a diametric compression using Monsanto Hardness Tester.

For each formulation, the hardness of six lozenges was determined. The lozenges were held along its oblong axis in between the two jaws of the tester. At this point, reading should be 0 kg/cm^2 . Then, constant force was applied by rotating the knob until the lozenges fractured. The value at this point was noted in kg/cm^2 .

Diameter

The diameter, size, and shape of lozenges depend on the molds selected. The lozenges of various sizes and shapes can be prepared, but generally, they are circular with either flat or biconvex faces.

Moisture content

By the gravimetric method, 1 g sample was weighed and placed in an oven at 60–70°C for 12–16 h. Final weight was determined to utilize a delicate muslin fabric and its weight was rechecked. Percentage friability is given by the equation.

$$\% F = (\text{Initial weight} - \text{Final weight} / \text{Initial weight}) \times 100.$$

Drug content

A 5 mg of lozenges were placed in 50 ml of phosphate buffer solution of pH 6.8 for 4 h on a rotary shaker. The filtered solution was measured using a UV-visible spectrophotometer.

In vitro dissolution studies

USP apparatus II (paddle type) was used for the study. Accurately weighed formulations of Loratadine lozenges were placed in 900 ml phosphate buffer of pH 6.8. The temperature was kept up at 37°C and mixed at a speed of 50 rpm. At 5 min time interval, a 5 ml aliquot of the sample was withdrawn and the volume was replaced with an equal measure of plain buffer kept at 37°C. The obtained samples were filtered ($\#0.45 \mu\text{m}$) and measured at 250 nm using UV-visible spectrophotometer [11].

Stability studies

The stability studies for lozenges were performed for optimized formulation (F7) at 40°C and 75% RH for 90 days as per ICH guidelines. The lozenges were assessed for various parameters such as hardness, weight variation, drug content, moisture content, and drug release according to procedures mentioned previously by analyzing the samples after every 1 month [12].

RESULTS AND DISCUSSION

The primary goal of this study was to plan and characterize Loratadine lozenges for patients suffering from a sore and itchy throat. Loratadine initially was tested for the melting point as an identification test for Loratadine. The melting point of Loratadine sample was found to be $135.00 \pm 1^\circ\text{C}$ which is as per the specifications mentioned in IP. Absorption maxima for Loratadine when observed under UV-visible spectrophotometer were found to be at 250 nm. This was observed from the peak in Fig. 1. Calibration curve of Loratadine was obtained at concentration of 5–30 $\mu\text{g/ml}$ with R^2 value=0.987.

Solid dispersion of Loratadine was prepared using beta-cyclodextrin. Table 1 shows that as the ratio of drug to polymer increased, the solubility of Loratadine increased. High solubility was observed with the drug-to-polymer ratio 1:3. Solid dispersion of drug with 1:3 ratio was used for further study.

Table 1: Solubility analysis of solid dispersion

Ratio	Solubility ($\mu\text{g/1 ml}$)
Drug	13.3
1:1	79.016
1:2	180.5
1:3	324.56

Loratadine lozenges were prepared using different ingredients by heating and congealing technique. Around nine formulations were prepared with a total weight of 3000 mg. Various ingredients such as sucrose, β -cyclodextrin, menthol, mannitol, acacia, xanthan gum, liquid glucose, microcrystalline cellulose, vegetative oil, coloring agent, and menthol were included in various proportion. Acacia and liquid glucose were used as a binder, xanthan gum as a whipping agent, microcrystalline cellulose was selected as a diluent and a disintegrant (to a lesser extent). Mannitol was used as diluents and has the property to produce a cooling sensation in the mouth. Vegetable oil was used as a lubricant. Menthol was utilized as a flavoring agent. It also gives a desirable soothing effect. The composition of lozenges using these excipients is shown in Table 2. Photographs of prepared lozenges are shown in Fig. 2.

The prepared lozenges of F1-F3 had a shiny appearance, but with a slightly sticky outer surface. Formulations F4-F6 had some bulgy surface, with a shiny appearance. They were not sticky. Formulations F7-F9 had a rough outer structure and appeared dull. The shape of the lozenges was because of the shape of the mold selected.

FTIR spectra of the drug, physical mixture of drug and excipients, and optimized formulation of lozenges are shown in Fig. 3. Interpretation of these spectra is shown in Table 3.

Characteristic bands of Loratadine were compared with the bands obtained for drug, drug-exipients physical mixture, and formulation (F7) of lozenges. It was observed that there was no disappearance or a significant shift in the bands position of the drug in any spectra's of physical mixture and formulation (F7) which proved that the drug and polymers used for the study were compatible.

The prepared lozenges were subjected to different evaluation tests. Table 4 shows the results of post-formulation parameters of lozenges such as hardness, weight variation, thickness, and diameter and percentage drug content. Table 5 shows the results of friability and moisture content. All the values of the parameters in the tables were observed within the limits with no significant deviation. Since all the materials were free flowing, lozenges obtained were of uniform weight due to uniform mold fill. The obtained hardness range showed good mechanical strength with an ability to withstand physical and mechanical stress conditions. Percentage of drug content was calculated for all the formulations. The drug content for all the formulations was found to be in the range of 91.9 ± 0.05 – $99.5 \pm 0.03\%$ w/w (i.e., 99–101% w/w) as per the specifications of IP 2007.

Friability values indicated a good mechanical resistance of the prepared sore throat lozenges. The moisture content of all the lozenges was within 2%.

In vitro release studies were performed for all the formulations. Percentage drug release from lozenges is shown in Table 6 and the release profile is represented in Fig. 4. From the *in vitro* release studies, it was observed that >90% of the drug was released within

30 min. *In vitro* release studies indicate that the formed lozenges provide a rapid onset of action and help in giving quick relief from sore throat. Acacia containing lozenges were found to release the drug rapidly. F7 had shown maximum drug release. The suggested ratio of the sugar to liquid glucose was 60–40% for attaining transparency and smoothness. This is because of prevention of sugar crystallization by liquid glucose. However, in the present investigation, sufficient transparency was attained with the use of sugar to liquid glucose 13%, 18%, and 20. This suggests that even low concentration of liquid glucose has the ability to retain the capacity to prevent crystallization of sugar.

All formulations drug release kinetics results revealed that the mode of drug release from lozenges followed the zero-order release kinetics with $R^2 > 0.8694$ (Table 7). Data were also aligned into the Korsmeyer-Peppas equation to determine the drug release mechanism further. The

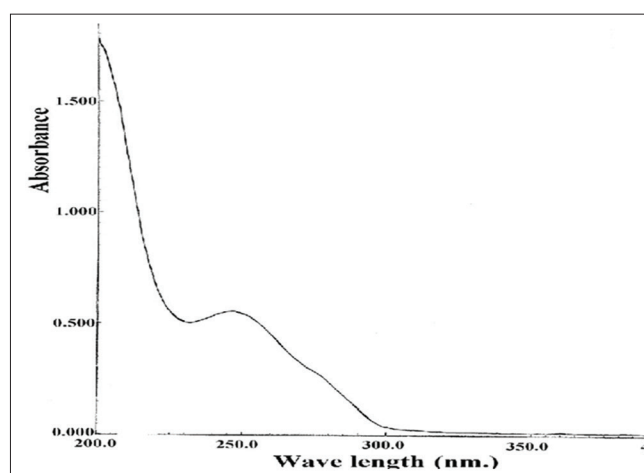


Fig. 1: Baseline curve of Loratadine in phosphate buffer 6.8

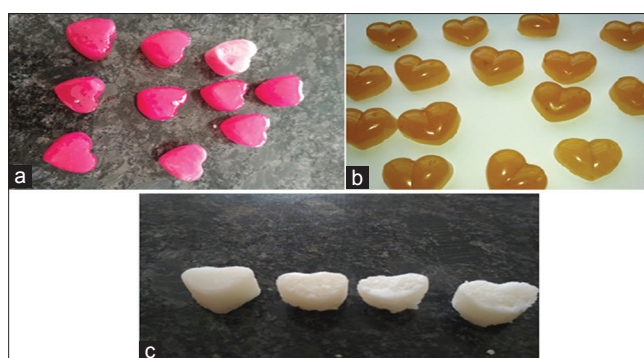


Fig. 2: Loratadine lozenges of (a) formulation F1, F2, F3 (b) formulation F4, F5, F6 (c) formulation F7, F8, F9

Table 2: Composition of Loratadine lozenges

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug	100	100	100	100	100	100	100	100	100
Beta-cyclodextrin	100	200	300	100	200	300	100	200	300
Sugar	2000	2000	2000	1800	1800	1800	2000	2000	2000
Mannitol	375	375	375	-	-	-	375	375	375
Acacia	400	300	200	-	-	-	-	-	-
Liquid glucose	-	-	-	600	500	400	400	300	200
Microcrystalline cellulose	10	10	10	10	10	10	10	10	10
Xanthan gum	-	-	-	375	375	375	-	-	-
Vegetable oil	15	15	15	15	15	15	15	15	15
Flavor	QS	QS	QS	QS	QS	QS	QS	QS	QS
Color	-	-	-	QS	QS	QS	-	-	-
Total	3000	3000	3000	3000	3000	3000	3000	3000	3000

Table 3: Interpretation of FTIR peaks for compatibility studies

Sample	IR absorption bands									
	C=O stretching	C-Cl stretching	O-H stretching of pyridine	C=N stretching of pyridine	C=C stretching	C-C skeletal stretching	C-N stretching of tertiary amine	N-H stretching	C-H stretching of pyridine	C-H stretching of aromatics
Loratadine	1703.88 cm ⁻¹	862.9 cm ⁻¹		1153.3 cm ⁻¹		3376.75 cm ⁻¹	1579.41 cm ⁻¹		3038.3 cm ⁻¹	2983.34 cm ⁻¹
Physical mixture 1	1780.5 cm ⁻¹	878.4 cm ⁻¹		1384.64 cm ⁻¹	2883.34 cm ⁻¹	3119.3 cm ⁻¹	1529.2 cm ⁻¹	3045.6 cm ⁻¹		2908.15 cm ⁻¹
Physical mixture 2	1633.82 cm ⁻¹	830.20 cm ⁻¹	1267.86 cm ⁻¹	1355.71 cm ⁻¹	2864.7 cm ⁻¹	3088.44 cm ⁻¹	1643.05 cm ⁻¹		2996.84 cm ⁻¹	
Loratadine lozenge F7	1642.1 cm ⁻¹	891.9 cm ⁻¹	1227.46 cm ⁻¹	1031.12 cm ⁻¹		2983.34 cm ⁻¹	1560.13 cm ⁻¹	3292.8 cm ⁻¹		2984.3 cm ⁻¹

FTIR: Fourier transform infrared

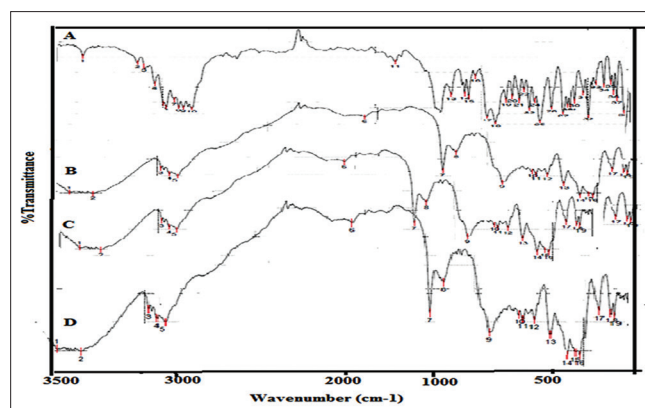


Fig. 3: Fourier transform infrared spectra for Loratadine, physical mixture, and Loratadine lozenge. Where A is Loratadine. B is physical mixture 1, containing Loratadine, Beta-cyclodextrin, mannitol, acacia, microcrystalline cellulose. C is physical mixture 2, containing Loratadine, beta-cyclodextrin, liquid glucose, microcrystalline cellulose, xanthan gum. D is Loratadine lozenge formulation F7

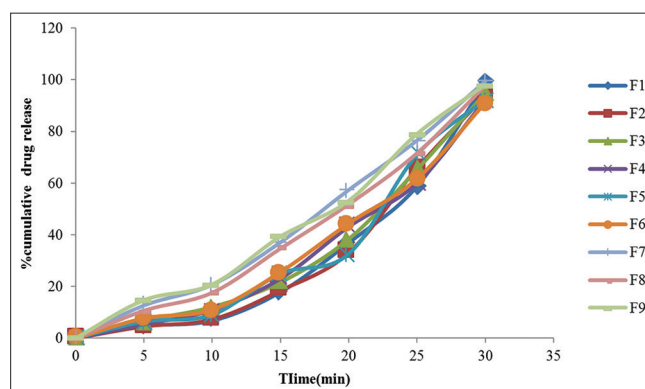


Fig. 4: Cumulative % drug release profile of formulation F1-F9

value n lies in between 0.45 and 0.89 which indicated that non-Fickian diffusion (anomalous diffusion), the process was significant.

Based on the results of post-formulation parameters and *in vitro* drug release, formulation F7 was considered as an optimized formulation. Further stability studies were performed for the formulation. Aging studies were performed at conditions of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and 75% RH $\pm 5\%$ for a period of 3 months. Samples were collected after every 1 month and tested. The obtained results are shown in Tables 8 and 9.

Stability studies of formulation F7 were carried out by placing the samples at temperature 40°C and relative humidity condition 75% RH. From the above observations, it was found that there was no significant change in the release characteristics and physicochemical properties of the lozenges used in the study. Based on the results, it can be concluded that the formulated sore throat lozenges of Loratadine were stable at stability conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and 75% $\pm 5\%$ RH) over a period of 3 months. Even though its stability was assured for 3 months, further studies as per the ICH guidelines are needed to establish its shelf-life.

In the present study, it was suggested that sugar-based medicated Loratadine lozenges will be ideal dosage forms for sore throat patients. The addition of hydrophilic polymers such as xanthan gum and microcrystalline cellulose yielded good results to release the drug in 6.8 pH buffer for a period of 30 min. The stability studies proved that the prepared Loratadine lozenges were stable when stored at the

Table 4: Evaluation of Loratadine lozenges for post-formulation parameters

Formulation	Hardness (kg/cm ²)	Weight variation (mg)	Thickness (mm)	Diameter (mm)	Drug content %
F1	10.5±0.1	3000.5±1.42	6.354±0.02	15.12±0.06	98.5±0.04
F2	9.4±0.2	2998.2±2.64	7.561±0.08	16.15±0.06	98.3±0.05
F3	10.6±0.2	3000.4±1.32	7.450±0.04	15.18±0.07	94.8±0.04
F4	10.3±0.3	3000.6±2.22	6.962±0.06	16.11±0.08	97.6±0.04
F5	11.6±0.4	2999.1±3.35	6.873±0.05	16.23±0.04	91.9±0.05
F6	9.9±0.3	3000.7± 2.14	7.552±0.06	14.24±0.04	99.5±0.03
F7	10.8±0.1	3000.8±2.65	6.450±0.02	14.10±0.05	99.8±0.02
F8	10.3±0.4	2997.4±3.23	7.841±0.04	13.17±0.04	97.8±0.02
F9	11.3±0.2	3000.3±2.53	6.780±0.02	13.15±0.09	98.9±0.03

Results indicate mean±SD, n=6

Table 5: Evaluation of Loratadine lozenges for post-formulation parameters

Formulation	Friability	Moisture content
F1	2.91±0.008	0.95±0.05
F2	2.98±0.005	0.91±0.05
F3	2.95±0.006	0.85±0.06
F4	2.87±0.008	0.88±0.04
F5	2.85±0.004	0.82±0.05
F6	2.65±0.009	0.83±0.06
F7	2.78±0.007	0.90±0.05
F8	2.65±0.008	0.87±0.05
F9	2.90±0.008	0.81±0.06

Results indicate mean±SD, n=6

Table 6: Percentage cumulative drug release of formulations F1-F9

Time (min)	Cumulative drug release %								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	4.68	4.51	6.73	5.36	6.45	7.71	12.68	10.66	14.72
10	6.76	7.25	12.07	10.86	9.05	10.99	20.69	17.6	20.8
15	17.84	18.43	21.65	23.04	24.97	25.64	37.1	34.7	39.37
20	36.94	33.06	38.37	43.14	32.64	44.49	57.38	51.83	53.22
25	58.788	65.8	65.29	59.99	71.03	61.7	76.54	71.6	79.06
30	98.78	93.8	94.83	92.31	92.41	91.1	99.47	97.76	98.08

Table 7: Drug release kinetics of formulation F1-F9

Formulations	Zero order	First order	Higuchi	Hixson-Crowell	Korsmeyer-Peppas	
	R ²	R ²	R ²	R ²	R ²	n
F1	0.8763	0.5353	0.5125	0.8682	0.8228	0.5041
F2	0.8694	0.7258	0.5737	0.8682	0.9435	0.4715
F3	0.9043	0.7128	0.6276	0.8682	0.957	0.5041
F4	0.8806	0.742	0.645	0.8682	0.9788	0.5041
F5	0.8782	0.7704	0.613	0.8682	0.8834	0.4715
F6	0.9012	0.7696	0.6722	0.8682	0.9473	0.5041
F7	0.9677	0.6611	0.7745	0.8682	0.9774	0.5041
F8	0.95	0.7087	0.7429	0.8682	0.9733	0.5041
F9	0.9673	0.7238	0.7811	0.8682	0.9025	0.5344

Table 8: Stability results of optimized formulation F7

Evaluation parameter	Optimized formulation F7			
	0 day	After stability study of 1 month	After stability study of 1 month	After stability study of 1 month
Hardness	10.9±0.3	10.03±0.2	10 ±0.1	9.8 ±0.6
Weight variation	3000.4±2.65	3000.3±4.65	3000.1±4.6	3000.1±4.6
% friability	2.50±0.004	2.52±0.001	2.52±0.005	2.52±0.005
Drug content	95.8±0.02	94.3±1.02	94.1±2.04	94.06±1.10
Moisture content	0.95±0.05	0.95±0.04	0.94±0.04	0.94±0.02

Results indicate Mean±SD, n=3

Table 9: Comparative *in vitro* dissolution data of formulation F7

Time in minute	Cumulative % release of Loratadine			
	Initial	1 st month	2 nd month	3 rd month
5	12.68	11.66	10.8	12.48
10	22.69	20.37	19.74	20.03
15	37.1	36.92	36.21	36.68
30	99.47	98.9	98.87	98.8

Results indicate Mean±SD, n=3

conditions mentioned above. In the future, these findings could be of potential use in designing such formulations for sore throat.

CONCLUSION

In the current investigation, Loratadine sweetened lozenges were prepared for the treatment of sore throat. The possible interaction between the drug and excipient was determined by FTIR spectroscopy which indicated that there was no interaction between the chosen drug and excipients. Lozenges were successfully prepared by heat coagulating strategy utilizing sugar, liquid glucose, acacia, xanthan gum, microcrystalline cellulose, β -cyclodextrin, flavor, and color. *In vitro* drug release indicated that the drug release was most extreme in formulation F7 (99.47±0.5%) at 30 min. Incorporation of synthetic polymers yielded great outcomes in terms of percentage drug release. These findings suggest that Loratadine lozenges can be considered as a potential delivery system for the treatment of sore throat.

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AUTHORS' CONTRIBUTIONS

The authors jointly declare that they have both contributed toward the research work. Rupali Chanda has conducted the experiments, collected,

and treated the data under the supervision of Dr. Lavanya Nallaguntla. The preparation, corrections, and revision of this manuscript have also been carried out by both authors.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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