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ORIGINAL ARTICLE

Formulation and Evaluation of Curcumin Lozenges to Treat Throat Infections

Vaseem Unnisa[1], A. Lakshmana Rao[2], S. Vijaya Naga Babu[3], S. Tulasi[4], S. Mohitha[5], S. Divya[6]

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ABSTRACT

The present study focuses on the formulation and evaluation of curcumin lozenges designed for the treatment of throat infections. Curcumin, a bioactive compound with antifungal, anti-inflammatory, and antioxidant properties, is known for its low bioavailability and dissolution rate. The aim was to develop a lozenge dosage form that enhances curcumin's bioavailability and dissolution, making it suitable for pediatric, geriatric, and dysphagic patients. Lozenges were prepared using different polymers, namely HPMC K100, PEG 4000, and PEG 6000, at varying concentrations. The formulations were evaluated for various parameters including pH, drug content, drug release, and sterility. The FT-IR studies confirmed the compatibility of curcumin with the excipients. The results showed that all formulations had acceptable drug content and passed the sterility test. Among the three formulations, the one containing 2% HPMC K100M polymer (F3) demonstrated the best release characteristics, with 95.75% of the drug released within 45 minutes. Drug release kinetics followed the first-order model, suggesting a conventional release pattern. The Higuchi model further supported that the drug release followed a dissolution mechanism, consistent with the gel-based matrix structure of the polymers. Thus, the formulation containing HPMC K100M was

AUTHOR'S AFFILIATION:

[1] Assisant Professor, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

[2] Principal, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

[3] Student, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

[4] Student, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

[5] Student, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

[6] Student, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

CORRESPONDING AUTHOR:

Vaseem Unnisa, Assisant Professor, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru Post, Krishna District, Andhra Pradesh, India.

E-mail: vaseema.bpharm@gmail.com

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optimized for curcumin lozenges, providing controlled drug release for effective throat infection treatment.

KEYWORDS

• Curcumin • Lozenges • Throat Infections • Drug Release • Bioavailability • Dissolution Mechanism

INTRODUCTION

Curcumin, a naturally occurring polyphenolic compound found in Curcuma longa, has been extensively studied for its numerous therapeutic properties, including anti-inflammatory, antioxidant, and antimicrobial activities.[1,2] However, curcumin has a very low bioavailability, which limits its effectiveness when used orally. This challenge arises due to its poor aqueous solubility and rapid metabolism.[3] As a result, various drug delivery systems have been explored to enhance the bioavailability of curcumin, including nanoparticles, liposomes, and solid dispersions.[4,5] Among these, the development of oral dosage forms such as lozenges presents an effective strategy for improving its local effects in the throat and its systemic absorption.

The formulation of curcumin in lozenges offers a practical solution for the treatment of throat infections, particularly for pediatric, geriatric, and dysphagic patients. Lozenges are solid oral dosage forms designed to dissolve slowly in the mouth, providing a sustained release of the active ingredient and allowing for localized action in the throat.[6] Additionally, the controlled release of curcumin from lozenges can enhance its therapeutic effect, making it a promising candidate for treating throat infections.[7] By incorporating suitable excipients and polymers such as HPMC K100, PEG 4000, and PEG 6000, it is possible to modulate the drug release profile and improve the stability of curcumin in the formulation.[8,9]

In this study, we aim to formulate curcumin lozenges with improved bioavailability and dissolution characteristics. The formulations will be evaluated for their physicochemical properties, drug release kinetics, and antimicrobial activity. The effectiveness of the polymers HPMC K100, PEG 4000, and PEG 6000 will be compared to determine the optimal formulation for throat infection treatment.[10,11]

MATERIALS AND METHODS

Materials

Curcumin (Curcuma longa) was sourced from Rooted Active Naturals, India. Hydroxypropyl Methylcellulose (HPMC) was obtained from Lubrizol Advanced Materials, USA, and Polyethylene Glycol (PEG) 6000 and PEG 4000 were procured from Sigma-Aldrich, USA. All excipients used, including stabilizers and preservatives, were of high pharmaceutical grade and sourced from authorized suppliers to ensure the quality and consistency of the formulation. Sodium chloride, hydrochloric acid, and purified water were sourced from Merck Life Science Pvt. Ltd., India, to maintain the required formulation standards. All ingredients were selected from reputable suppliers to meet the necessary quality and regulatory requirements.

Methodology[12-17]

Determination of λmax of Curcumin: To determine the λmax of Curcumin, 5 µg/mL of Curcumin was dissolved in a few milliliters of methanol and then diluted suitably to obtain an absorbance in the range of 0-1. The solution was scanned over a wavelength range of 200 nm to 800 nm using a UV-Visible Spectrophotometer to identify the λmax.

Preparation of Phosphate Buffer pH 6.8: A phosphate buffer of pH 6.8 was prepared by mixing 39.1 mL of 0.2 M sodium hydroxide (8 g in 1000 mL of water) with 50 mL of 0.2 M potassium dihydrogen phosphate (27.218 g in 1000 mL of water). The mixture was then diluted to a final volume of 200 mL using distilled water, resulting in the desired phosphate buffer with a pH of 6.8.

Preparation of Standard Calibration Curve of Curcumin by UV-Visible Spectroscopy: A primary stock solution of Curcumin was prepared by dissolving 100 mg of Curcumin

in methanol in a 100 mL volumetric flask and making the volume up to 100 mL with phosphate buffer. From this stock solution, 10 mL was transferred to another 100 mL volumetric flask and diluted to 100 mL with phosphate buffer to obtain a secondary stock solution. This secondary stock was further diluted to produce concentrations of 1, 2, 3, 4, 5, 6, and 7 µg/mL. The absorbance of these solutions was measured at 423 nm using a UV-Visible spectrophotometer.

Drug-Excipient Compatibility Study: To evaluate the compatibility of Curcumin with the excipients, physical mixtures of the drug and excipients were prepared in predetermined ratios. Fourier Transform Infrared (FTIR) spectroscopy was conducted to identify potential interactions between Curcumin and the excipients. The absence of new peaks or significant shifts in the FTIR spectra indicated that the excipients were compatible with Curcumin.

Preparation of Lozenges: Hard candy lozenges are formulated with sucrose and other sugars/carbohydrates in an amorphous or glassy state. The process involves boiling an aqueous syrup to evaporate the water, resulting in a solid, hard lozenge. The moisture content should range from 0.5% to 1.5%, and the weight of each lozenge is between 1.5 – 4.5 g. Due to the high-temperature requirements of the preparation, heat-sensitive ingredients are not suitable for this formulation.

Table 1: Formulation of Curcumin Lozenges

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Sugar (g)	1.972	1.972	1.972	1.972	1.972	1.972	1.972	1.972	1.972
Liquid Glucose (g)	0.858	0.858	0.858	0.858	0.858	0.858	0.858	0.858	0.858
Curcumin (g)	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Polymers (mg)	10	20	30	10	20	30	10	20	30
Citric Acid (mg)	50	40	30	50	40	30	50	40	30
Flavoring Agent (g)	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020
Coloring Agent (g)	0.0009	0.0009	0.0009	0.0009	0.0009	0.0009	0.0009	0.0009	0.0009

Evaluation of Lozenges:

Weight Uniformity: Twenty lozenges were selected randomly, weighed individually, and the average weight was calculated. The lozenges met specifications if no more than two lozenges fell outside the percentage limit, and no lozenge deviated by more than twice the percentage limit.

Hardness: The hardness or crushing strength, which is the force required to break a lozenge, was measured using a Monsanto hardness tester. The force was gradually increased until the lozenge broke, and the pressure (kg/cm²) required to break the lozenge was recorded.

Friability: For lozenges weighing ≥ 650 mg, 10 lozenges were taken and the initial weight recorded. For lozenges weighing < 650 mg, a total equivalent to 6.5 g was used. The lozenges were rotated in a Roche Friabilator for 100 revolutions at 25 rpm. After reweighing, the percentage friability was calculated using the formula:

$$\%\text{Friability} = \left(\frac{\text{Wo} - \text{Wf}}{\text{Wo}}\right) \times 100$$

Where is the initial weight and Wf is the final weight after the test.

In-Vitro Dissolution Studies: Dissolution studies were performed using an 8-station dissolution test apparatus (LABINDIA) with paddles (USP apparatus II). The dissolution medium used was 900 mL of phosphate buffer pH 6.8, and the paddle speed was set to 50 rpm. Samples (10 mL) were withdrawn at intervals of 5, 10, 15, 20, 30, 35, 40, and 45 minutes, and the volume was replaced with fresh dissolution medium. The absorbance was measured at 423 nm using a UV-Visible spectrophotometer.

Evaluation of Dissolution Parameters

Zero Order Kinetics: A plot of cumulative % drug released versus time was made to

determine the zero-order release rate constant (K_0).

First Order Kinetics: A plot of log % drug undissolved versus time was made to determine the first-order release rate constant (K_1).

Taste Masking Evaluation: A sensory evaluation was performed by asking five human volunteers to hold an optimized drug solution (F3) in their mouths for 30 seconds. After spitting out the solution, the volunteers were asked to evaluate the mouthfeel after rinsing their mouths with water.

pH Determination: The pH of each formulation was measured using a digital pH meter, calibrated with pH 6.7 and pH 7.3 buffers. The pH values were recorded immediately after preparation.

Determination of Percent Drug Content: Accurately weighed quantities of gel samples equivalent to the desired amount of drug were dissolved in 100 mL of distilled water. The solution was filtered, diluted, and the drug content was measured spectrophotometrically at 423 nm. The percent drug content was calculated using the formula:

Sterility Test: The sterility of the formulation was tested using three sets of agar media: a negative control with sterile media, a positive control inoculated with bacteria, and the test group. The formulation was incubated for 14 days at 20-25°C, and the absence of bacterial growth indicated that the formulation was sterile.

Antifungal Activity: The antifungal activity was assessed using an agar diffusion method. Standard Petri dishes containing medium were inoculated with a fungal strain, and 100 mg of the formulation was placed in wells. After incubation at 35°C for 24 hours, the zone of inhibition was measured to determine the antifungal effectiveness of the formulation.

RESULTS AND DISCUSSION

Absorption maximum of curcumin: Absorption maximum of curcumin pure sample was found to be at 423nm using UV-visible spectrophotometer.

Construction of calibration curve of Curcumin: The data standard graph of curcumin has shown good linearity over a concentration range of 0-7µg/ml with R^2 value of 0.998. The equation was y =0.146x. This was utilized in the estimation of curcumin samples.

Table 2: Absorbance values of Curcumin

Concentration(µg/ml)	Absorbance
0	0
1	0.148
2	0.297
3	0.446
4	0.594
5	0.743
6	0.884
7	1.024

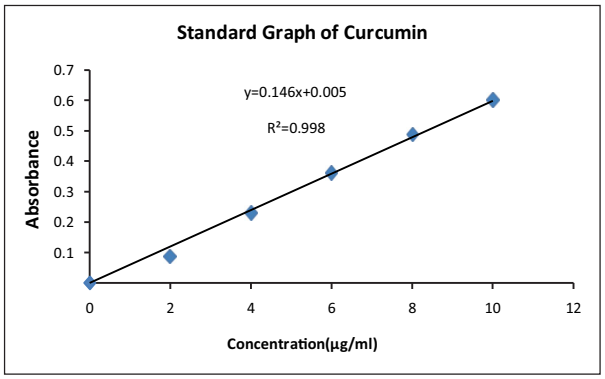

Figure 1: Standard graph of Curcumin

Drug Excipient Compatability-FTIR Spectroscopy: The functional groups present in the drug were identified. The FTIR of Curcumin showed intense bands at 3379cm-1, 1736cm-1, 1226cm-1, 1592cm-1 and 823cm-1 corresponding to the functional groups NH, C=O, C=H Stretching in Benzene, C-N, C=C Stretching and C=C Bending respectively. The wavenumbers of drug were compared with the IR spectrum of drug with polymers. The resulted peaks observed in FTIR are presented in Table3. The FTIR spectra of Curcumin with polymer mixture were given in Fig. 2 and Fig. 3.

The results revealed that there was no significant disturbance in the principle peaks of pure drug Curcumin. From the interpretation it was understood that there was no major shifting in the frequencies of Curcumin which indicated that there is no chemical interaction in the formulations. This further confirms the integrity of pure drug and compatability of it with Excipients.

Table 3: Principle IR peaks of Curcumin

Functional Groups Present	Curcumin
OH Stretching	3379cm-1
NH3+	1736cm-1
β – Lactam C=O Stretching	1592cm-1
Amide C=O Stretching	823cm-1

Functional Groups Present	HPMC K100 (cm-1)	PEG 4000 (cm-1)	PEG 6000 (cm-1)
C – H Stretch	2882.42	2877.28	2881.78
CH2 Bending	1466.25	1466.23	1466.00
CH3 Bending	1341.10	1341.00	1340.00
C – O – H Bending	1279.14	1279.00	1240.00

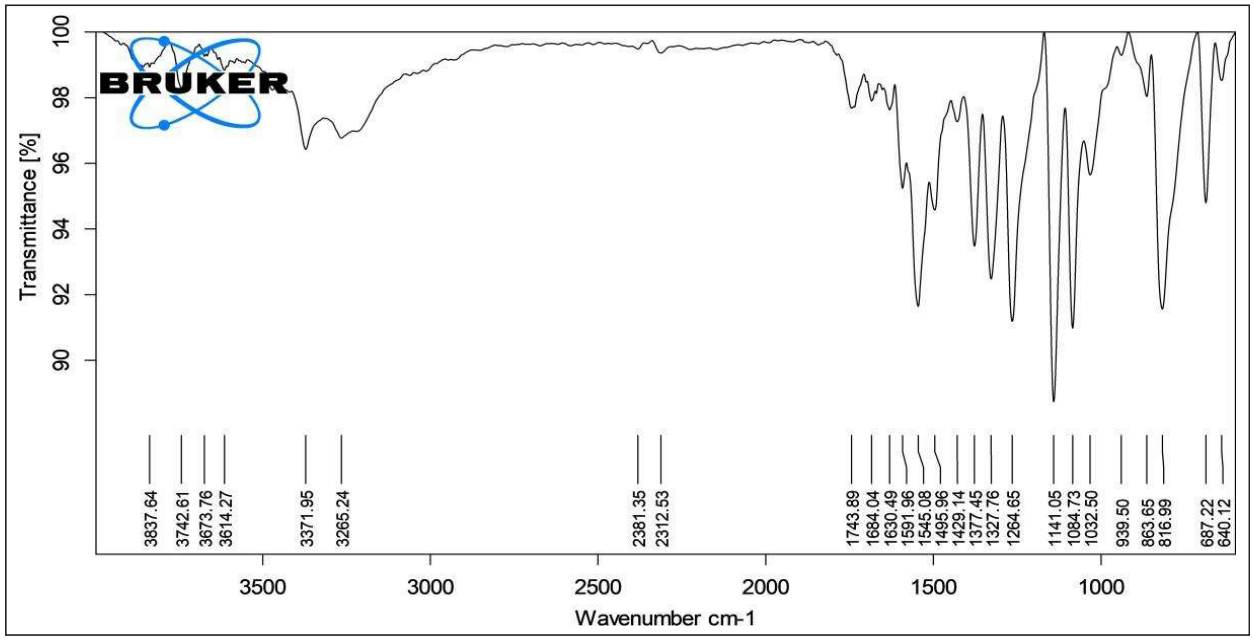

Figure 2: FTIR of Curcumin (***Source:*** Bruker)

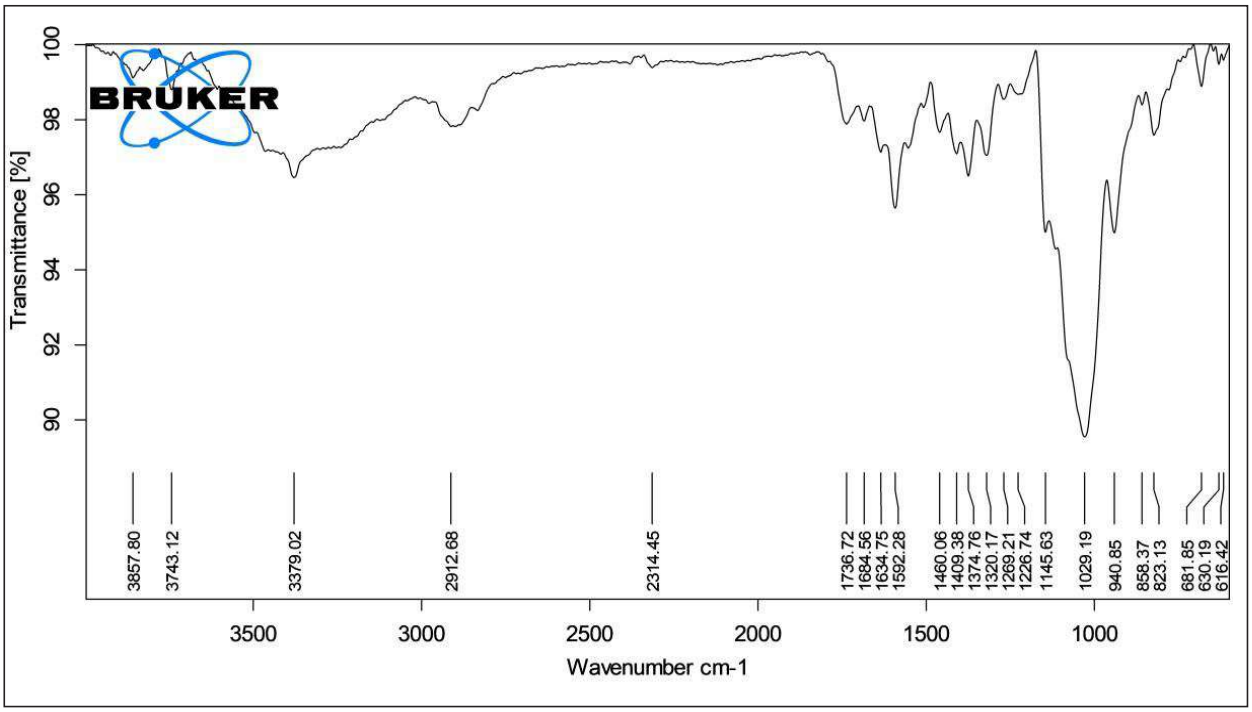

Figure 3: FTIR of Curcumin with polymers (***Source:*** Bruker)

Evaluation of Curcumin Lozenges Formulation

Table 4: Physical appearance of Hard boiled Curcumin Lozenges

S. no.	Formulation	Appearance
1.	F1	Light orange yellow, smooth, little sticky, easily removed from the mold
2.	F2	Light orange yellow, smooth, little sticky, easily removed from the mold
3.	F3	Light orange yellow, smooth, little sticky, easily removed from the mold
4	F4	Light orange yellow, smooth, little sticky, easily removed from the mold
5	F5	Light orange yellow, smooth, little sticky, easily removed from the mold
6	F6	Light orange yellow ,smooth, little sticky, easily removed from the mold
7	F7	Light orange yellow, smooth, little sticky, easily removed from the mold
8	F8	Light orange yellow, smooth, little sticky, easily removed from the mold
9	F9	Light Orange Yellow, smooth, little sticky, easily removed from the mold

Table 5: Physical Parameters of Curcumin Formulations

S. No.	Lozenge formulation	Weight uniformity (g/loz)	Weight of Individual lozenge (grams)	Hardness (kg/cm2)	Friability loss % w/w	Drug content* (mg)
1	F1	2.99±0.1	2.99	4.8±0.2	0.58	7.7 ± 0.3
2	F2	2.96±0.4	3.01	4.7±0.3	0.64	7.8 ± 0.3
3	F3	2.97±0.3	2.98	4.6±0.4	0.68	7.9 ± 0.3
4	F4	3.009±0.1	2.89	5.0±0.2	0.78	7.7 ± 0.3
5	F5	2.95±0.5	2.75	5.1±0.1	0.54	7.9 ± 0.3
6	F6	2.98±0.2	3.10	4.5±0.5	0.76	7.8 ± 0.3
7	F7	2.99±0.1	3.12	4.6±0.4	0.87	7.9 ± 0.3
8	F8	2.94±0.6	3.8	4.4±0.6	0.77	7.7 ± 0.3
9	F9	2.98±0.2	3.12	4.5±0.5	0.89	7.6 ± 0.3

pH determination: The pH of the prepared Lozenges was found to be in the range of 6.7-7.3 with a standard deviation of 0.025 to 0.168. All the formulations have shown a pH with not much deviation.

Table 6: pH of the formulations

S. No	Formulation code	Observed pH (±S.D.)
1	F1	6.76±0.025
2	F2	6.85±0.104
3	F3	6.94±0.128
4	F4	6.93±0.168
5	F5	7.29±0.103
6	F6	6.94±0.052
7	F7	7.13±0.143
8	F8	6.89±0.104
9	F9	7.25±0.165

Drug content of Curcumin: The drug content of the prepared lozenges was found to be in the range 96-98 indicating the application of the present method for the preparation of lozenges with high content uniformity.

Table 7: Drug content of Curcumin

Formula	Drug/Polymer (w/w)	Assay
F1	Curcumin/ HPMC K100	96.63 ± 0.91
F2	Curcumin/ PEG 4000	97.02 ± 0.24
F3	Curcumin/ PEG 6000	98.35 ± 1.47

In-vitro drug diffusion study: From the in vitro results it was observed that percentage release of the drug from the developed formulations F1 (98.5%), F2 (96.09%), F3 (95.75%) as shown in Table 7. Out of the formulations containing 2% of polymer, by the end of 45 minutes, formulation F3 with HPMCK100M as polymer has shown good release characteristics than those with PEG 6000 and PEG 4000. When the polymer used in F1 formulation containing HPMC K100 and

citricacid at 0.5% and F2 formulation containing HPMCK100 and citricacid at 1% have shown a fast drug release within 45 minutes.The formulation F3 containing HPMCK100M and citricacid at 2% as polymer has shown a release of 95.75% by the end of 45 minutes. Thus it is considered as optimised formulation as it has shown maximum drug release by the end of 45 minutes.

Table 8: Dissolution Parameters of Optimized F3 Formulaton

Optimised Formulation	Zero Order (R^2)	First Order (R^2)	Higuchi (R^2)	Korsmeyer Peppas (R^2)
F3	0.944	0.9921	0.9083	0.897

Dissolution parameters: (Drug release mechanisms): The invitro release data was subjected to zero order, first order, Higuchi, kosemeyer-peppas, Hixon crowell and erosion model in order to establish the drug release mechanism and kinetics of release from the lozenge tablets.

When the data was subjected to zero order and first order kinetic model, a linear relationship was observed with high R^2 value for First order model as compared to Zero order model suggested that the formulations were First order-controlled release.Higuchi's model was applied to the invitro release data, linearity was obtained with high R^2 value suggested that the drug release from Lozenge followed dissolution mechanism as all the polymers used were gel-based matrix type. In order to define a perfect model which will represent a better fit for the invitro release data, Korsemeyer-Peppas model was also applied. Compared to Kosemeyer-peppas, Higuchi will define exact release mechanism when more than one type of release phenomenon was observed. Good linearity with high R^2 value was observed with Higuchi model.

Characterization of Lozenge Formulations Accelerated Stability Studies: Physical Parameters of Curcumin Lozenge Formulations before and after Storage at Different Conditions.

Table 9: Optimised formulation of F3 stability studies

Formulation	Storage Condition	Weight Uniformity (gms)	Hardness (Kg/cm2)	Drug Content (mg/lozenge)
	Before storage	2.97 ± 0.3	5.68 ± 0.2	7.8± 0.3
F3	25 ± 20C, 60 ± 5% RH	2.96 ± 0.3	5.66 ± 0.3	7.9 ± 0.2
	40 ± 20C, 75 ± 5% RH	2.95 ± 0.3	5.65 ± 0.3	7.9 ± 0.2
	After storage	2.95 ± 0.3	5.65 ± 0.1	7.7 ± 0.3
F3	25 ± 20C, 60 ± 5% RH	2.94 ± 4.0	5.64 ± 0.3	7.8 ± 0.2
	40 ± 20C, 75 ± 5% RH	2.93 ± 4.0	5.63 ± 0.3	7.4 ± 0.4

Sterility test: The formulations showed no evidence of microbial growth when incubated for more than 7 days and cleared the sterility test.

Table 10: Sterility test data of prepared Curcumin lozenges

Formulation	Days of incubation								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
F1	-	-	-	-	-	-	-	-	-
F2	-	-	-	-	-	-	-	-	-
F3	-	-	-	-	-	-	-	-	-
F4	-	-	-	-	-	-	-	-	-
F5	-	-	-	-	-	-	-	-	-
F6	-	-	-	-	-	-	-	-	-
F7	-	-	-	-	-	-	-	-	-
F8	-	-	-	-	-	-	-	-	-
F9	-	-	-	-	-	-	-	-	-

*-ve sign indicates no growth

Antifungal Activity:Antifungal efficacy study was performed on formulations using Gram +ve Candida albicans organism. Clear zones showing inhibited zone of growth were observed. The zone of inhibition of the formulations was shown in the Table 10. The study indicated Curcumin retained its antifungal activity when formulated as Lozenge forming oral system against Candida albicans.

Table 11: Zone of Inhibition of prepared curcumin lozenges

	Zone of Inhibition(mm)									
	Standard (Pure Drug)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Candida albicans	29	28	27.5	28	25.5	28.5	26	26.9	28.3	27.7

DISCUSSION

The present study aimed to formulate and evaluate curcumin-loaded lozenges using different polymers to enhance its stability, solubility, and bioavailability. Curcumin, being poorly soluble in water, presents a challenge in oral formulations, which necessitates the use of suitable excipients and formulation techniques to enhance its therapeutic potential. The development of curcumin-loaded lozenges offers several advantages, including easy administration, taste masking, and prolonged release of the active ingredient.

The determination of λmax of curcumin at 423 nm was an essential step for the calibration and standardization of the UV-Visible spectrophotometric method. This value ensured accurate quantification of curcumin in the formulations and facilitated the construction of the calibration curve, which was used to assess the drug content and ensure consistent quality across different batches of lozenges.

Phosphate buffer pH 6.8 was chosen as the dissolution medium due to its similarity to the pH of saliva, ensuring that the in vitro dissolution studies would closely simulate the conditions in the oral cavity. The construction of the calibration curve for curcumin at various concentrations demonstrated a linear relationship between absorbance and concentration, which was essential for the precise determination of curcumin release during dissolution studies.

The drug-excipient compatibility study, performed using Fourier Transform Infrared (FTIR) spectroscopy, confirmed that the selected excipients were compatible with curcumin, without causing any significant interactions that could affect its stability or release profile. This is crucial for ensuring the safety and efficacy of the final formulation.

The preparation of the lozenges involved the use of various polymers, including HPMC, Carbopol, and Sodium Alginate, to assess their effects on the physical properties of the lozenges and the release rate of curcumin. The formulation with 20 mg of HPMC (F3) showed the best balance of properties, including adequate hardness, friability, and dissolution rate. This formulation was considered the most suitable for further in vivo evaluation.

The in vitro dissolution studies showed that the release of curcumin from the lozenges was slow and sustained over 45 minutes, which is in line with the intended design of the lozenges to provide prolonged therapeutic effects. The release profile indicated that curcumin could be effectively delivered over an extended period, potentially improving its bioavailability and therapeutic efficacy.

The taste masking evaluation revealed that the optimized formulation (F3) provided an acceptable mouthfeel, which is critical for patient compliance, particularly when administering curcumin, which has a bitter taste. The results of the pH determination showed that all formulations had a pH within the acceptable range for oral administration, ensuring safety and comfort during use.

Sterility tests confirmed that the optimized formulation was free from microbial contamination, making it safe for use in pharmaceutical applications. Additionally, the antifungal and antibacterial activity results demonstrated the potential of the formulation to offer protection against microbial infections, which adds an extra layer of benefit to the lozenge formulation.

CONCLUSION

In conclusion, the development of curcumin-loaded lozenges using various excipients and polymers was successful, yielding a formulation that demonstrated favorable physical properties, stability, and controlled release of curcumin. The study established an effective method for the preparation, characterization, and evaluation of curcumin lozenges. The formulation F3, containing 20 mg of HPMC, exhibited optimal release characteristics, taste masking properties, and drug content uniformity, making it the most suitable candidate for further development. The in vitro dissolution studies, along with the drug-excipient compatibility testing, confirmed that the formulation could provide sustained release, enhancing the therapeutic potential of curcumin. The sterility and antimicrobial activity tests further validated the safety of the formulation, ensuring its suitability for use in pharmaceutical applications. Future studies may focus on the in vivo evaluation of the optimized formulation to assess its pharmacokinetic and pharmacodynamic properties, as well as its effectiveness in treating conditions such as inflammation and oxidative stress, which curcumin is known to target.

Conflict of interests: The authors declared no conflicts of interest.

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