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ORIGNAL ARTICLE

Revolutionizing Oral Care: Diclofenac Sodium and Zinc Sulfate-Loaded Lozenges for Targeted Local Delivery for the Management of Oral Ulcers and Soft Tissue Lesions

Saba Naeem[1*], Asad Majeed Khan[1], Fatima Kazmi[1], Waleed Rafique[1], Afshan Shakoor[1], Adnan Malik[1], Ayesha Nawaz[1], Bisma Niaz[1], Saima Tariq[1], Mahnoor Shafique[1]

[1]Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, Lahore University of Biological and Applied Sciences, Lahore, Pakistan

Correspondence
Saba Naeem
Email: sabanaeem1126@yahoo.com

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All the authors have no conflict of interest

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Abstract

Soft lozenges were developed as distinctive localized drug delivery system for managing oral ulcers along with soft tissue lesions. Prepared formulations incorporated drugs including diclofenac sodium for analgesic and anti-inflammatory effects, zinc sulfate for epithelial repair and menthol for soothing action in buccal cavity. Lozenges were prepared with methyl cellulose and PEG 6000 through molding technique. Comprehensive characterization included FTIR analysis, physicochemical evaluation such as hardness, surface pH, weight variation, friability and in vitro dissolution studies. First-order release kinetics with Fickian diffusion was revealed through drug release kinetics evaluation whereas FTIR study validated absence of interactions. These findings suggest that these lozenges offer a patient-friendly effective approach for localized oral therapy.

Key Words: Oral ulcers, Soft tissue lesions, Localized drug delivery, Diclofenac sodium, Zinc sulphate, Pain management, Wound healing

1. Introduction

Buccal cavity offers distinctive advantages for both local and systemic drug delivery such as bypassing the first-pass metabolism and enabling targeted therapy. Localized delivery is particularly beneficial for conditions including oral ulcers, infections, and mucosal lesions due to the presence of mucosal lining across buccal cavity [1]. Localized delivery within buccal cavity has been effectively proven and possesses a variety of applications particularly in dental diseases, fungal and bacterial infections, treatment of sore throat among many others [2]. Oral mucosa is comprised of stratified squamous epithelium supported by a basement membrane and connective tissue, covering an area of approximately 100 cm^2 [3]. There are various dosage forms commercially available for buccal delivery including lozenges, sprays, buccal tablets, films, and solutions [4].

Oral ulcers can be acute or chronic. Acute ulcers are often caused by trauma, infections, or conditions like Behcet's disease, while chronic ulcers are linked to bacterial or parasitic infections, autoimmune disorders, and conditions like lupus and oral lichen planus. Topical gels and mouth rinses are limited in their effectiveness due to poor contact with lesions, but soft lozenges offer sustained drug release, improving treatment efficacy and patient compliance [5, 6]. Zinc sulphate has been reported in treating and prevention of recurrent oral ulcers because of its properties of maintenance of epithelial integrity and wound healing [7]. It has also been utilized for managing various ulcerative conditions, including gastric ulcers, sickle cell ulcers, aphthous stomatitis, and other soft tissue lesions of the oral cavity. [8-11]. Nonsteroidal anti-inflammatory class drug(NSAID), diclofenac sodium, which is endowed with antipyretic, anti-inflammatory and analgesic characteristics, reduces prostaglandin synthesis and

make it effective in managing both acute and chronic inflammatory conditions [12,13].

Lozenges are solid unit dosage forms designed for gradual dissolution in the oral cavity, typically composed of a sweetened base with flavoring agents and, optionally, active pharmaceutical ingredients. They are prepared primarily by molding (pastilles) or compression (troches). Lozenges improve patient compliance, particularly for individuals with swallowing difficulties, and enable sustained drug release, additionally ensuring prolonged contact with oral and pharyngeal mucosa for targeted delivery thereby ensuring continuous drug delivery to the targeted tissues. [14]. When compared to compressed lozenges, soft or molded have pliable texture owing to the high sugar content combined with other excipients including polyethylene glycol (PEG), gelatin or acacia gum [15, 16].

Present study sought to formulate a dosage form that would offer both local efficacy and systemic absorption for the treatment of oral lesions and mouth ulcers. Unlike hard lozenges these are designed to minimize mechanical abrasion to ulcerated mucosal tissues while enabling the incorporation of multiple active drugs for synergistic therapeutic action. The lozenges were formulated with sugar base incorporating PEG 6000, acacia gum, and methyl cellulose as excipients, along with menthol for flavor and coloring agents. This formulation was specifically designed to enhance the retention time of zinc sulfate and diclofenac sodium in the oral cavity, allowing for sustained local action. Additionally, the formulation aims to improve the bioavailability of these active compounds by circumventing first-pass metabolism and reducing gastric irritation. These characteristics are expected to promote effective wound healing and provide pain relief, particularly for ulcerative and soft tissue lesions within the oral cavity.

2. Experimental

2.1 Material

Diclofenac Sodium and Zinc sulphate (analytical grade, BDH laboratories, UK), PEG 6000 (Pharmaceutical grade, Sigma Aldrich, Germany), Accacia gum (Pharmaceutical grade, Sigma Aldrich, Germany), Menthol (Pharmaceutical grade, Sigma Aldrich, Germany), Mint flavor, food color (light green/ blue), Ethanol, Sodium hydroxide (NaOH), Potassium dihydrogen phosphate, Potassium chloride (KCl), Phosphoric acid, HCl and Distilled water was procured from the research laboratory, Faculty of Pharmaceutical Sciences, UBAS, Lahore.

2.2 Preparation of soft lozenges

Lozenges were created using heating and congealing procedure as described by Rathod et al. [17]. All the ingredients were firstly accurately and precisely weighed on an analytical balance the feed ratio per batch is presented in **Table 1.** The weighed amount of sugar was transferred into a beaker. With the help of measuring cylinder, distilled water was measured and poured into the beaker containing sugar. The beaker was then heated on low flame until all the sugar was dissolved and then cooked for about 15-20 min at low heat when the sugar reached desired consistency the heat was turned off. When temperature ranged around 60-70°C weighed amount of PEG 6000 and Methyl Cellulose were added and mixed for 5 min. Both drugs and remaining excipients were added. The mixture was stirred until uniform consistency was obtained and the color was evenly distributed throughout the mixture. The mixed contents were carefully poured into the lubricated mold and allowed to cool for 4-5 hr. at room temperature. The coloring agent added was different for formulation identification. The lozenges were then taken out of mold and packaged in butter paper and aluminum foil separately and stored in an air tight container till characterization.

Table 1: Composition of Lozenges concoctions

Components	Formulations								
	$Zinclo_1$	**$Zinclo_2$**	**$Zinclo_3$**	**$Zinclo_4$**	**$Zinclo_5$**	**$Zinclo_6$**	**$Zinclo_7$**	**$Zinclo_8$**	**$Zinclo_9$**
Diclofenac Sodium (mg)	250	250	250	250	250	250	250	250	250
Zinc Sulphate (mg)	100	100	100	100	100	100	100	100	100
Sugar (g)	25	30	35	25	25	25	25	25	25

Citric Acid (mg)	50	50	50	50	50	50	50	50	50
PEG-6000 (mg)	500	500	500	500	550	490	500	500	500
CMC (mg)	400	400	400	400	400	400	400	450	500
Menthol (mg)	25	25	25	25	25	25	25	25	25
Color (mg)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

2.3 Weight variation

To check the weight variation 20 lozenges were weighed, average was taken, then individual weight of each lozenge was compared with average weight.

2.4 Friability test

Roche Friabilator, with 25 rpm for 4 minutes, was utilizedfor the testing of friability. 5 tablets from each batch were used. The lozenges were weighed accurately then placed in the friabilator and after 4 min they were taken out, dedusted and weighed [17]. Percentage weight loss was calculated utilizing equation 1,

$$\%\ Friability = \frac{(initial\ weight - weight\ after\ friability) \times 100}{Initial\ weight} \quad \text{..... eq 1}$$

2.5 Hardness Test

The hardness test was performed using Monsanto hardness tester.

2.6 Surface pH

Test for surface pH was executed utilizing the Sorensen's phosphate buffer having pH of 6.2 in which the formulations were kept in order for them to swell first. After the lozenges swelled, pH values were recorded with the help of pH meter. Electrode was dipped and allowed to equilibrate in the solution for 1 minute [18].

2.7 Fourier transform infrared (FT-IR) spectroscopy

Infrared spectrum (IR), utilized for structural alignment, presence and identification of different functional groups, was performed for all grounded raw material samples i.e., Diclofenac sodium, Zinc sulphate, PEG 6000, Methyl cellulose and prepared lozenges. Fourier transform infrared spectroscopy with attenuated total reflectance mode, (ATR)-FTIR, (Shimadzu, Disburg, Germany) having 650-4000 cm^{-1} specified range was used.

2.8 Standard calibration curve

Serial dilutions were prepared from 1% stock solution to obtain concentrations ranging from 10–100 µg/mL. Individual spectra were measured utilizing UV spectrophotometer. Dilutions of diclofenac sodium and zinc sulphate were evaluated at 310nm and 319nm wavelength, respectively. At designated concentrations (mg/ml), absorbance was systematically recorded and calibration curve were constructed utilizing Microsoft excel.

2.9 Invitro drug release studies

To assess drug release patterns, USP dissolution apparatus-II was used posessing a buffer solution of pH 6.8 mimicking the pH in oral cavity. Apparatus consisted of 6 buckets each contained 900ml of buffer solution. 1 soft lozenge was placed in each bucket and the apparatus was run at 50 rpm at 37°C ± 0.5°C. Five ml of buffer was withdrawn and replaced with buffer at different time intervals. All the samples withdrawn were analyzed using UV-spectrophotometer. Following equation was used to calculate percentage drug release

$$\%\ Drug\ release = \frac{sample\ absorbance}{standard\ absorbance} \times 100$$

This calculation was validated using calibration curves for both drugs.

2.10 Drug release kinetics

For regression analysis, the data of drug release from the formulations was fitted into various release kinetic models including first-order, Higuchi, zero-order and Korsmeyer–Peppas, using DDSolver (Excel add-in).

Dug release independent of concentration of drug present in the formulation obeys zero-order release kinetics calculated by following formula:

$$Q_t = Q_0 + K_0 t$$

K_0 represents drug release rate constant, initial quantity in lozenges represented by Q_0 and Q_t representing drug release with t time.

When the drug release is concentration dependent, formulation represents first order release kinetics which is illustrated through following equation:

$$Log\ W = Log\ W_0 - \frac{k_t}{2.303}$$

Here, the amount of drug present in the formulation is represented by W, K represents first order rate

constant, initial amount of drug in formulation by W_0 with the effect of time t.

When a drug release is governed by Fick's law, it is believed to be following Higuchi release model which states that the release of drug from insoluble matrix-based formulation is square root of time t and therefor is a time dependent process.

$$F_t = K_2 t^{1/2}$$

Where F_t represents amount of undissolved drug and Higuchi constant is represented by K_2.

When drug release mechanism is unclear or more than one release processes are involved, we apply Korsmeyer-Peppas model, expressed by the following equation:

$$\frac{F_t}{F_\infty} = K_3 t^n$$

Where fraction, F_t/F_∞, represents drug release at t time, K3 is Korsmeyer-Peppas constant and n is release exponent. For drug release, $n \leq 0.45$ depicts Fickian release, non-Fickian value lies between $0.45 < n > 0.89$ and when $n \geq 0.89$ case II relaxation or super case II transport is represented [19].

3. Results and Discussion

3.1 Organoleptic properties

Heating and congealing technique was successful in preparation of molded soft lozenges. All lozenges were smooth, elegant in appearance with light blue color, transparent and were easy to remove from the mold. The lozenges obtained are represented in **Figure 1.**

3.2 Weight variation

The average weight of one soft lozenge was measured 3.45 – 3.48 g. The variation of weight within a batch of formulation is represented in **Table 2.**

3.3 Hardness of soft lozenges

Hardness of fabricated lozenges ranged from 1.70 ± 0.2 to 2.09 ± 0.3 kg/cm^2.

Average hardness of individual formulations is represented in **Table 2.**

3.4 Friability

The percent loss calculated after the friability test of all formulations was < 1%, represented in **Table 2,** indicating the ability of lozenges to withstand shock during transportation and handling.

3.5 Surface pH

The surface pH measured more or less was neutral confirming that the formulation will not irritate the oral mucosa and the values are represented in **Table 2.**

Table 2: Physical Evaluation of Zinclo concoctions

Formulation	Parameters				
	Weight	Thickness	Hardness (kg/	Surface pH	Friability

	Variation (g)	(mm)	cm^2)		
Zinclo$_1$	3.45 ± 0.2	7.48 ± 0.05	1.70 ± 0.2	6.69 ± 0.05	0.00
Zinclo$_2$	3.45 ± 0.7	7.48 ± 0.10	1.91 ± 0.4	6.70 ± 0.10	0.00
Zinclo$_3$	3.48 ± 0.3	7.46 ± 0.08	2.01 ± 0.4	6.74 ± 0.20	0.00
Zinclo$_4$	3.43 ± 0.8	7.48 ± 0.07	2.05 ± 0.3	6.68 ± 0.03	0.00
Zinclo$_5$	3.50 ± 0.7	7.49 ± 0.13	1.88 ± 0.1	6.75 ± 0.11	0.01
Zinclo$_6$	3.47 ± 0.4	7.47 ± 0.04	1.81 ± 0.5	6.70 ± 0.07	0.00
Zinclo$_7$	3.43 ± 0.9	7.46 ± 0.07	2.1 ± 0.3	6.69 ± 0.01	0.00
Zinclo$_8$	3.42 ± 0.5	7.48 ± 0.05	2.04 ± 0.1	6.76 ± 0.05	0.01
Zinclo$_9$	3.45 ± 0.5	7.48 ± 0.05	2.13 ± 0.3	6.69 ± 0.04	0.00

3.6 FT-IR

The FT-IR of Zinc sulphate, Diclofenac Sodium, PEG 6000 and Methyl cellulose is represented in **Figure 2.**

FT-IR of zinc sulphate reviled 3 major peaks. At 3168.2 cm^{-1} a broad vibrational band can be seen which is representation of symmetric molecular stretching of water while another peak, at 1636.3 cm^{-1}, corresponds to its bending vibration. Sharp peak seen at 1060.4 cm^{-1} associates with $S0_4^{2-}$ [20]. The diclofenac FT-IR shows various peaks. The N-H stretching of secondary amine group can be observed at 3386.3 cm^{-1} and N-H stretching represented by clear peak at 3257.7 cm^{-1}. Since aromatic rings are known to be present, a stretching can be observed at 3080.6 cm^{-1}. Different sharp peaks in the range of 1400 cm^{-1} to 1550 cm^{-1} associate and confirm the presence of aromatic ring [21]. FT-IR spectroscopy have clearly observable peak of aliphatic C-H stretching at 2881.2 cm^{-1}. The sharp peak present at 1095.8 cm^{-1} confirms stretching vibration of C-O-H group while the 1278.5 cm^{-1} stretch confirms O-H group. Peak at 1466.7 cm^{-1} together with 1340.0 cm^{-1} are because of C-H bending vibration [22]. Methyl cellulose FT-IR revealed stretching of O-H at 3341.6 cm^{-1}. C-H stretching vibration can be observed at 2885.0 cm^{-1}. 1410.8 cm^{-1} and 1331.3 cm^{-1} stretching of C-H bond of CH_2 and CH_3 is observed. C-O-C stretch can be observed at 1049.2 cm^{-1} and 1015.7 cm^{-1} [23, 24]. FT-IR of fabricated soft lozenges showed no interaction.

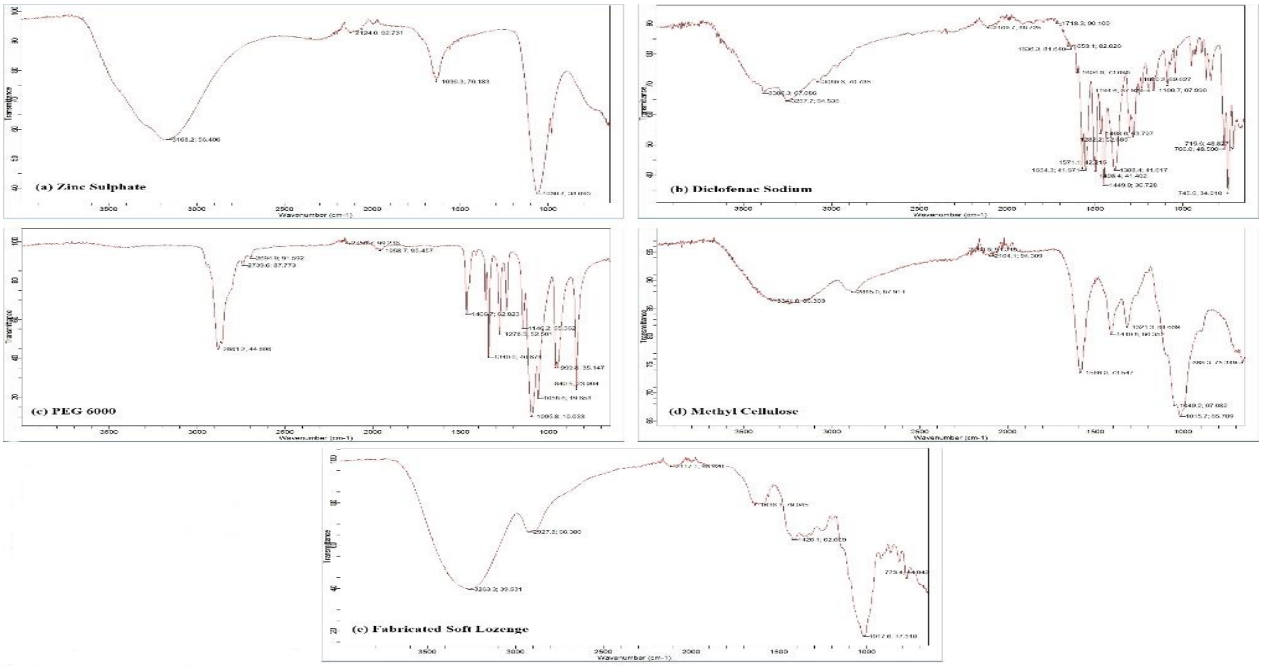

Figure 1. FTIR (a) Zinc sulphate, (b) Diclofenac sodium, (c) PEG 6000, (d) Methyl cellulose, (e) Fabricated soft lozenge

3.7 Invitro dissolution studies and Drug release kinetics

All formulations underwent dissolution studies. It was seen that the formulations released the drugs at 6.8 pH, our study lasted from 20 minutes to 30 minutes in different formulations. Drug release pattern of Zinclo formulations is represented in **Figure 3 and 4**. The drug release from all the formulations showed first order release. A little difference in release pattern was seen because of increasing and decreasing quantities of ingredients. The formulation $Zinclo_3$ showed slower drug release as compared to $Zinclo_1$ and $Zinclo_2$ as the concentration of sugar was maximum in $Zinclo_3$. The increasing quantity of PEG resulted in a bit slower release due to denser matrix in $Zinclo_5$ as compared to $Zinclo_4$ and $Zinclo_6$. $Zinclo_6$ had a faster release rate due to lesser quantity of PEG. Zinclo formulations 7-9 had varying quantities of CMC. As CMC also plays a role as disintegrating agent it can be seen from the release pattern that $Zinclo_9$ had the fastest release rate. $Zinclo_9$ exhibited the fastest release profile, likely due to higher CMC content, whereas Zinclo3 showed slower release due to increased sugar concentration.

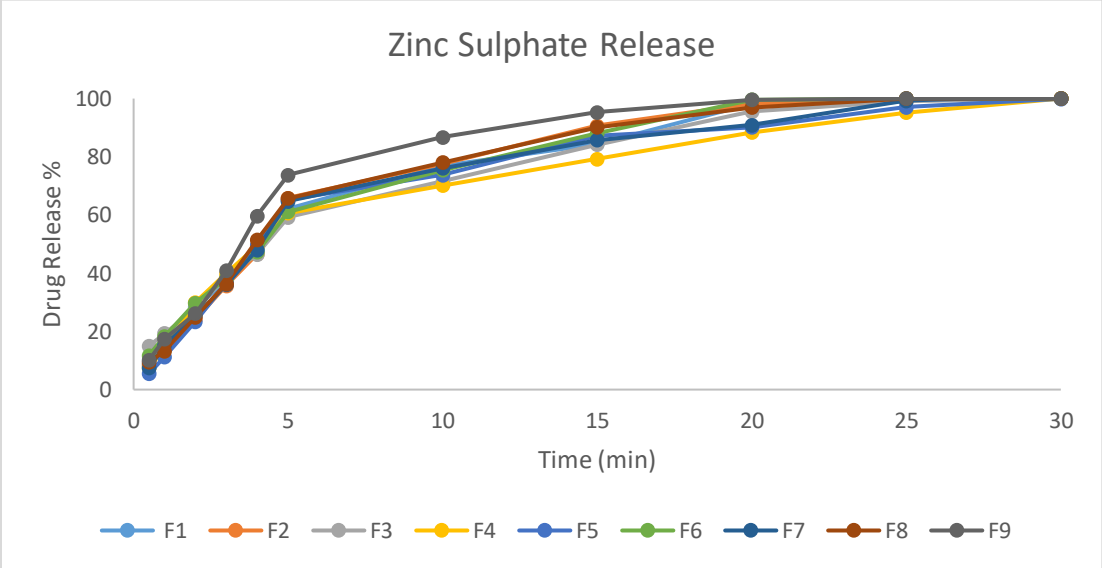

Figure 2: Zinc Sulphate release pattern

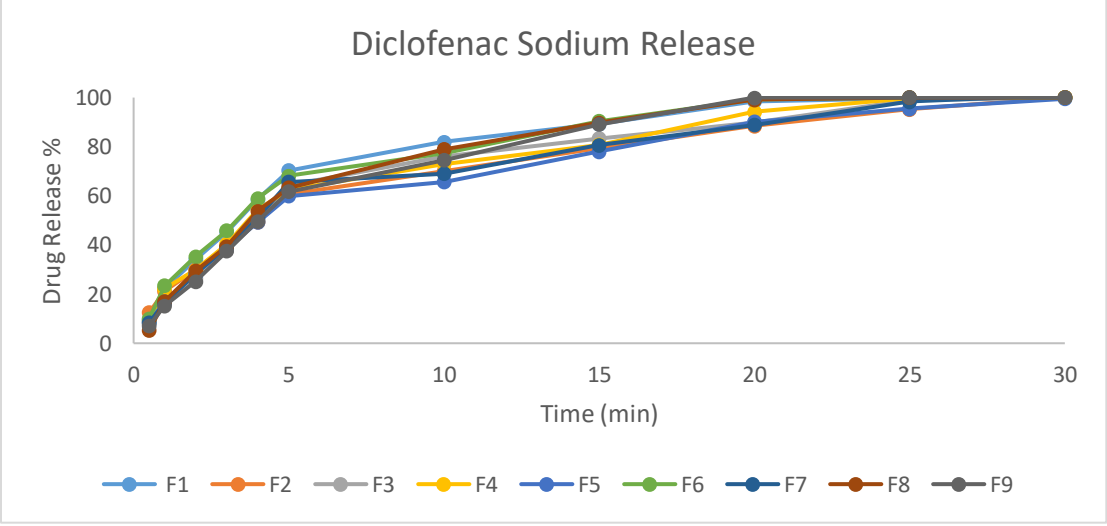

Figure 3: Diclofenac Sodium release pattern

3.8 Drug Release Kinetics

We applied four kinetic models on the drug release results gathered by dissolution. Korsmeyer-Peppas model, First-order, Higuchi and Zero-order models were employed for evaluation of release kinetics from formulations. The most suitable model was considered based on the value of each model's regression coefficient (R^2). Selection of goodness of fit, was based on the predicted R^2 values which was nearest to 1. Our data was best fitted with the First-order release model, presented in **Table 3** and **Table 4**. All the formulations followed First order release kinetics for both drugs. Coefficient of regression for Korsmeyer-Peppas model was found between 0.374 and 0.47. diffusion mechanism coefficient "n" showed mostly Fickian diffusion.The Korsmeyer-Peppas model fitting yielded regression coefficients (R^2) ranging from 0.374 to 0.47, indicating a moderate to weak correlation. This suggests that the drug release mechanism is likely a combination of processes, such as diffusion and erosion, rather than a single, diffusion-controlled mechanism.

4. Conclusion

This study successfully formulated soft lozenges incorporating diclofenac sodium and zinc sulfate for localized management of oral ulcers and soft tissue lesions delivering dual therapy in a single dosage form where diclofenac diclofenac sodium provides effective analgesia along with inflammation reduction and Zinc sulfate promoting epithelial repair. Sugar based matrix affirms the palatability and patient compliance. The dosage form design ensures and enables the targeted delivery of drugs locally at the site of lesions and will thus provide rapid and sustained action in buccal cavity. Physicochemical characterization validated adequate hardness, friability, and surface pH, while our drug dissolution studies revealed first-order release kinetics along with Korsmeyer–Peppas analysis which indicated predominantly Fickian diffusion with some formulations exhibiting borderline non-Fickian behavior, suggesting a coupling of polymer relaxation and diffusion mechanisms. The findings present soft lozenges as innovative, patient-friendly alternative to conventional topical therapies, potentially reducing systemic side effects and improving treatment outcomes. Future work should include muco-adhesion studies, long-term stability testing, and clinical trials to validate efficacy and safety, paving the way for their integration into routine oral care.

Table 2: Drug release kinetics of Zinc Sulphate

Formulation	Zero Order	First Order	Higuchi-model	Korsmeyer-Peppas model	
				R^2	n
Zinclo$_1$	0.4617	0.9904	0.9374	0.9490	0.438
Zinclo$_2$	0.4770	0.9889	0.9241	0.9326	0.445
Zinclo$_3$	0.4350	0.9805	0.9551	0.9720	0.427
Zinclo$_4$	0.4356	0.9687	0.9403	0.9568	0.427
Zinclo$_5$	0.4853	0.9813	0.9195	0.9274	0.447
Zinclo$_6$	0.4300	0.9905	0.9424	0.9584	0.429
Zinclo$_7$	0.4747	0.9853	0.9325	0.9425	0.442
Zinclo$_8$	0.4435	0.9895	0.9178	0.9298	0.436
Zinclo$_9$	0.2307	0.9847	0.8519	0.8916	0.393

Table 3: Drug release kinetics of Diclofenac Sodium

Formulation	Zero Order	First Order	Higuchi-model	Korsmeyer-Peppas model	
				R^2	n
Zinclo$_1$	0.1367	0.9887	0.8650	0.9279	0.374
Zinclo$_2$	0.3436	0.9569	0.9415	0.9728	0.405
Zinclo$_3$	0.4281	0.9818	0.9282	0.9439	0.429
Zinclo$_4$	0.3390	0.9693	0.9279	0.9583	0.406
Zinclo$_5$	0.4563	0.9618	0.9506	0.9654	0.431
Zinclo$_6$	0.1425	0.9832	0.8760	0.9392	0.374
Zinclo$_7$	0.4171	0.9619	0.9309	0.9492	0.423
Zinclo$_8$	0.4001	0.9937	0.9170	0.9351	0.424
Zinclo$_9$	0.4924	0.9916	0.9358	0.9438	0.447

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