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Original Article

Formulation, Optimization, and Evaluation of Lornoxicam Medicated Chewing Gum Using Ion Exchange Resin Taste Masking

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ABSTRACT

Background: This study aimed to develop and evaluate a taste-masked Medicated Chewing Gum (MCG) of Lornoxicam (LXM) using Kyron T-114, a weak cation exchange resin, to improve palatability and patient compliance. LXM, a potent non-steroidal anti-inflammatory drug, suffers from poor acceptability due to its bitterness, making it a suitable candidate for resin-based complexation. **Materials and Methods:** The drug-resin interaction was optimized by varying resin activation, drug-to-resin ratio, pH, swelling time, and stirring conditions, achieving a maximum drug loading of 81.59% at a 1:2 ratio. The optimized complex was incorporated into a chewing gum base and characterized for physicochemical, mechanical, and performance attributes. Differential scanning calorimetry and Fourier transform infrared spectroscopy confirmed drug-resin complexation and excipient compatibility. **Results and Discussion:** The optimized formulation exhibited good flow properties, hardness, adhesiveness, and uniformity, with friability below 1% and drug content of 98.24±1.23%. *In vitro* studies demonstrated rapid release, with 88.26% of the drug released within 20 min. Accelerated stability testing confirmed no significant changes in appearance, softness, or drug release over six months. **Conclusion:** The findings suggest that Kyron T-114-based ion exchange complexation is a robust approach for masking the bitterness of lornoxicam, and MCGs represent a promising, patient-friendly dosage form for fast and effective pain management.

Keywords: Lornoxicam, Medicated Chewing Gum, Taste Masking, Ion Exchange Resin, Kyron T-114, PEG 400.

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INTRODUCTION

Several oral dosage forms have emerged due to the growing interest in innovative drug delivery systems that enhance patient compliance, therapeutic efficacy, and minimize systemic adverse effects (Lou *et al*., 2023). Among them, Medicated Chewing Gums (MCGs) have emerged as a new and patient-friendly formulation offering multiple clinical and pharmaceutical benefits. Medicated chewing gums are single-dose solid preparations intended for chewing and not swallowing, with the potential for drug absorption through the oral mucosa or via delivery after mastication into the gastrointestinal tract (Kaushik *et al*., 2019). This delivery method is especially favorable for drugs requiring a quick onset, as it bypasses first-pass metabolism and is effective due to increased buccal absorption. MCGs are easy to administer without water, allowing for a longer drug residence time on the oral mucosa (Homayun *et al*., 2019; Zhang *et al*., 2002). They are helpful in patients with swallowing difficulties or problems with conventional tablets or capsules. Moreover, chewing increases the production of saliva, which helps dissolve the Active Pharmaceutical Ingredient (API) and thus facilitates absorption (Logrippo *et al*., 2017). Despite these strengths, palatability and sufficient profiles of drug release, which form one of the significant difficulties in developing MCGs, particularly in bitter-tasting drugs, are challenging (Wang *et al*., 2024).

Lornoxicam (LXM) is a non-steroidal anti-inflammatory medicine of the oxicam group, possessing potent analgesic and anti-inflammatory activity. Its application has been common in the treatment of acute pain, postoperative pain, and inflammatory conditions such as osteoarthritis and rheumatoid arthritis (Balfour *et al*., 1996). Nevertheless, LXM has a bitter taste, and therefore its applicability to oral products is relatively low, unless some taste-masking techniques are applied. In addition, its pharmacological profile requires rapid action, making it one of the best compounds to use with buccal delivery systems, such as MCG.

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Taste masking plays a significant role in patient compliance, especially when an oromucosal or chewable formulation is adopted. Among all the taste masking methods, the application of Ion Exchange Resins (IERs) has gained popularity due to their simplicity, safety, and effectiveness (Hu *et al*., 2023). Ion exchange resins are non-covalent, reversible, high-molecular-weight insoluble polyelectrolytes capable of forming complexes with ionizable drug molecules (Golden, 2000). These complexes can inhibit the liberation of the drug into saliva, thereby concealing its bitter taste, but they also facilitate the liberation of the drug under acidic conditions in the stomach or during the formation of an ion pair complex with electrolytes in the gastrointestinal fluids (Szejtli *et al*., 2005).

Weak cation exchange resin, such as Kyron T-114, has been found useful, particularly in complexations with basic drugs, such as Lornoxicam, based on its carboxylic functional groups. The resultant drug-resinates are tasteless, stable, and can be directly compressed into oral dosage forms, such as MCGs (*Development of Taste-Masked Oral Dispersible Tablets of Cefpodoxime Proxetil*, n.d.; Bollam *et al*., 2025).

Considering the therapeutic potential of Lornoxicam and the growing need for patient-compliant dosage forms, this study aims to develop a taste-masked medicated chewing gum formulation utilizing ion exchange resin (Kyron T-114; Sener *et al*., 2008; Tan *et al*., 2018). This research focuses on optimizing the drug-resin complexation process for maximum drug loading and effective taste masking.

MATERIALS AND METHODS

Materials

Lornoxicam (LXM) was obtained as a gratis sample from Hetero Drugs Ltd., Kyron T-114 from Corel Pharma Chem, and Gum base (Health in Gum) was gifted from Cafosa. Other excipients were of analytical grade. Aspartame and Sucralose were obtained from Himedia Pvt. Ltd., (Mumbai, India). Peppermint flavor was obtained from Triveni Chemicals (Vapi, India). Polyethylene glycol 400 AR, castor oil, Dibutyl phthalate, and Glycerin AR were obtained from S.D. Fine chemicals (Mumbai, India). Talc, Magnesium stearate, and Aerosil were obtained from Central Drug House (P) Ltd., (New Delhi, India). All other chemicals in the investigation were of analytical reagent grade.

Method of Preparation

Preparation of Drug-Resin Complex

LXM and Kyron T-114 were accurately weighed into their relative proportions (drug: resin) using an analytical balance. The sample Kyron T-114 was pipetted into a clean beaker containing 30 mL of distilled water. The resin structure was activated by allowing the mixture to swell at room temperature for 30 min. Then, the pH of the dispersion was accurately adjusted to 5.0-5.5 with a 1 M Potassium Hydroxide (KOH) solution, and the conditions were optimized for ionic interaction with the drug. The accurately weighed quantity of Lornoxicam was added to the pre-swollen and pH-adjusted resin dispersion (*"Formulation, Optimization And Evaluation of Medicated Chewing Gum for Combination Therapy,"* 2014). The mixture obtained was continuously stirred for 4 hr to facilitate the complete complexation of the resin and the drug. The mixture was then filtered after the stirring process, and the residue (drug-resin complex) was collected that was followed by a triple wash with 75 mL of distilled water to eliminate any unbound drug and excess reagents (Li *et al*., 2021). The resin was then washed and air-dried. The dried drug-resin complex was analyzed regarding the drug loading percentages using UV-visible spectroscopy. The filtrate was used to determine the amount of unbound drug, and the amount of bound drug was determined by difference to determine the efficiency of drug loading (Daihom *et al*., 2020).

Preparation of LXM-loaded taste-masked MCG

The direct method of compression was employed in the formulation of the medicated chewing gum. The volatile liquid flavour was added slowly to a free-flowing, compactable gum material, which was continuously mixed in a Sigma blade mixer over 5 min in this method. The flavoured gum was then screened through a 30# sieve, and then the pre-weighed, pre-sifted LXM, anti-adherent agent (Talc), and organoleptic agent were added and mixed for a further 10 min. This was followed by the addition and mixing of 30# pre-sifted lubricant (Magnesium stearate) and glidant (Aerosil) accurately into the mixture, and remixed for 10 min. Finally, the prepared blend was compressed into a formulation using a rotary compression machine. Individual excipient selection and optimization were achieved by an individual obstacle-to-solution method. Out of all the preliminary feasibility batches of weight adjustment to infer a suitable chewable mass, 1000 mg of LXM was settled, which resulted in a good chewable mass. Optimization trials were conducted for glidants, anti-adherents, lubricants, sweeteners, flavours, and plasticizers, and other parameters like the effect of drug resin ratio, pH, resin activation, swelling time, temperature, and stirring time (Chaudhary *et al*., 2012).

Optimization of LXM-loaded taste-masked MCG

Optimization of glidant, antiadherant, and lubricant

As previously mentioned, a mix for direct compression was made, with batches A1, A2, and A3 having Aerosil concentrations of 0.1%, 0.3%, and 0.5%, respectively, as indicated in Table 1. In order to maximise flowability, the angle of repose was changed. Several tests from batches A3-A7 were conducted to optimise the talc concentration between 1 and 5% to avoid pricking and the mix adhering to the die and punches (Jivraj *et al*., 2000). In batches A8-A10, magnesium stearate was chosen and added at quantities of 0.5%, 1%, and 1.5% to enable simple ejection

following compression. A batch containing only drug and Health in gum was prepared as batch A0 to observe the effect of glidant, antiadherant, and lubricant on compressibility and flow properties. All these batches were evaluated for flow property and compressibility (Shah *et al.*, 2008).

Optimization of sweetener and flavor

Artificial sweetener aspartame was used in varying proportions (3-6%) in batch A11-A16, while peppermint oil was added to the gum base for flavor adsorption, as shown in Table 2. (Choi *et al.*, 2024). Then, it was screened through a 30# sieve and utilized in formulation, which increased the total flavour lasting time up to 5-10 min.

Optimization of plasticizer/softener

The formulation used PEG-400, Castor oil, glycerine, and dibutyl phthalate in varying concentrations (0.5-2%) in batches A20-A35 for smooth chewability, as shown in Table 3 (Gomez-Caturla *et al.*, 2024).

Effect of resin activation on %drug loading

Kyron T-114, an ion-weak cation exchange resin, was chosen for taste masking of LXM due to its bitterness, affecting the %drug loading. This was ascertained by treating Resin-Kyron T-114 to two distinct media: (1) acid treated with 1N HCl, and (2) alkali treated with 1N NaOH. The necessary amount of resin was

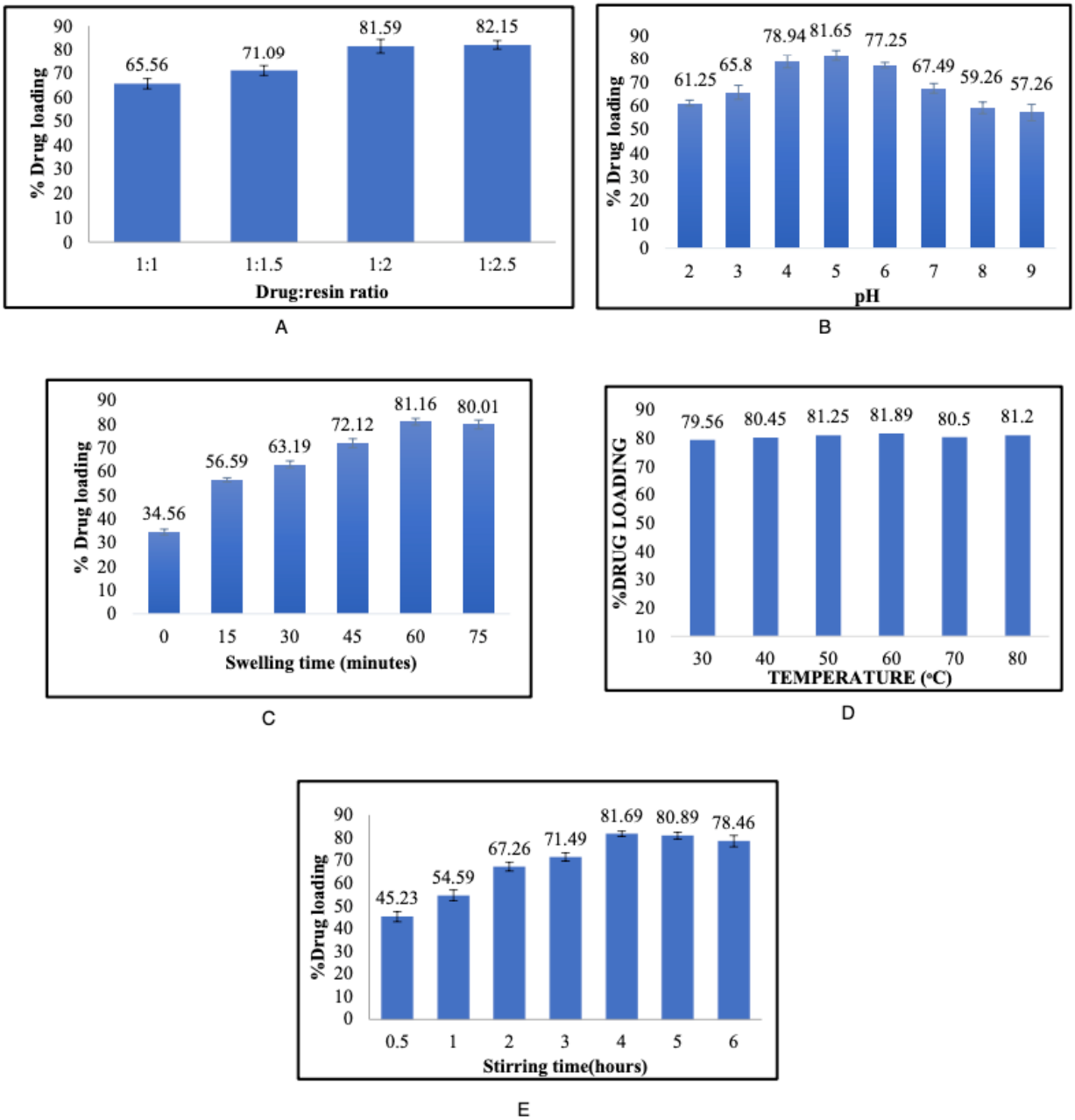

Figure 1: (A) Effect of drug:resin ratio, (B) Effect of pH, (C) Effect of swelling time (D) Effect of temperature (E) Effect of stirring time.

Table 1: Optimization of glidant, antiadherant, and lubricant.

	A0	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10
	Quantity in mg										
LXM: Kyron T-114 (Quantity equivalent to 4 mg of LXM)	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4
Health in gum	884.6	879	879	879	879	879	879	879	879	879	879
PEG 400	-	10	10	10	10	10	10	10	10	10	10
Aspartame	-	60	60	60	60	60	60	60	60	60	60
Aerosil	-	1	3	5	5	5	5	5	5	5	5
Talc	-	10	10	10	20	30	40	50	10	10	10
Magnesium stearate	-	10	10	10	10	10	10	10	5	10	15
Peppermint	-	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Total weight of MCG (mg)	Q.S. to 1000 mg										

Table 2: Optimization of sweeteners and flavour.

Ingredient /Trial no.		A11	A12	A13	A14	A15	A16	A17	A18	A19
		Quantity in mg								
Drug	LXM: Kyron T-114 (mg) (Quantity equivalent to 4 mg of LXM)	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4
Total chewable gum base	Health of gums	879	879	879	879	879	879	879	879	879
Plasticizer/Softener	PEG 400	10	10	10	10	10	10	10	10	10
Sweetener	Aspartame	3	6	8	-	-	-	6	6	6
Glidant	Aerosil	5	5	5	5	5	5	5	5	5
Antiadherant	Talc (%)	20	20	20	20	20	20	20	20	20
Lubricant	Magnesium stearate (%)	10	10	10	10	10	10	10	10	10
Flavor	Peppermint	0.5	0.5	0.5	0.5	0.5	0.5	-	-	-
Total weight of MCG (mg)		Up to 1000 mg								

weighed and placed in a funnel on Whatman filter paper No. 41. This was then cleaned three times using either 1 N HCl or 1 N NaOH, after being washed with deionized water. The resins were then repeatedly cleaned with deionized water until their pH levels were neutral (Siddiqui *et al.*, 2023). The drug was injected into this modified resin, and the drug loading percentage was calculated. The drug-to-resin ratio was maintained at 1:1 across all samples. When the resin was not activated, the percentage of drug loading achieved was 42±0.095%. Upon activation with acid, the drug loading increased significantly to 65±0.125%, indicating a marked improvement in affinity or binding efficiency. Activation with alkali also enhanced loading, although to a slightly lesser extent, resulting in 61±0.065% drug loading. All the samples were performed in triplicate. These results show that increased drug loading was achieved through acid activation. Kyron T-114 is a cation exchanger, indicating that acid activates it more than alkali does. Due to the lower drug loading from non-activated resin, acid-activated resin was utilized. After activation was confirmed by batch process, all independent variables were examined using batch process, and the resin was prepared using an optimal parameter based on the percentage of drug loading (Akbari *et al.*, n.d.).

Effect of drug-resin ratio

To determine the %drug loading, the drug-to-treated resin ratio, optimized through trials with various ratios (1:1, 1:1.5, 1:2, and 1:2.5), significantly impacts complex formation and percentage drug loading, ultimately affecting taste masking ability (Singh *et al.*, 2014). Figure 1 (A) shows that drug loading increases with resin concentration up to 1:2, then no noticeable difference was observed, choosing 81.59% drug loading as indicated by the Drug: Kyron T-114 ratio of 1:2.

Effect of pH

To assess the effect of pH, seven batches were prepared by dispersing 3 g of resin in 30 mL of deionised water (pH adjusted to 2-9 using 1M KOH) for 30 min. 1 g LXM was added to each mixture. The highest drug loading was achieved at pH 5, i.e., 78.21% which was close to the pKa of LXM, but increased pH led to decreased drug loading, indicating the pH's impact on solubility and ionization (Sheng *et al.*, 2025). These findings justify that LXM's pKa of 4.7 indicates its soluble and fully ionized nature within this pH range, while complexation occurs at high pH due to excessive H+ ions competing with the drug due to a stronger affinity towards the -COO groups on the resin (Helmy *et al.*, 2017). Thus, as per Figure 1 (B), pH 5 was optimized for complex formation.

Effect of swelling time of the resin

To determine the drug loading efficiency over a range of time periods (for 0, 15, 30, 45, 60, and 75 min), five batches of Kyron T-114 were prepared by swelling resin in 30 mL of demineralised water for varying lengths of time, lowering the pH to 5, adding 1 g of LXM, and stirring for 4 hr (Dong *et al.*, 2012). The study found that Kyron T-114's 60-min swelling time in deionized water yields the highest drug loading, as shown in Figure 1 (C), attributed to its maximum swelling and hydrating effects, whereas unswollen resin matrix efficiency is less (Wang *et al.*, 2022).

Effect of temperature

The study involved dispersing 3g of resin into 30 mL of deionized water, stirring for 60 min, and adding 1g of the drug, stirring for 4 hr at various temperatures, i.e., 30, 40, 50, 60, 70, and 80°C to estimate drug loading efficiency (Zhang *et al.*, 2020). Figure 1 (D) demonstrates uniform drug loading on Kyron T-114 at 27-80°C, suggesting higher temperatures can increase ion diffusion rate by reducing exchange zone thickness. However, continuous stirring prevents thick exchange zones, preventing temperature influence on complexation of LXM-MCG (*Diffusion: How Temperature Impacts Particle Movement*, n.d.).

Effect of stirring time

Seven batches of Kyron T-114 were prepared by soaking 3 g of resin in 250 mL of demineralized water (pH 5) for 60 min and adding 1 g of LXM under continuous stirring. The samples were withdrawn at different intervals of 30 min up to 6 hr to determine drug loading efficiency (Pn *et al.*, n.d.). The ion balance in the exchange between the ions in the solution is stoichiometric and therefore susceptible to the stirring time. Figure 1 E represents the %drug loading at a stirring time of 30 min to 6 hr. Further increase in stirring time to greater than 4 hr also did not enhance the complexation values. Increased stirring time to 4 hr did not improve complexation values, suggesting optimizing 4 hr of contact time between drug and resin for optimal ion exchange.

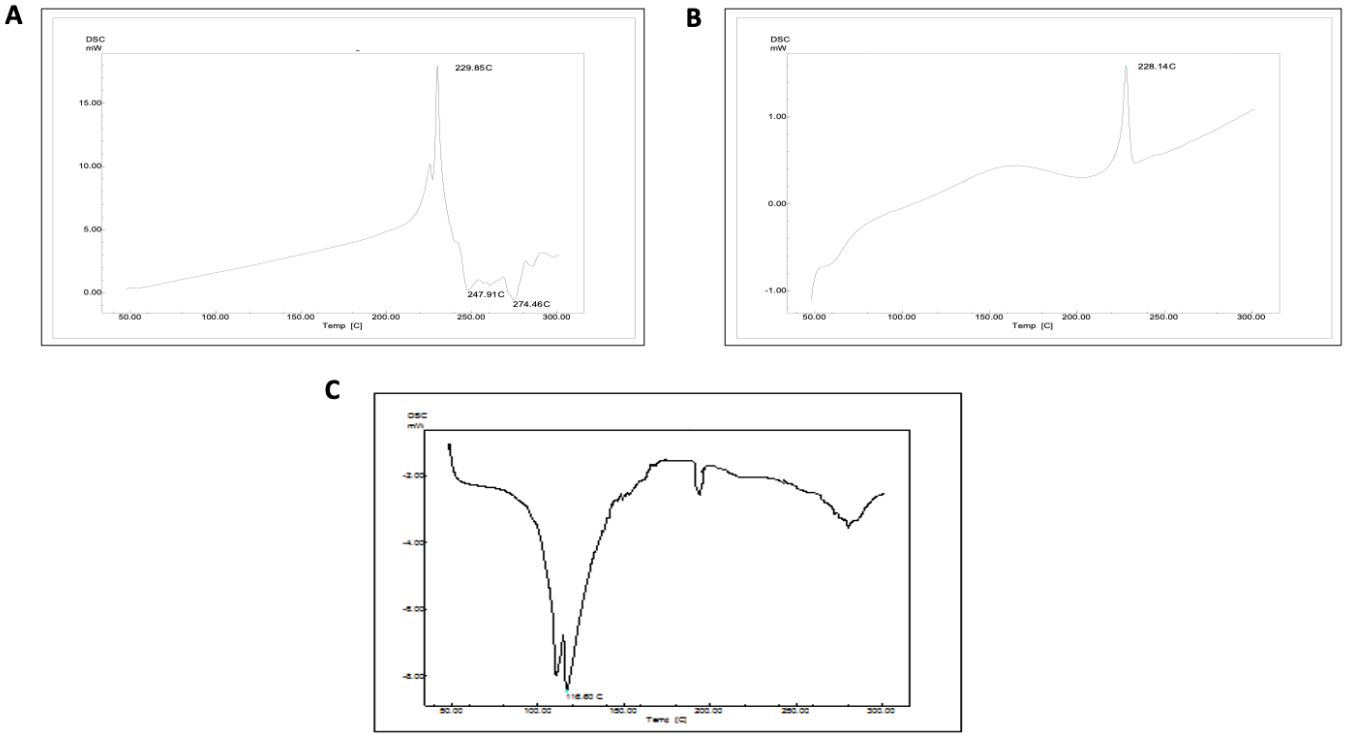

Figure 2: (A) DSC graph of LXM (B) DSC graph of LXM: Kyron T-114 resinate (C) DSC graph of optimized LXM-MCG (powdered mixture).

Table 3: Selection and optimization of plasticizer/softener.

Ingredients	A20	A21	A22	A23	A24	A25	A26	A27	A28	A29	A30	A31	A32	A33	A34	A35
	Quantity in mg															
LXM: Kyron T-114 (Quantity equivalent to 4 mg of LXM)	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4	15.4
Health of the gum	879	879	879	879	879	879	879	879	884	879	874	869	884	879	874	869
PEG 400	5	10	15	20	-	-	-	-	-	-	-	-	-	-	-	-
Castor oil	-	-	-	-	5	10	15	20	-	-	-	-	-	-	-	-
Glycerin	-	-	-	-	-	-	-	-	5	10	15	20	-	-	-	-
Di butyl phthalate	-	-	-	-	-	-	-	-	-	-	-	-	5	10	15	20
Aspartame	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60
Aerosil	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Talc	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
Magnesium stearate	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Peppermint	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

Evaluation of taste-masked Lornoxicam

Differential Scanning Calorimetry (DSC)

The thermal characteristics and phase change behavior of LXM-Kyron T-114 resinate and powdered mixture were examined using PerkinElmer DSC, sealed in aluminium cells and heated from 30 to 300°C at a heating rate of 10°C/min (Patel and Patel, 2023).

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectra of LXM-Kyron T-114 resinate and powdered mixture were obtained using JASCO V5300 FTIR, scanned over 400 to 2000 cm-1, and prepared on a KBr-press (Patel *et al.*, n.d.).

Pre-compression parameters

Batch A1-A8's pre-compression powder mixture was assessed for flow properties, including angle of repose, bulk density, tapped density, Compressibility index, and Hausner's ratio as per pharmacopeial procedure (*(PDF) Lab Report for Angle of Repose*, n.d; ."Powder Flow," 2019).

Texture analysis

The Brookfield ® QTS-25 texture analyzer was utilized to assess the texture properties of directly compressed MCG (Patel *et al.*, 2023). The text evaluates textural properties of solid and self-supporting samples, including hardness and adhesiveness. A 50 mm ∅ compression probe was used, and a constant force was applied to the self-supporting MCG surface, resulting in a deformation curve (Patel *et al.*, 2024).

Weight variation test

The test, conducted on uncoated compressed dosage forms, involved randomly weighing twenty MCGs and calculating their arithmetic mean weight. This ensured the formulation complied with the test if at least two of the individual masses deviated from the average mass by more than 5% (*European Pharmacopoeia 10th Edition*, n.d.).

Friability test

Ten MCG units were de-dusted, weighed, and placed in an Electrolab ® EF-2 Friabilator. The drum was rotated 100 times at 25 rpm. The difference in weights represents friability, with a maximum loss of mass of 1.0% acceptable from a single test or the mean of three tests (*European Pharmacopoeia 10th Edition*, n.d.).

In vitro drug release of LXM-MCG by a modified chewing machine

The chewing machine uses a temperature-regulated vessel, a beaker mounted on a water bath, and an electrically operated vertical piston to simulate mouth movements. A 50 mL beaker was covered with a 10# wire mesh and a gum piece, and placed on a water bath to maintain a temperature of 37±0.5°C. The European Pharmacopoeia recommends using 20 mL of buffer (pH 6) in a chewing chamber at 60 strokes per minute, with

artificial saliva as the dissolution medium at 40 mL. The 0.1 N HCl samples of 5 mL each were taken after 0, 5, 10, 15, 20, 25, and 30 min and replaced with fresh aliquots of equal volume to determine the concentration of the drug. HCl can be used to dilute, breaking the ion exchange resin complex, and isolate the drug concentration. The samples were then immediately filtered through a 0.45 µmm filter, and the amount of drug was measured by a UV spectrophotometer at 378 nm wavelength (Momin *et al.*, 2024).

Stability study of taste-masked LXM-MCG

The optimized LXM-MCG was preserved in a bottle at 30°C±2°C/65% RH±5% RH over a duration of six months. The gum was assessed after 6 months for ageing manifestations, softness, physical deformity, drug content, as well as drug release in 20 min (Satya Venkata Sakuntala *et al.*, 2021).

RESULTS

DSC

The DSC curves of pure LXM (Figure 2 (A) show an anhydrous crystalline drug with a 229°C melting point. Figure 2 (B) indicates the LXM: Kyron T-114 ratio that exhibited a changed shape and decreased sharpness, indicating complex formation. Figure 2 (C) revealed that the spectrum was similar to the powdered mixture containing LXM: Kyron T-114 resinates. These findings confirm the compatibility of all excipients with LXM.

FTIR

As shown in Figure 3, the FTIR spectrum of LXM (A) exhibited characteristic peaks at 1546 cm^{-1} and 1594 cm^{-1} corresponding to N-H bending, 3067 cm^{-1} due to N-H stretching, and 1646 cm^{-1} attributed to C=O stretching. Additionally, peaks at 1146 cm^{-1} and 1382 cm^{-1} were observed, indicating O=S=O stretching, while a peak at 830 cm^{-1} corresponded to C-H bending. In contrast, Kyron T-114 (B) showed no such intense peaks. The LXM: Kyron T-114 complex (C) demonstrated interactions between the LXM and Kyron T-114 molecules. Furthermore, the FTIR spectrum of the optimized LXM-MCG formulation (D) retained all the characteristic peaks of the LXM: Kyron T-114 complex, confirming compatibility.

Pre-compression parameters of taste masked LXM blend

The three determinations (n=3) reveal that the powder exhibited a bulk density of 0.44±0.02 g/mL and a tapped density of 0.51±0.02 g/mL. From these values, the compressibility index was

Table 4: Stability of optimized batch.

Months	Drug content*	Drug release in 20 min*
0	98.24±1.23	88.26±1.15
1	98.21±1.05	88.48±1.45
2	98.18±0.59	88.36±1.59
3	98.15±0.87	88.59±0.98
4	98.12±1.02	88.59±1.47
5	98.13±1.12	88.49±0.82
6	98.14±1.09	88.36±0.79

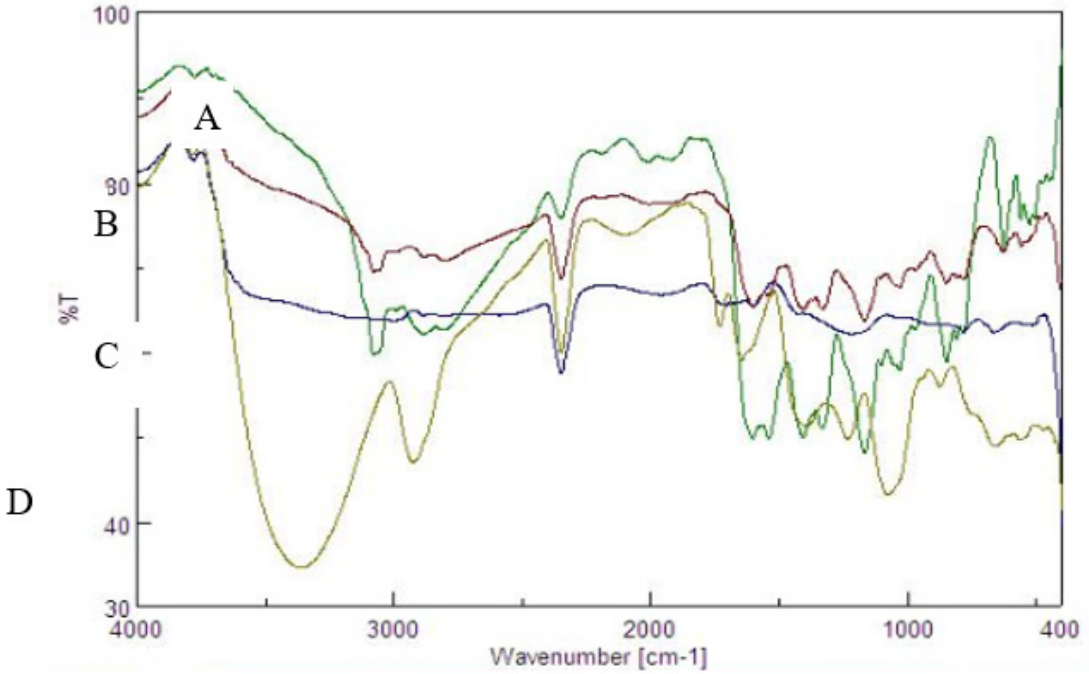

Figure 3: FTIR spectra of A-LXM, B-LXM: Kyron T-114, C-Kyron T-114, and D-Optimized LXM-MCG (powdered mixture).

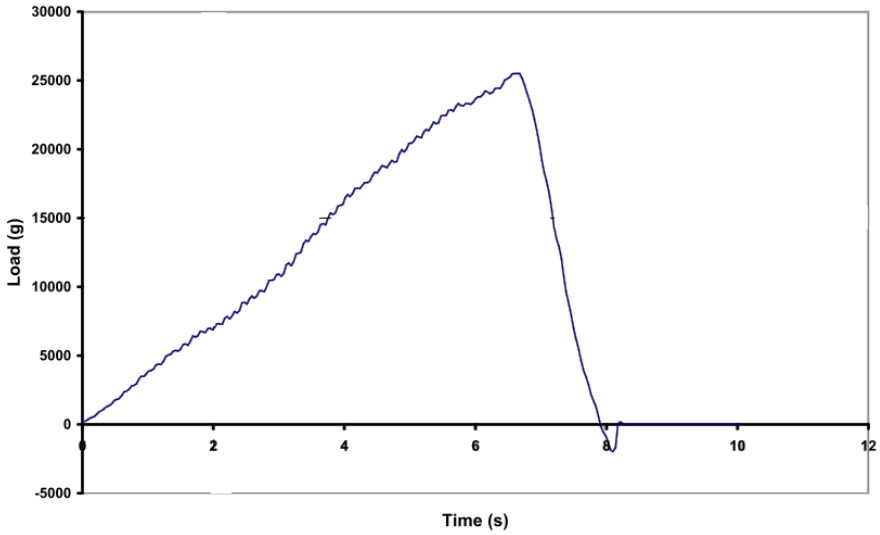

Figure 4: Load vs Time graph.

calculated and found to be 13.72±0.54%, and the Hausner's ratio at 1.159±0.004. Both parameters fall into the "Good" category, which indicates favorable flow characteristics. Additionally, the angle of repose was measured at 29.28±0.72º, which likewise corresponds to "Good" flowability. Thus, the findings of the evaluation of the optimized drug resin complex's compressibility and flow properties are satisfactory.

Texture analysis

The optimized batch, Batch A21, was tested for hardness and gum firmness. It required constant forces to reach a breaking point, a bearing load of 24900 g/cm, as shown in Figure 4. The gum crumbled first, then congealed, allowing faster release of LXM, unlike traditional gums.

Weight variation test of taste-masked LXM-MCG

The optimized MCG formulation was within 5% of the mean mass and was compatible with tests of mass uniformity by having an average mass of 1074 mg. All of the ten random MCGs also passed the uniformity of content test, with the 4.12±0.13 mg average LXM content being within the acceptable range of 85-115%.

Friability test of taste-masked LXM-MCG

Following 100 rotations in the friabilator, the final MCG formulation passed the friability test with a total weight loss of 10 MCG of 0.39%, below the 1.0% compliance limit.

In vitro drug release of taste-masked LXM-MCG

In vitro drug release of taste-masked LXM-MCG was determined by a modified chewing gum apparatus, and the results are shown graphically in Figure 5.

Stability of taste-masked LXM-MCG

To ensure stability as per the WHO requirements, the optimized batch was stored in a bottle at 30ºC±2ºC and subjected to 65% RH±5% RH. It was analyzed in terms of softness, drug content, and drug release. The physical appearance and color of the stored sample remained unchanged, retained its softness, and there was no remarkable variation in drug content and release in the optimized MCG after 6 months, as shown in Table 4.

DISCUSSION

In the present study, the formulation of taste-masked LXM via resin complexation and Medicated Chewing Gum (MCG) development was systematically characterized using thermal analysis (DSC), spectroscopic evaluation (FTIR), pre-compression and post-compression assessments, mechanical testing, and stability evaluation. These findings collectively validate the structural interactions, formulation robustness, and stability of the optimized chewing gum system. The DSC analysis revealed a marked transformation in the thermal behavior of LXM when complexed with Kyron T-114. Whereas pure LXM exhibited a sharp endothermic melting peak indicative of its anhydrous crystalline nature, this characteristic peak was substantially attenuated and broadened in the LXM: Kyron T-114 resinate and powdered optimized formulations. This alteration in peak shape and reduced sharpness suggests successful complex formation, likely resulting from intermolecular interactions that disrupt crystal packing. Thus, DSC provides strong evidence for successful excipient compatibility and complexation. Corroborating these thermal findings, the FTIR spectra further confirmed molecular-level interactions. The characteristic peaks associated with pure LXM were preserved in the LXM: Kyron T-114 complex and optimized MCG spectra. This retention of functional group signatures, alongside the absence of new peaks, affirms that the mixture and complex formation preserved

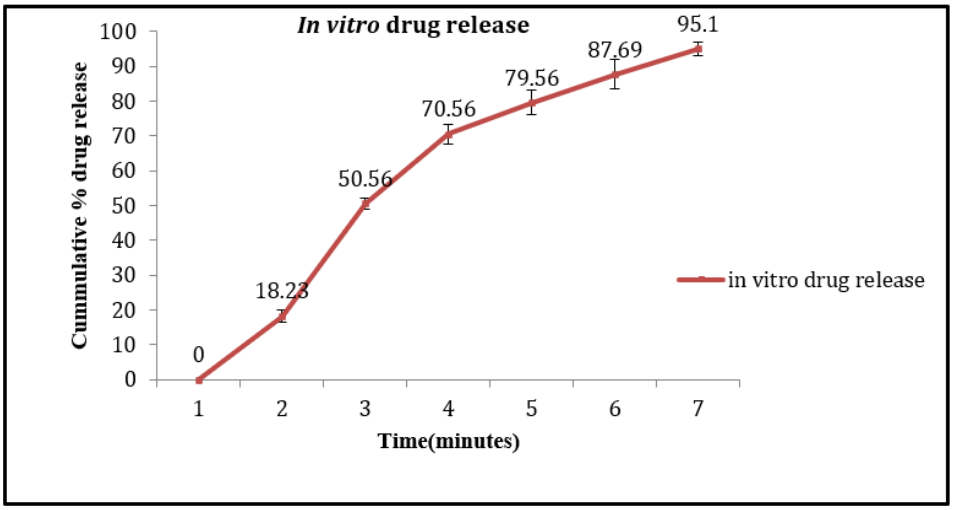

Figure 5: *In vitro* drug release of taste-masked LXM-MCG.

chemical integrity while indicating compatibility between LXM and formulation excipients. Such spectroscopic stability highlights the formulation's chemical robustness. From a technological perspective, the pre-compression evaluation of the taste-masked powder blend exhibited favorable flow properties. Mechanical testing via texture analysis demonstrated that the gum's behavior, initial crumbling followed by congealing, suggests the potential for controlled release upon mastication, differentiating it from conventional gums and enhancing real-world performance. Post-compression quality control tests further confirmed the formulation's consistency. Weight variation analysis indicated an average mass which was within ±5% of the mean, while dose uniformity revealed an average LXM content that was comfortably within the acceptable 85-115% range. Additionally, friability testing exhibited the mechanical robustness of the gum matrix. *In vitro* drug release, performed using a modified chewing gum apparatus, depicted favorable release dynamics. Importantly, the optimized LXM-MCG remained stable under accelerated storage conditions for six months. No significant changes were observed in physical appearance, softness, drug content,nt, and drug release. Such stability is indicative of good shelf-life potential and formulation integrity under ICH-recommended conditions. Collectively, these findings demonstrate that LXM can be effectively taste-masked via resin complexation and formulated into a mechanically robust medicated chewing gum with consistent quality, predictable release, and promising shelf stability. The convergence of thermal, spectroscopic, physical, and stability data underlines the formulation's reliability and suitability for patient-friendly oral delivery.

CONCLUSION

The present investigation successfully formulated a taste-masked LXM-MCG utilizing Kyron T-114 as an ion exchange resin. Systematic optimization of formulation parameters ensured maximum drug loading, efficient taste masking, and favorable organoleptic properties. Comprehensive evaluation confirmed that the optimized formulation possessed desirable mechanical strength, uniformity, and stability, along with rapid drug release characteristics suitable for buccal delivery. The incorporation of LXM into a chewing gum dosage form not only overcomes the challenge of bitterness but also offers advantages such as enhanced patient compliance, ease of administration without water, and faster onset of therapeutic action. These results show that MCGs based on ion exchange resin have the potential to be a viable substitute for traditional oral formulations in the efficient treatment of inflammatory and pain diseases.

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ABBREVIATIONS

MCG: Medicated chewing gum; **LXM:** Lornoxicam; **IERs:** Ion exchange resins; **KOH:** Potassium hydroxide; **HCl:** Hydrochloride; **NaOH:** Sodium hydroxide; **DSC:** Differential Scanning Calorimetry; **FTIR:** Fourier Transform Infrared Spectroscopy; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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