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Review

### Design and Development of Lornoxicam Orodispersible Films for Rapid Pain Relief in Inflammatory Disorders

Dr. G. Praveen Kumar<sup>1\*</sup>, T. Nikitha<sup>2</sup>, B. Mounika<sup>3</sup>

<sup>1</sup>Associate Professor; <sup>1</sup>Principal, Professor & HOD; <sup>2</sup>MPharm Final Year Student, Department of Pharmaceutics, Sahasra Institute of Pharmaceutical Sciences, Hanumakonda 506007, Telangana, India

\*Author for Correspondence: Dr. G. Praveen Kumar  
Email: prof.dr.gunn@gmail.com

	<p><b>Abstract</b></p>
<p>Published on: 24.02.2026</p>	<p>This study intended to design and produce fast-acting lornoxicam orodispersible films (ODFs) to deliver rapid analgesic and anti-inflammatory relief while enhancing patient compliance, especially for those with dysphagia or needing on-the-go dosage. Lornoxicam, a powerful oximicam-class NSAID characterized by low aqueous solubility and significant gastrointestinal irritation potential, was integrated into thin polymeric films fabricated via the solvent-casting technique utilizing HPMC E15 as the film-forming polymer. Superdisintegrants, including sodium starch glycolate (SSG) and croscarmellose sodium (CCS), were assessed to improve film wetting and disintegration. The pre-formulation FTIR study validated drug-excipient compatibility, and UV-visible spectrophotometry facilitated precise drug measurement. All created films were evaluated for physicochemical parameters, including thickness, folding durability, surface pH, weight variation, and drug content uniformity, all of which adhered to approved standards. In-vitro disintegration and dissolution analyses revealed swift disintegration and expedited drug release, with the improved formulations attaining over 80% release within 10 minutes and practically total release by 20 minutes. The release kinetics were optimally characterized by the Korsmeyer–Peppas model, signifying non-Fickian diffusion. Accelerated stability experiments validated the formulation’s physical and chemical integrity throughout the testing duration. The formulated lornoxicam ODFs demonstrate significant potential as a rapid-acting, patient-friendly substitute for traditional NSAID dosage forms.</p>
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<p>2026  All rights reserved.</p>  <p><a href="https://creativecommons.org/licenses/by/4.0/">Creative Commons Attribution 4.0 International License.</a></p>	<p><b>Keywords:</b> Lornoxicam, HPMC E15, Orodispersible Films, Inflammatory Disorders, Solvent-casting.</p>

## INTRODUCTION

Oral administration is the most favoured method for medication delivery due to its ease, non-invasiveness, and high patient adherence. Traditional solid-dose formulations, including tablets and capsules, provide obstacles such as dysphagia, delayed onset of action, and complications with first-pass metabolism.<sup>i</sup> Oral medicine distribution is thought to be the most practical, economical, and secure drug delivery route because it has the highest compliance rate, particularly among paediatric and elderly patients. The successful delivery of the drug to the body is the ultimate goal of every medication delivery method. The oral disintegrating dose form is the most widely used commercial product among the various dosage forms<sup>ii</sup>.

Because it is the easiest to ingest, the oral cavity is the best location for the delivery of an oral disintegrating dosage form. Analgesics, neuroleptics, cardiovascular agents, antiallergic medications, and erectile dysfunction drugs are among the good drug possibilities for such a system. When applied on the tongue, a dose form like these dissolves rapidly, releasing the medication that dissolves in saliva. This is superior to a traditional dosage form in terms of absorption and quick beginning of action<sup>iii</sup>.

These characteristics often undermine therapy efficacy and patient compliance, particularly in at-risk populations such as children, the elderly, and individuals with psychiatric conditions. Oro-dispersible films (ODFs) provide an effective solution by swiftly disintegrating in the oral cavity without requiring water, hence improving patient convenience and accelerating therapeutic onset.<sup>iv</sup> The development of thin Oro Dissolving Film Technology has addressed the shortcomings of traditional fast dispersion or dissolving tablet formulations. The film has convenient packaging, is easy to create, handle, and administer, and it raises the danger of choking and the anxiety of choking. It also reduces the disagreeable

flavour. Other names for these thin polymer films are mouth dissolving films (ODF), fast dissolving films (QDF), rapidly dissolving films (RDF), melt-in-mouth dosage forms (MDF), and oral dissolving films (ODF)<sup>v</sup>. Lornoxicam, a powerful NSAID from the oxicam class, is extensively utilized for the management of acute and chronic inflammatory disorders due to its significant analgesic and anti-inflammatory properties. Nonetheless, its traditional oral administration is linked to a delayed beginning of action and gastrointestinal adverse effects. Lornoxicam's brief half-life (3-5 hours) and significant first-pass metabolism render it an ideal choice for rapid-acting formulations. Administering Lornoxicam via an ODF may facilitate expedited drug release, prompt therapeutic response, and enhanced patient comfort, particularly during acute pain episodes.<sup>vi</sup>

Despite numerous investigations establishing ODFs for various NSAIDs, the systematic formulation of Lornoxicam Orodispersible Films utilizing optimal polymer-plasticizer matrices and superdisintegrants is still constrained. A patient-friendly, fast-dissolving Lornoxicam method must be developed to guarantee consistent dose, prompt onset, and minimized gastrointestinal impact.

This project intends to create, construct, and assess Lornoxicam orally disintegrating films (ODFs) utilizing appropriate film-forming polymers and disintegrants to facilitate rapid disintegration, promote dissolution, and improve therapeutic efficacy for the management of inflammatory pain.

## MATERIALS AND METHODS

### Chemicals

Lornoxicam was obtained as a gift sample from UniChem laboratories Ltd., Mumbai, India. HPMC E15 was purchased from Colorcon Asia Pvt. Ltd., Hyderabad. Mango peel pectine was purchased from Shilex Chemicals Pvt. Ltd., Delhi. Mannitol, Citric acid and Sodium saccharine were purchased from S.D.

Fine-Chemical Ltd, Mumbai. Mango flavor was obtained from Pentagon trading company, Mumbai. All the used reagents and chemicals were of analytical grade.

#### Fourier Transform Infrared (FT-IR) Spectroscopy

Using a FTIR spectrophotometer (Shimadzu FTIR-8400S, Japan), the drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm<sup>-1</sup> spectral region was covered. The sample is first dispersed in KBr (100 mg) using a motor, and the materials are subsequently triturated into a fine powder bed inside the container

using a compression gauge. Five tons of pressure was applied for five minutes. Following the light route, the film was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

#### Formulation Design<sup>vii</sup>:

A natural polymer known as mango peel pectin and several HPMC E15, were used to create LNX ODFs using the solvent casting method.

Different formulation's formulas:

Table 11: Formulation of Lornoxicam (LNX) ODF

Ingredients (mg)	LX1	LX2	LX3	LX4	LX5	LX6
Lornoxicam (LNX)	10	10	10	10	10	10
HPMC E15	80	80	80	80	80	80
Mango peel pectin	0	40	60	80	100	120
Glycerin	16	24	28	32	36	40
Mannitol	12	18	21	24	27	30
Citric acid	2	2	2	2	2	2
Sod. Saccharine	2	2	2	2	2	2
Mango Flavor	*	*	*	*	*	*
Water	*	*	*	*	*	*

Q.s. is represented by '\*'.

#### Preparation of ODF

We employed the solvent casting method to make Lornoxicam ODF. The ODF of LNX was produced using HPMC E15 and mango peel pectin as a natural superdisintegrant. The polymer was then allowed to expand for five to six hours. The drug solution had been added to the previously described polymeric

solution after LNX had been dissolved in a predetermined volume of solvent. Next was the addition of plasticiser glycerine, pore former like mannitol. Sweetener and flavour were also added. Mixing in a cyclo mixer about 15 to 20 minutes will homogenise the drug content. A two-hour magnetic stirrer stirs the solution to expel all air bubbles, then it is left. The solution is then cast in a square glass plate

(10 cm x 10 cm x 1.7 cm, Othmro, Amazon, India) and air-dried overnight to form a film. The dried film was carefully removed from the mould, inspected for faults, and trimmed to the specific size (2x2 cm<sup>2</sup>) for each strip. The investigation excluded film samples with cuts, air bubbles, or other problems.

#### **Evaluation of oral dissolving films formulations:**

For ODF formulations, various quality control tests were carried out. Different Performed in vitro examinations are: Measurement of thickness, Weight variation, Folding endurance, Drug content uniformity, Surface pH, Assay, In vitro disintegration time.

#### **In Vitro Dissolution Test**

The in-vitro dissolution of Candesartan ODFs was conducted utilizing a USP Type II (paddle) dissolution apparatus (EI-1916, Electronics India). Each film was immersed in 500 mL of pH 6.8 phosphate buffer, maintained at  $37 \pm 0.5$  °C, and agitated at 50 rpm. At specified intervals (2–20 minutes), 5 mL samples were extracted and substituted with fresh medium. Samples were examined at 376 nm utilizing a UV-Visible spectrophotometer (EI-1372), and cumulative drug release was determined from the standard calibration curve. All tests were conducted in triplicate.

#### **Release Kinetics<sup>viii</sup>**

Utilising the results of the in-vitro diffusion study, the

order and mechanism of drug release kinetics of LNX films were examined. Plotting of the kinetic models included the zero order, first order, and Higuchi equations; the release was calculated using the Korsmeyer-Peppas equations.

#### **Stability studies**

The optimized LNX ODF formulations underwent expedited stability testing in accordance with ICH Q1A (R2) criteria. Films were encased in aluminum foil strips, situated in airtight containers, and maintained at  $40 \text{ °C} \pm 2 \text{ °C} / 75\% \text{ RH} \pm 5\%$  for a duration of 60 days. Samples were extracted at specified intervals (0, 30, 60 and 90 days) and analyzed for drug content to evaluate any physical or chemical alterations. All tests were conducted in triplicate, and average values were documented.

## **RESULTS & DISCUSSION**

#### **Calibration of LNX**

Prepare the stock solution by combining 50 mg of LNX with 100 ml of water. Ten millilitres of this stock solution were extracted and diluted with water to achieve a total volume of one hundred millilitres. A calibration curve was established utilising diverse concentrations (5–25 µg/ml) and the appropriate dilution of the stock solution. The absorbance was measured at 376 nm. In Figure 1, the LNX standard curve was shown. In a phosphate buffer with a pH of 6.8, LNX was calibrated; linearity was found with R<sup>2</sup> value of 0.9998.

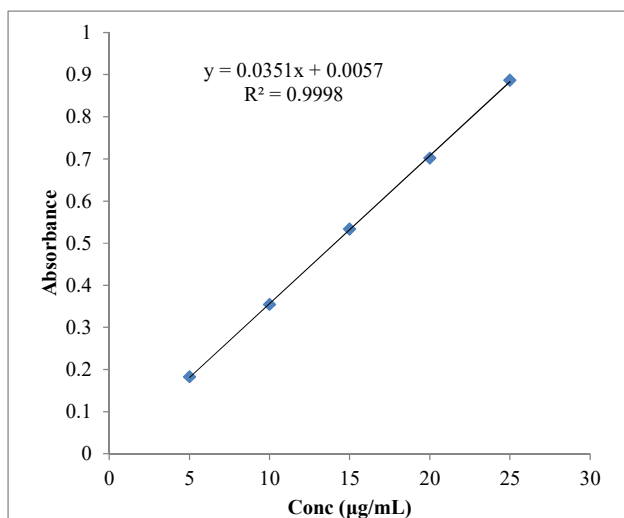


Figure 1: Standard Calibration Curve of LNX in 6.8 pH phosphate buffer

**Drug – excipient Compatibility Studies**

FTIR spectrometer (Bruker Alpha II FTIR Spectrometer, Mumbai, India) was used to determine the drug excipient compatibility, and the graphs from the figure 2 and 3 were displayed. To find out if there was any interaction between the excipients and LNX,

the physical mixture was put through FTIR analysis. The lack of a drug-carrier chemical interaction is confirmed by the absence of any drug-characteristic peak appearance or disappearance. Optimized sample, which were pure LNX with mango peel pectin, underwent FTIR analysis to determine the presence of the pure API in the mixture and to describe it.

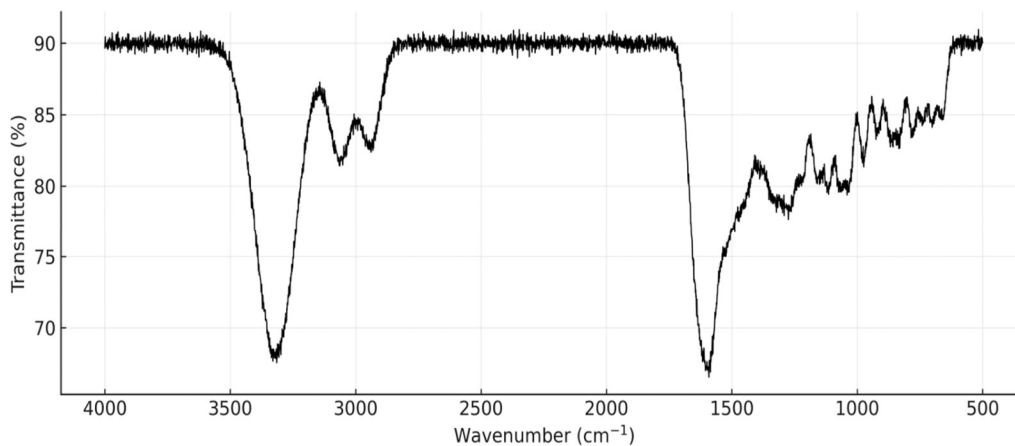


Figure 2: FTIR Spectrum of pure LNX.

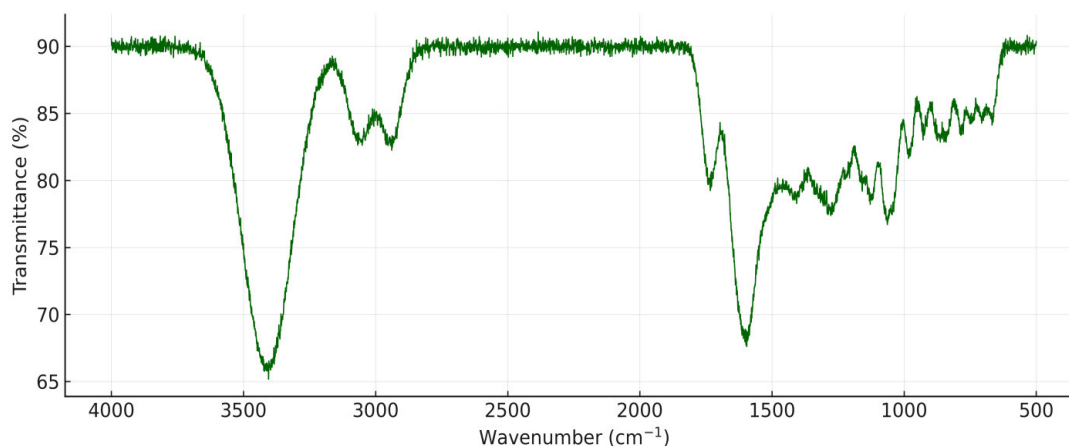


Figure 3: The optimised formulation's FTIR spectrum.

The FTIR spectra of pure Lornoxicam exhibited a broad N–H stretching band around  $3320\text{ cm}^{-1}$ , aromatic and aliphatic C–H vibrations at  $3060$  and  $2940\text{ cm}^{-1}$ , and pronounced typical amide C=O and aromatic C=N/C=C peaks within the range of  $1645$ – $1520\text{ cm}^{-1}$ , thereby affirming the preservation of the oxamic structure. The O–H band in the Lornoxicam–HPMC E15–mango peel pectin orodispersible film exhibited increased breadth and intensity at approximately  $3410\text{ cm}^{-1}$ , attributable to significant hydrogen bonding within the polysaccharide–polymer matrix. A specific ester carbonyl band at approximately  $1735\text{ cm}^{-1}$  and a carboxylate peak around  $1420\text{ cm}^{-1}$  signified the presence of pectin, whereas intensified C–O–C/C–O absorptions between  $1258$ – $1072\text{ cm}^{-1}$  demonstrated contributions from both HPMC and pectin. Crucially, all prominent Lornoxicam peaks persisted without much

diminution, indicating that the medication retained chemical stability and was physically integrated into the polymeric film without signs of incompatibility.

#### Evaluation of ODF:

##### Thickness

Each formulation's thickness (LX1–LX6) was examined; the findings are displayed in the table 2. Film thickness escalated proportionately with the total polymer load, ranging from  $98.7 \pm 0.8\text{ }\mu\text{m}$  (LX1) to  $141.8 \pm 1.2\text{ }\mu\text{m}$  (LX6), indicative of elevated solids and uniform doctor-blade casting. The extremely low standard deviations ( $\leq 1.2\text{ }\mu\text{m}$ ) across all batches signify exceptional dope homogeneity, homogenous substrates, and regulated drying essential conditions for dosage and mechanical consistency.

Table 2: The thickness, folding endurance, and pH of the surface and disintegration time of all formulations.

F. Code	Thickness ( $\mu\text{m}$ ) $\pm$ SD	Folding endurance (folds)	Surface pH	In-vitro disintegration Time (sec)
LX 1	$98.7 \pm 0.8$	$165 \pm 8$	$6.66 \pm 0.05$	$28 \pm 3$
LX 2	$110.9 \pm 0.9$	$180 \pm 9$	$6.67 \pm 0.05$	$20 \pm 3$

LX 3	118.4 ± 1.0	195 ± 10	6.66 ± 0.05	17 ± 2
LX 4	126.1 ± 1.0	200 ± 9	6.65 ± 0.05	15 ± 2
LX 5	134.0 ± 1.1	190 ± 9	6.64 ± 0.06	16 ± 2
LX 6	141.8 ± 1.2	185 ± 10	6.63 ± 0.06	18 ± 3

**Folding endurance:** All films exhibited excellent flexibility and toughness ( $\geq 165$  folds), with a maximum at LX4 =  $200 \pm 9$ , while LX3–LX5 maintained substantial robustness (190–195 folds). The minor reduction at the maximum polymer level (LX6 =  $185 \pm 10$ ) indicates enhanced matrix stiffness as the gauge increases, despite a consistent plasticiser ratio, which is characteristic of an increase in total polymer and film thickness.

#### Surface pH of Films:

The measured surface pH consistently ranged from 6.63 to 6.67 across all batches, indicating good local buffering via the citrate system and compatibility with the buccal environment. This narrow range reduces the risk of mucosal irritation and enhances palatability, without any pectin- or HPMC-induced deviation towards extremes, despite variations in polymer chemistries.

**In-vitro disintegration:** The in-vitro disintegration time decreased as the concentration of mango-peel pectin increased to moderate levels, resulting in greater hydrophilicity and capillary wicking, with the quickest disintegration times recorded for LX4 ( $15 \pm 2$  s) and LX3 ( $17 \pm 2$  s). Minor deceleration at the extremes LX1 ( $28 \pm 3$  s) devoid of pectin and LX6

( $18 \pm 3$  s) at the maximum gauge indicates diminished wicking pathways in the HPMC-predominant matrix and thicker pectin films, respectively, however all batches continued to fall within a quick ODF range.

**Weight variation:** Table 3 displays how each formulation's, the mean film weight increased with the total polymer content (HPMC fixed at 80 mg; pectin ranging from 0 to 120 mg), from  $128.60 \pm 2.06$  mg (LX1) to  $198.40 \pm 3.00$  mg (LX6).

**Drug Content Uniformity:** All formulations approximated the label claim, ranging from  $98.4 \pm 3.0\%$  (LX1) to  $100.0 \pm 2.5\%$  (LX4), with the mid-polymer levels LX3 ( $99.7 \pm 2.6\%$ ) and LX4 ( $100.0 \pm 2.5\%$ ) exhibiting the narrowest distribution.

**Assay:** Batch assays consistently ranged from 95% to 105%, averaging  $98.7 \pm 2.6\%$  (LX1) to  $100.2 \pm 2.3\%$  (LX4), indicating precise loading and a reliable UV methodology. Precision was somewhat enhanced for mid-range formulations (LX3–LX4), corresponding with their greater uniformity metrics. The dataset substantiates the consistent dosing and manufacturability of Lornoxicam ODFs, with LX3–LX4 providing the optimal equilibrium of mass control, content uniformity, and assay precision.

Table 3: Weight variation, drug content uniformity, and assay determination

F. Code	Weight variation	Drug Content Uniformity	Assay
LX 1	128.60 ± 1.96	98.4 ± 3.0	98.7 ± 2.6
LX 2	145.20 ± 2.25	99.1 ± 2.8	99.4 ± 2.5
LX 3	160.40 ± 3.41	99.7 ± 2.6	99.9 ± 2.4
LX 4	174.80 ± 2.63	100.0 ± 2.5	100.2 ± 2.3
LX 5	188.00 ± 3.12	99.5 ± 2.7	99.6 ± 2.4
LX 6	198.40 ± 3.01	99.3 ± 2.9	99.5 ± 2.5

### In-vitro dissolution

For LX1 through LX6, the table displays the cumulative medication release percentage. All Lornoxicam ODFs exhibited fast dissolving in a pH 6.8 buffer (USP-II, 50 rpm, 37 °C). After 10 minutes, the cumulative release was rated as follows: LX4 (85.72%) > LX3 (78.64%) > LX5 (74.18%) > LX6

(69.85%) > LX2 (62.38%) > LX1 (54.76%). After 20 minutes, all batches attained near-total release ( $\geq 95\%$ ), with LX4 at around 99.96%, LX5 at approximately 98.92%, LX3 at approximately 98.47%, LX6 at approximately 98.41%, LX2 at approximately 97.03%, and LX1 at approximately 95.52%.

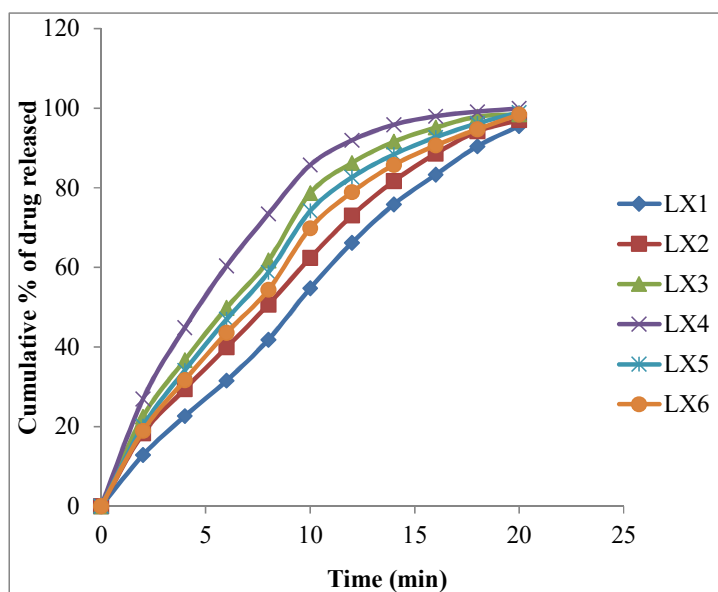


Figure 4: In vitro dissolution studies of formulations (LX1-LX6)

**Application of Release Rate Kinetics to Dissolution**

**Data:** A variety of models were used to study drug release kinetics. A number of release models, including first-order, zero-order, higuchi, and korsmeyer-peppas,

were fitted to the acquired data in order to investigate the medication release rate mechanism of the dose form Kinetics.

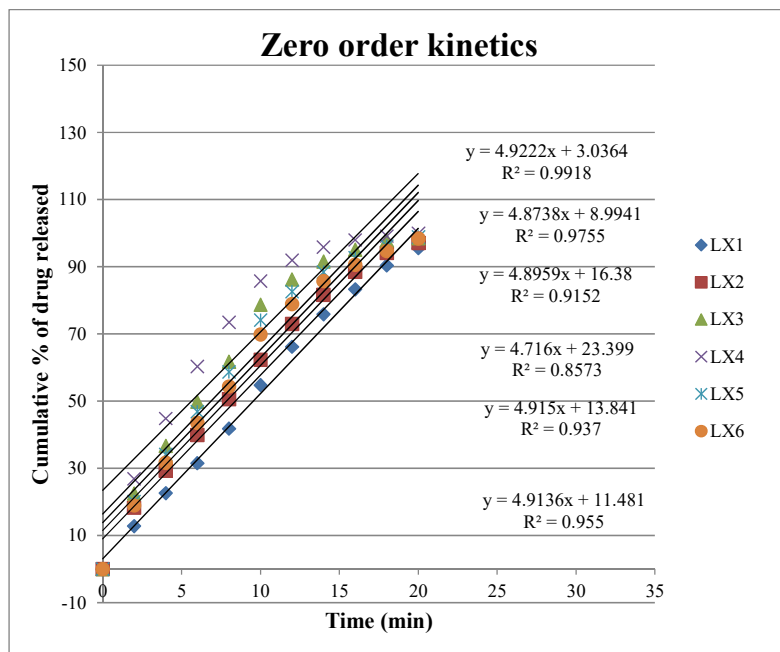


Figure 5: Zero order release kinetics graph of LNX formulations (LX1-LX6)

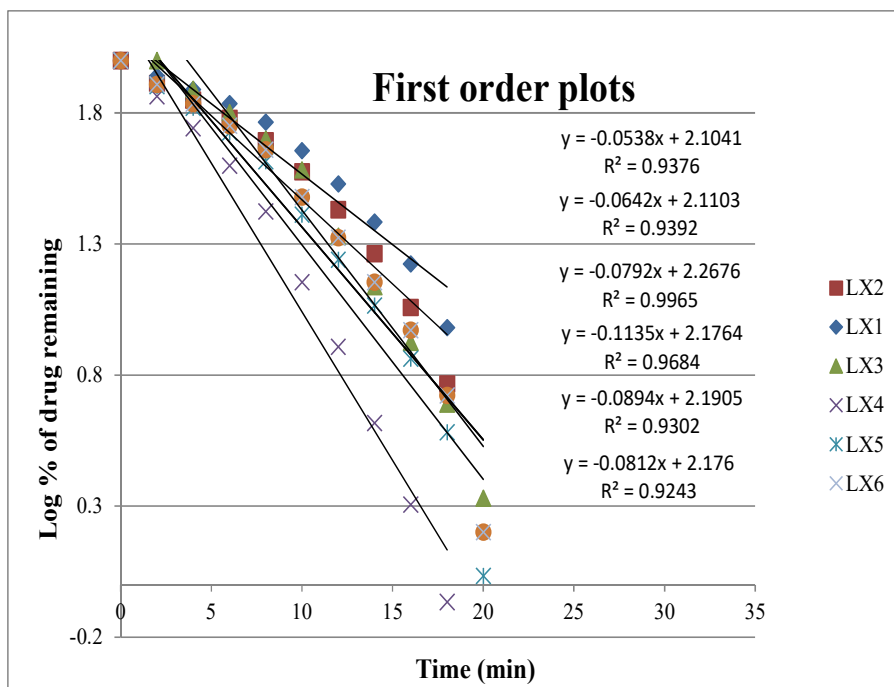


Figure 6: First order release kinetics graph of LNX formulations (LX1-LX6)

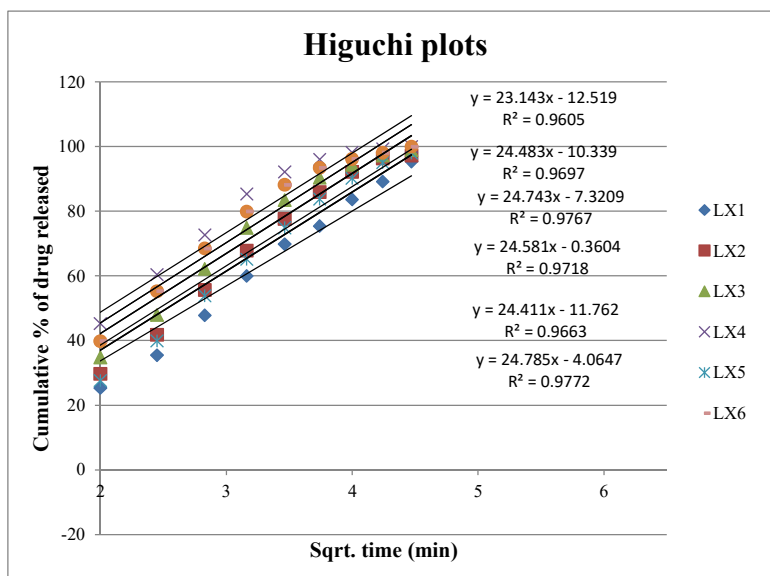


Figure 7: Higuchi release kinetics graph of LNX formulations (LX1-LX6)

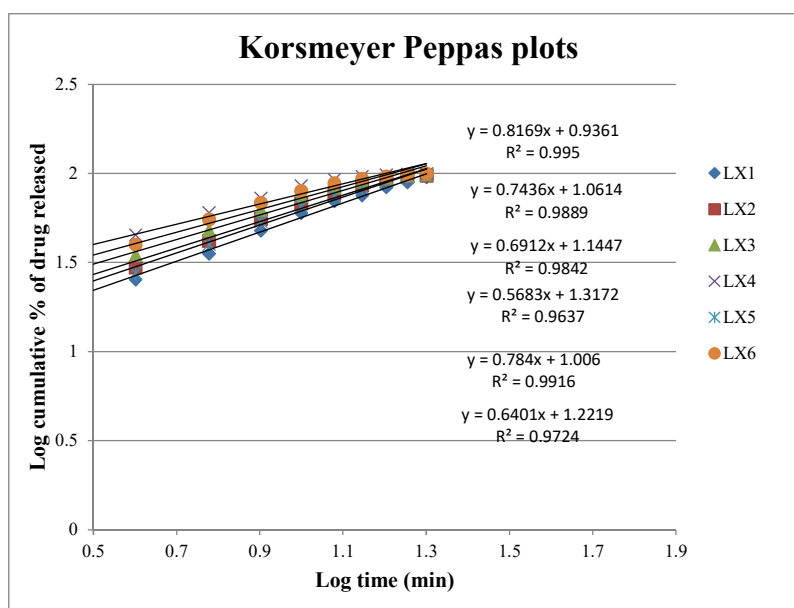


Figure 8: Korsmeyer-Peppas graph of LNX formulations (LX1-LX6)

Release-rate modelling demonstrated significant linearity across the models. The Korsmeyer–Peppas model exhibited the most superior match (R<sup>2</sup> reaching 0.995 for LX1; 0.9916 for LX5; and  $\geq 0.9637$  for all), but the Higuchi model also shown a commendable fit (R<sup>2</sup> ranging from 0.9605 to 0.9772), suggesting a significant diffusion component. The zero-order fit

had the highest strength for LX1 (0.9918) and maintained a significant correlation for LX2 (0.9755) and LX6 (0.9550). First-order shown superiority for LX3 (0.9965) and was also elevated for LX4 (0.9684). The Peppas release exponent n varied from 0.5683 to 0.8169 across all formulations.

### Stability Studies:

According to ICH recommendations, stability studies were conducted to evaluate the stability of the medication formulation. The optimized formulation LX4 demonstrated remarkable stability over a period of 90 days. At ambient temperature, the drug content exhibited negligible variation, signifying minimal degradation and robust matrix protection. Under accelerated circumstances (40 °C/75% RH), a slight, consistent decrease was noted, however results remained within standard test ranges (95-105%). The consistent, progressive decline without sudden decreases indicates the absence of moisture-induced degradation or incompatibility between the medicine and excipient. In summary, LX4 remains stable for a minimum of three months; it is advisable to utilise normal moisture-resistant packaging and to store it at

temperatures below 30 °C to maintain test levels near their initial state.

### CONCLUSION

The research effectively developed lornoxicam orodispersible films by a solvent-casting method, exhibiting superior mechanical strength, fast disintegration, and improved dissolution. Superdisintegrants markedly enhanced wetness and disintegration, facilitating a rapid start of analgesic effect. Optimized films demonstrated nearly whole drug release after 20 minutes and exhibited durability under accelerated storage conditions, validating their appropriateness for clinical application. The data indicate that lornoxicam ODFs provide an effective, convenient, and patient-centered dosage form for fast pain management in inflammatory diseases, demonstrating significant potential for practical therapeutic use.

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