RESEARCH PAPER

Development, Evaluation and Optimization of Hydrogel-Based Mouth Dissolving Film of Lornoxicam

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ABSTRACT
Abstract:
Aim: The aim of the present study was to develop, evaluate, and optimize a hydrogel-based mouth dissolving film (MDF) of Lornoxicam to enhance its dissolution rate and improve patient compliance.
Objectives: The objectives of the present study were to develop Lornoxicam mouth dissolving films using different film-forming polymers and suitable excipients, to investigate drug–excipient compatibility, and to evaluate the physicochemical, mechanical, and drug-release characteristics of the prepared films. The study further aimed to identify the best-performing formulation based on film quality, mechanical properties, disintegration behavior, drug content, and in-vitro drug release, followed by stability evaluation of the optimized formulation.
Methodology: The study involved preformulation investigations of Lornoxicam, including identification by FTIR spectroscopy, melting point determination, and drug–excipient compatibility studies. Lornoxicam mouth dissolving films were prepared by the solvent casting method using different film-forming polymers, plasticizers, and other suitable formulation excipients. The prepared films were evaluated for weight variation, thickness, surface pH, folding endurance, tensile strength, percentage elongation, drug content, and disintegration time. In-vitro drug-release studies were performed using phosphate buffer medium of pH 6.8 at 37 ± 0.5°C using a USP dissolution apparatus, and drug concentration was determined spectrophotometrically at 380 nm. The release data were further fitted to zero-order and first-order kinetic models. Among the formulations, F5 demonstrated the most favorable overall performance, showing a disintegration time of 10 seconds, drug content of 99.60%, folding endurance of 258 folds, tensile strength of 2.220 kg/cm², and cumulative drug release of 99.10% within 10 minutes. 8. result and Discussion 8. result and Discussion 8. result and Discussion Stability evaluation of F5 showed no significant physical changes and only minor changes in drug content under the investigated storage conditions.
Conclusion: The present study successfully demonstrated the feasibility of developing Lornoxicam mouth dissolving films with satisfactory physicochemical and mechanical properties. Among the prepared formulations, F5 was identified as the best-performing formulation, exhibiting rapid disintegration (10 seconds), high drug content (99.60%), good mechanical strength, and 99.10% cumulative drug release within 10 minutes. The stability findings further indicated that F5 maintained its physical characteristics and drug content with only minor changes during the study period. Therefore, the developed Lornoxicam mouth dissolving film, particularly formulation F5, represents a promising rapidly disintegrating oral film system for further pharmaceutical and clinical investigation.
Keywords: Lornoxicam, Mouth Dissolving Film, Hydrogel, Solvent Casting, Drug Release, Optimization, NSAIDs.
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Introduction:

Oral drug delivery systems represent the most widely accepted and convenient route for drug administration due to their ease of use, non-invasive nature, cost-effectiveness, and high patient acceptability. Conventional oral dosage forms such as tablets and capsules have dominated the pharmaceutical market for decades because of their stability, accuracy in dosing, and ease of large-scale manufacturing. These systems rely primarily on gastrointestinal absorption after disintegration and dissolution in the stomach or intestinal fluids. However, despite their widespread use, conventional dosage forms present several limitations, particularly in special populations such as pediatric, geriatric, and dysphagic patients who often experience difficulty in swallowing solid dosage forms. Furthermore, conventional tablets and capsules are associated with delayed onset of action due to the time required for disintegration and dissolution, and they may undergo first-pass metabolism, leading to reduced bioavailability. In addition, certain drugs, especially non-steroidal anti-inflammatory drugs (NSAIDs), are known to cause gastrointestinal irritation, ulceration, and discomfort when administered orally in traditional forms. These challenges have driven the need for innovative drug delivery systems that can overcome the drawbacks associated with conventional oral formulations while maintaining therapeutic efficacy.

In recent years, mouth dissolving films (MDFs) have emerged as a promising alternative oral drug delivery system that addresses many of the limitations of conventional dosage forms. MDFs are thin, flexible polymeric films that rapidly disintegrate or dissolve when placed on the tongue, releasing the drug directly into the oral cavity without the need for water. This unique characteristic offers significant advantages, including rapid onset of action due to pre-gastric absorption and improved bioavailability by bypassing first-pass metabolism in some cases. MDFs are particularly beneficial for pediatric and geriatric patients, as well as for individuals suffering from nausea, vomiting, or difficulty in swallowing. The formulation of MDFs typically involves hydrophilic polymers, plasticizers, sweeteners, and flavoring agents to ensure rapid disintegration, acceptable taste, and mechanical strength. Among various advancements, hydrogel-based films have gained attention due to their superior water retention capacity, flexibility, and enhanced drug release characteristics. Hydrogels are three-dimensional polymeric networks capable of absorbing significant amounts of water or biological fluids, which facilitates rapid swelling and disintegration of the film upon contact with saliva. This property not only enhances drug release but also improves the overall patient experience by providing a smooth and comfortable dosage form.

Lornoxicam, a potent NSAID belonging to the oxicam class, has been widely used for the management of pain and inflammation associated with various clinical conditions such as rheumatoid arthritis, osteoarthritis, and postoperative pain. It exerts its pharmacological action primarily through inhibition of cyclooxygenase (COX) enzymes, thereby reducing the synthesis of prostaglandins responsible for inflammation and pain. Despite its therapeutic efficacy, Lornoxicam faces several formulation challenges, including poor aqueous solubility and a relatively short half-life, which may limit its bioavailability and necessitate frequent dosing. Additionally, like other NSAIDs, it is associated with gastrointestinal side effects such as irritation, ulceration, and bleeding when administered in conventional oral dosage forms. These limitations highlight the need for alternative delivery approaches that can enhance its solubility, improve patient compliance, and minimize adverse effects. The development of hydrogel-based mouth dissolving films of Lornoxicam offers a novel strategy to overcome these challenges by enabling rapid drug release, improved absorption, and reduced gastrointestinal exposure. Such an approach holds significant potential in improving therapeutic outcomes and patient adherence, making it a promising area of research in modern pharmaceutics.

Material and Methods

Preparation of calibration curve of Lornoxicam:

Lornoxicam's normal stock solution was created by dissolving 100 mg of the medication in the bare minimum of distilled water, and then adding SGF to make up the remaining volume. By diluting the primary stock solution ten times, a secondary stock solution with a concentration of 100µg/ml was created from the standard stock solution. Aliquots ranging from 0.5 ml to 2.5 ml were transferred from this secondary stock solution into a succession of 10 ml volumetric flasks. The final volume was then made up with buffer to give the concentration ranging from 5µg/ml to 25µg/ml. At 320 nm, the absorbance of these solutions was measured in a UV Visible spectrophotometer using SGF as a blank. Three determinations were averaged.

Method of Preparation for Oral Dissolving Film

Calculation of Oral dissolving film

Diameter of Petri dish: (Dose of Lornoxicam as per record 8mg)

Radius of the petri dish = 6 cm Diameter = Radius/2 = 6/2 =3 cm.πr^2=3.14 x3x3 =28.26 cm^2

Now, Dose is % mg and cut the pieces in 2 cm x 2 cm = 4 $cm^2$4cm^2contain 5 mgof drug.

So, 28.26 cm^2 contains = 28.26/4 = 7.06 and 7.06 x 5 = 35.32 mg drugSo2 ml contain 35.32 mg drug

Then, 10 ml contain drug =176.60 mg drug

Method of preparation For the film preparation, the solvent casting method was utilised. Weighed the polymer precisely and submerged it in 10 millilitres of water. Aspartame and the specified amount of citric acid were added to this mixture, and it was agitated for 45 minutes. Stir the solution continuously while adding the polymer solution after it has been well combined. PEG 400 plasticizer was finally added, stirring constantly. After 45 minutes of vigorously stirring the final dispersion, the solution was sonicated for 15 minutes to eliminate any remaining air bubbles. The dispersion was then placed aside for an hour to allow the foams to subside. Glycerol was used to lubricate the petri dish in the interim to reduce the possibility of film damage during removal. After transferring two millilitres of the final dispersion into the measuring cylinder, the solution was poured into a 28.26 cm2 clean, dry petri plate. After that, the films were dried for one to two hours at 40°C in a vacuum tray dryer. After that, the films were taken out and chopped to a size of (2x2) cm2. After that, these films were kept in appropriate packaging at room temperature.

Table1: Formulation of Hydrogel based Mouth Dissolving Films Placebo

Excipients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lornoxicam									
Water Soluble									

Polymer									
HPMCE-15	50	-	-	-	-	-	25	-	-
HPMCK-100	-	50	-	-	-	-	25	-	-
PVPK-30	-	-	50	-	-	-	-	25	-
PVPK-25	-	-	-	50	-	-	-	25	-
Sodium alginate	-	-	-	-	50	-	-	-	25
Sodium CMC	-	-	-	-	-	50	-	-	25
Plasticizer									
Glycerin	25	-	-	12.5	-	12.5	12.5	-	-
PG	-	25	-	12.5	12.5	-	-	12.5	-
PEG-400	-	-	25	-	12.5	12.5	-	-	12.5
Saliva Stimulant									
Citric acid	5	10	5	10	5	10	5	10	5
Superdisintegrants									
Kyron	-	10		20	-	-	10	20	-
Na Cross carmellose	20		10	-	10	20			20
Surfactant									
SLS	5	10	5	10	5	10	5	10	5
Sweetener									
Na Saccharin	10	10	-	10	-	-	10	10	10
Mannitol	-	-	10	-	10	10	10	10	-
Flavoring agent									
Vanillin	10	10	10	10	10	10	10	10	10
Distilled Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

Trials Taken to Study the Effect of Various Polymer Concentrations on Mouth Dissolving Film

Table 2: Formulation of Hydrogel based Mouth Dissolving Films

Excipients	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Lornoxicam mg	502.40	502.40	502.40	502.40	502.40	502.40	502.40	502.40	502.40
Water Soluble Polymer									
HPMCE-15	50	-	-	-	-	-	25	-	-
HPMCK-100	-	50	-	-	-	-	25	-	-
PVPK-30	-	-	50	-	-	-	-	25	-
PVPK-25	-	-	-	50	-	-	-	25	-
Sodium alginate	-	-	-	-	50	-	-	-	25
Sodium CMC	-	-	-	-	-	50	-	-	25
Plasticizer									
Glycerin	25	-	-	12.5	-	12.5	12.5	-	-
PG	-	25	-	12.5	12.5	-	-	12.5	-
PEG-400	-	-	25	-	12.5	12.5	-	-	12.5
Saliva Stimulant									
Citric acid	5	10	5	10	5	10	5	10	5
Super disintegrates									
Xanthum Gum	-	10		20	-	-	10	20	-
Sodium Croscarmellose	20		10	-	10	20			20
Surfactant									
SLS	5	10	5	10	5	10	5	10	5
Sweetener									
NaSaccharin	10	10	-	10	-	-	10	10	10
Mannitol	-	-	10	-	10	10	10	10	-
Flavoring agent									
Vanillin	10	10	10	10	10	10	10	10	10
Distilled Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

Method of preparation of Drug Incorporated

Water-soluble film-forming polymers such as HPMC E-15, HPMC K100, PVP K-25, PVP K-30, Sodium CMC, and Sodium alginate were selected and taken in concentrations of 25% or 50%. These polymers were mixed with plasticizers including glycerin,

propylene glycol (PG), and polyethylene glycol (PEG-400) at concentrations of 12.5% or 25% in a beaker containing distilled water. The solution was stirred on a heated magnetic stirrer at 40°C for 1 hour to obtain a uniform polymeric solution. After adequate heating, sweetening agents such as mannitol and sodium saccharin were added along with the flavoring agent vanillin in 10% of the total formulation. The mixture was further stirred for a few minutes, after which other excipients such as surfactants, saliva stimulants, and superdisintegrants were added in concentrations of 5% or 10% and 10% or 20%, respectively. Finally, 0.5% of the drug (FLZ) was incorporated into the mixture and stirred continuously on a magnetic stirrer for 6 hours at 750 rpm until a homogeneous viscous solution was formed.

The prepared solution was then poured into a Petri dish containing a square-shaped aluminum foil base. Care was taken to ensure uniform pouring to avoid the formation of air bubbles. The Petri dishes were kept at room temperature for 24 hours to allow drying. After drying, a flexible and elastic film was obtained. The films were carefully removed and stored in a dark place under non-humid conditions to prevent degradation.

A total of nine formulations were prepared and coded as F1 to F9. All formulations were further evaluated to obtain an optimized formulation.

Result and Discussion:

a) Chemical Compatibility:

Compatibility study of pure drug Lornoxicam with other excipients were carried out prior to the formulation of films. IR spectra of pure drug and DSC of physical mixture of drug-excipients were obtained, which are depicted below.

Figure.1: FTIR Spectrum of Lornoxicam

Figure 2: FTIR Spectrum of Lornoxicam + Cross Carmelose Sodium

Figure 3: FTIR Spectrum of Lornoxicam+Kyron

Figure 4: FTIR Spectrum of Lornoxicam+HPMC

Figure 5: FTIR Spectrum of Lornoxicam+ All polymers excipients

Figure 6: DSC of Lornoxicam

Table 3: IR Compatibility Study of Drug with Different Polymers

Sr. No.	Combination (Drug + Polymer)	Characteristic IR Peaks (cm^{-1})	Liquefaction	Compatibility
1	Lornoxicam (Pure Drug)	794, 669, 1496, 1685, 1606, 2937	No	Compatible
2	Lornoxicam + Sodium Starch Glycolate (SSG)	796, 664, 1493, 1681, 1604, 2936	No	Compatible
3	Lornoxicam + Kyron T-314	801, 675, 1502, 1690, 1600, 2920	No	Compatible
4	Lornoxicam + HPMC	805, 670, 1510, 1685, 1605, 2930	No	Compatible
5	Lornoxicam + All Polymers (Combined Excipients)	793, 678, 1502, 1681, 1606, 2936	No	Compatible

Table 4: Mean Absorbance Values and Statistical Data of the Calibration Curve for the Estimation of Lornoxicam

S. No.	Concentration(µg/ml)	Mean Absorbance* ±S.D
1	2	0.0797 ± 0.00042
2	4	0.1479 ± 0.00015
3	6	0.2152 ± 0.00018
4	8	0.2829 ± 0.00024
5	10	0.3526 ± 0.00031

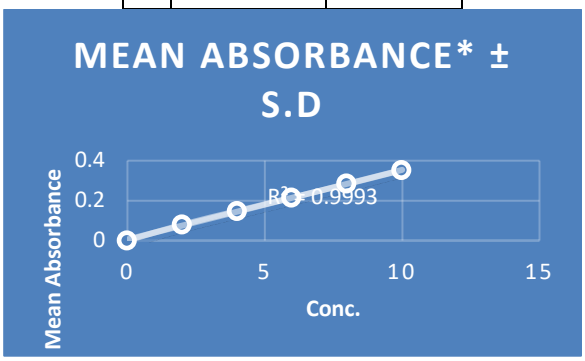


Figure 7: Calibration Curve of Lornoxicam

Table 5: Evaluation of Placebo Mouth

Dissolving Films

Parameter	FORMULATION CODE									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Weight variation (mg)	18.10 ± 0.10	20.95 ± 0.11	21.05 ± 0.12	22.30 ± 0.08	20.85 ± 0.05	19.85 ± 0.09	22.05 ± 0.06	19.60 ± 0.10	20.75 ± 0.07	23.80 ± 0.06
Thickness (mm)	0.036 ± 0.012	0.037 ± 0.010	0.036 ± 0.009	0.038 ± 0.010	0.037 ± 0.009	0.036 ± 0.010	0.037 ± 0.011	0.038 ± 0.010	0.037 ± 0.012	0.039 ± 0.010
Surface pH	5.80	6.10	6.20	5.95	6.40	5.90	5.85	6.30	6.70	6.35
Folding endurance	210	225	240	260	255	235	238	248	252	265
Tensile Strength (kg/cm²)	0.750 ± 0.08	0.860 ± 0.05	0.980 ± 0.07	2.100 ± 0.09	2.220 ± 0.12	2.300 ± 0.06	1.540 ± 0.05	1.600 ± 0.04	1.650 ± 0.08	1.850 ± 0.07
Percent Elongation (%)	2.50	2.46	2.47	2.42	2.53	2.40	2.36	2.30	2.33	2.39
Disintegration time (sec)	28 ± 0.45	24 ± 0.20	18 ± 0.40	24 ± 0.50	10 ± 0.15	35 ± 0.22	38 ± 0.50	29 ± 0.40	26 ± 0.60	32 ± 0.45
Drug content (%)	96.50 ± 0.40	98.40 ± 0.70	97.40 ± 0.35	96.70 ± 0.50	99.60 ± 0.60	98.70 ± 0.55	98.40 ± 0.30	96.40 ± 0.50	97.20 ± 0.35	97.80 ± 0.40

Table 6: Physical Characterization of Mouth Dissolving Mouth Films

Parameters	FORMULATION CODE									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Weight variation (mg)	19.25 ± 0.32	22.00 ± 0.28	20.75 ± 0.30	21.40 ± 0.35	23.50 ± 0.38	17.90 ± 0.29	22.60 ± 0.22	18.90 ± 0.34	20.70 ± 0.20	22.70 ± 0.31
Thickness (mm)	0.040 ± 0.010	0.046 ± 0.011	0.038 ± 0.012	0.050 ± 0.013	0.047 ± 0.010	0.048 ± 0.011	0.046 ± 0.012	0.049 ± 0.011	0.050 ± 0.012	0.037 ± 0.011
Surface pH	6.65	6.90	6.45	6.80	6.95	6.85	6.60	6.90	6.80	6.70
Folding endurance	210	220	232	240	258	222	235	245	255	268

Table 7: Dissolution Parameters for Formulations

S. No	Formulation Code	t25% (min)	t50% (min)	t70% (min)	t90% (min)	Cumulative % Drug Release in 10 min
1	**F1**	2.50	5.50	8.20	>10	83.20
2	**F2**	2.70	6.20	8.50	>10	87.80
3	**F3**	2.05	4.10	6.10	>9	96.80
4	**F4**	1.40	3.10	4.30	>8	97.30
5	**F5**	0.95	1.90	2.00	>5	99.10
6	**F6**	3.00	6.10	8.30	>10	80.20
7	**F7**	3.05	5.60	8.20	>10	82.90
8	**F8**	2.20	4.60	7.20	>10	89.80
9	**F9**	2.05	4.10	6.10	>10	95.90

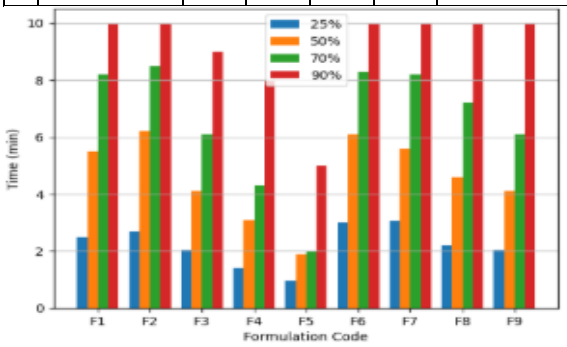


Figure 8: Comparison of Dissolution Parameters (T25%, T50%, T70%, T90%) Of Mouth Dissolving Films of Lornoxicam

Table 8 In vitro release data of Lornoxicam tablet -Zero Order Release

Time	FL1	FL2	FL3	FL4	FL5	FL6	FL7	FL8	FL9
0	0	0	0	0	0	0	0	0	0
0.5	34.75	38.88	37.78	38.85	43.81	42.52	40.21	45.94	44.81
1	64.64	67.15	66.96	69.05	71.82	70.55	71.55	73.56	72.33
1.5	71.56	74.55	73.75	73.95	80.77	79.75	75.81	82.91	78.62
2	80.55	85.93	84.55	86.75	87.05	86.59	88.32	89.15	87.54
2.5	84.25	89.11	88.56	88.76	91.51	90.11	90.55	93.65	91.58
3	88.83	90.27	89.89	90.78	95.74	93.11	92.53	97.85	94.95

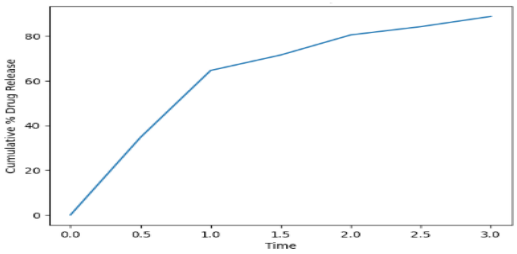


Figure 9: In vitro release curve of Lornoxicam tablet -Zero Order Release in pH 6.8 Phosphate Buffer

Table 8 In vitro release data of Lornoxicam tablet -First Order Release

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	2.000	2.000	2.000	2.000	2.000	2.000	2.000	2.000	2.000
0.5	1.815	1.786	1.794	1.786	1.751	1.760	1.777	1.733	1.742
1	1.549	1.517	1.519	1.491	1.447	1.469	1.454	1.422	1.442
1.5	1.454	1.406	1.419	1.414	1.280	1.306	1.384	1.233	1.330
2	1.289	1.148	1.189	1.124	1.111	1.127	1.067	1.035	1.096
2.5	1.197	1.037	1.058	1.051	0.927	0.995	0.975	0.803	0.925
3	1.048	0.988	1.005	0.964	0.632	0.838	0.873	0.332	0.703

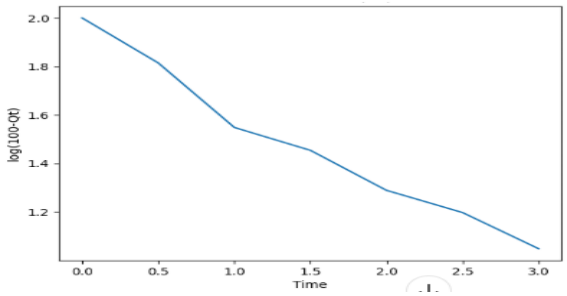


Figure 10: In vitro release data of Lornoxicam tablet -First Order Release in pH 6.8 Phosphate Buffer

Table 9 In vitro release data of Lornoxicam tablet –Higuchi Model

Time	√Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0.000	0	0	0	0	0	0	0	0	0
0.5	0.707	34.75	38.88	37.78	38.85	43.81	42.52	40.21	45.94	44.81
1	1.000	64.64	67.15	66.96	69.05	71.82	70.55	71.55	73.56	72.33
1.5	1.225	71.56	74.55	73.75	73.95	80.77	79.75	75.81	82.91	78.62
2	1.414	80.55	85.93	84.55	86.75	87.05	86.59	88.32	89.15	87.54
2.5	1.581	84.25	89.11	88.56	88.76	91.51	90.11	90.55	93.65	91.58
3	1.732	88.83	90.27	89.89	90.78	95.74	93.11	92.53	97.85	94.95

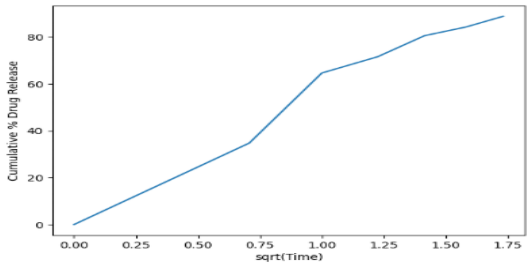


Figure 11: In vitro release data of Lornoxicam tablet –Higuchi Model in pH 6.8 Phosphate Buffer

Table 10 In vitro release data of Lornoxicam tablet -Korsemeyer Model

Time	log(Time)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	-0.301	1.5411	1.5590	1.5777	1.5889	1.6411	1.6299	1.6004	1.6662	1.6511
1	0.000	1.8111	1.8827	1.8826	1.8839	1.8556	1.8849	1.8555	1.8667	1.8559
1.5	0.176	1.8555	1.8872	1.8868	1.8869	1.9007	1.9002	1.8800	1.9119	1.8996
2	0.301	1.9006	1.9334	1.9227	1.9338	1.9400	1.9338	1.9446	1.9500	1.9442
2.5	0.398	1.9926	1.9500	1.9947	1.9948	1.9962	1.9555	1.9557	1.9972	1.9962
3	0.477	1.9949	1.9956	1.9954	1.9958	1.9981	1.9969	1.9966	1.9991	1.9977

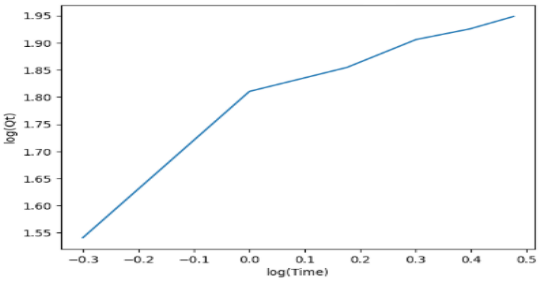


Figure 12: In vitro release data of Lornoxicam tablet -Korsemeyer Model in pH 6.8 Phosphate Buffer

Table 11: Kinetic Value Obtained From In Vitro Release

Formulation	Zero Order		First Order	
	Ko (mg/h)	R^2	K1 (hr^{-1})	R^2
F1	7.510	0.575	0.488	0.960
F2	7.545	0.495	0.490	0.979
F3	7.600	0.465	0.486	0.971
F4	7.455	0.470	0.405	0.973
F5	8.650	0.670	0.482	0.998
F6	8.080	0.555	0.455	0.860
F7	7.760	0.535	0.268	0.993
F8	6.520	0.475	0.295	0.947
F9	7.890	0.615	0.382	0.912

Table 13: Physical Stability of formulation F5

Parameters	Appearance	pH	Tensile Strength	Percent Elongation (%)	Folding Endurance
Room Temperature	White, smooth	6.95	2.230	2.53	258
37 ± 5°C	No significant change	6.93	2.225	2.51	256
4–5°C	No significant change	6.96	2.228	2.52	257

Chemical evaluation

The drug content of the formulation was estimated over a period of 3 months. The results were tabulated as follows.

Table 14: Drug content of formulation F5

Storage condition	Withdrawal period (monthly)			
	0	1	2	3
4-5°C	99.87	98.87	97.78	96.89
Room Temperature	99.79	98.69	97.93	97.75
37±5°C	99.87	98.87	97.78	96.70

Conclusion

The current investigation included the formulation, preparation, and evaluation of a oral dissolving film of Lornoxicam for all of the criteria considered. After being inserted into the oral cavity, the film that has been produced has the ability to disintegrate quickly. Because of its compactness, simplicity of production, and self-administration capabilities. This is due to the fact that it is the most convenient. On the other hand, patients of any age, including children and the elderly, have trouble swallowing traditional medications, which results in poor patient compliance. The revolutionary medication delivery technique that we have created is referred to as "Oral dissolving film." This was done in order to overcome this shortcoming. A revolutionary form of film that dissolves in saliva is

being introduced here. The benefits include the ability to administer the medication without the need of water, at any time and in any location. These films are widely used as a dosage form for the treatment of muscular spasms and tone because of the benefits they provide in terms of patient compliance, quick beginning of action.

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