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Formulation Development and Evaluation of Orodispersible Tablets

Divya Jadhao* *, Pooja Gawandar, Dr. K R Biyani

Anuradha College of Pharmacy, Chikhli.
Email id: divyajadhao523@gmail.com

ABSTRACT

The study aimed to develop and evaluate Lornoxicam orodispersible tablets (ODTs) using various superdisintegrants to improve patient compliance and rapid onset of action. Preformulation studies confirmed the suitability of Lornoxicam as a candidate for ODT formulation, with the melting point of 240-242°C and solubility in organic solvents. UV-spectroscopic analysis identified the λmax at 362 nm in phosphate buffer pH 6.8, confirming the drug's linear absorbance profile. FT-IR compatibility studies revealed no significant interactions between Lornoxicam and the excipients used, particularly the superdisintegrants. Total right formulations (F1 to F8) were prepared using four different superdisintegrants Ac-Di-Sol, Low-substituted Hydroxypropyl Cellulose (LHPC), Sodium Starch Glycolate (SSG), and Kollidon CL at two concentrations (7 mg and 15 mg). The micromeritics properties of the powder blends indicated acceptable flow and compressibility characteristics for all formulations. The formulation F4, containing 15 mg LHPC, emerged as the most promising in terms of rapid disintegration, superior drug release, and excellent mechanical properties. The overall results confirm that optimizing the type and concentration of superdisintegrants is essential for developing a fast-disintegrating, patient-friendly oral dosage form of Lornoxicam with reliable therapeutic efficacy and stability.

Keywords: Orodispersible tablet. Kollidon.Compatibility, Stability, etc**.**

Introduction

A popular and practical way to administer drugs, the oral route offers a variety of dose forms, including tablets, capsules, powders, suspensions, and solutions. It is thought to be less intrusive and safer, reducing the possibility of problems and infections. Food interactions, first-pass metabolism, and gastric pH can all affect the oral route, which is appropriate for long-term treatment in chronic diseases. Rapid disintegration, a smooth texture, a pleasing flavor and odor, consistent medication distribution, mechanical strength, resistance to moisture, and compliance with production processes are all desirable qualities for orodispersible tablets.

When they come into contact with saliva, they ought to dissolve rapidly, making administration simple and facilitating immediate medication release. Additionally, they ought to taste and smell good, particularly to young and old people. To ensure consistent dosing and therapeutic efficacy, the active pharmaceutical component should be evenly dispersed throughout the tablet matrix.

Drug absorption is influenced by solubility in gastrointestinal fluid and permeability across the membrane, with physical and chemical properties influencing solubility. Tablet disintegration significantly impacts drug dissolution rate.

A batch of tablets must fulfill certain standards in order to pass the official disintegration test. By expanding the surface area of tablet fragments and overcoming cohesive forces that hold particles together, disintegrants—essential components in tablet formulations—induce the disintegration process.

Materials & Methods

Preformulation studies are crucial in drug development, evaluating the physicochemical properties of a drug substance before formulating it into a dosage form. These studies provide insights into the drug's intrinsic characteristics, enabling the creation of a safe, effective, and stable dosage form.

The main goal is to produce data that helps the formulator create a stable dosage form. Preformulation research is essential for establishing a solid foundation for subsequent formulation development and optimization efforts.

Determination of the melting point of Lornoxicam involves a capillary method, while solubility is determined in different solvents.

UV spectroscopy is used to prepare a stock solution of Lornoxicam, and a standard curve is prepared by dissolved Lornoxicam in phosphate buffer 6.8.

Drug-excipient compatibility studies assess the compatibility of a drug substance with various excipients used in formulation. These studies help formulate scientists make informed decisions regarding excipient selection, formulation design, and process optimization.

Formulation of Lornoxicam Orodispersible Tablets:

Direct compression and superdisintegrant addition were used to create Lornoxicam orodispersible tablets. Various concentrations of super disintegrants, including sodium starch glycolate, croscarmellose sodium, crospovidone, and LHPC, were employed. Avicel pH 102 and aspartame were employed as sweeteners. After that, rotary tablet punching machines were used to compress.

Table 1: Composition of Orodispersible Tablets of Lornoxicam

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Lornoxicam	8	8	8	8	8	8	8	8
Ac-Di-Sol	7.5	15		-	-	-	-	-
L-HPC	-	-	7.5	15	-	-	-	-
Sodium Strach Glycolate	-	-	-	-	7.5	15	-	-
Kollidon CL							7.5	10
Aspartame	2	2	2	2	2	2	2	2
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mg. stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Avicel 102	129.5	122	129.5	122	129.5	122	129.5	122
Total Weight	150	150	150	150	150	150	150	150

Result and Discussion

The purity of Lornoxicam was confirmed by its melting point, which was between 240 and 242°C. It was soluble in organic solvents such as acetone, chloroform, dimethyl formamide, and DMSO, but insoluble in water and only weakly soluble in ethanol and methanol. The Shimadzu UV spectrophotometer was used to measure the maximum wave length, which was 265 nm.

The Lornoxicam standard calibration curve, prepared from 2 to 16 µg/ml, shows a straight line at concentrations ranging from 2 to 16 µg/ml. As concentration increases, so does absorption, following Beer-Lambert's Law. i.e $y = 0.0541x + 0.0229$ $R^2 = 0.9984$.

Table 2: Micromeritics Properties of Powder Blend (F1 to F8)

Batch	Angle of Repose (θ)	Bulk Density (g/cc)	Tapped Density (g/cc)	Compressibility Index (%)	Hausner's Ratio
F1	27.60	0.166	0.180	7.73	1.08
F2	28.61	0.161	0.173	7.51	1.08
F3	26.16	0.163	0.184	8.24	1.09
F4	25.42	0.168	0.200	15.50	1.10
F5	26.32	0.157	0.185	12.64	1.14
F6	27.28	0.181	0.201	10.45	1.12
F7	28.46	0.170	0.204	15.76	1.19
F8	28.67	0.178	0.198	10.10	1.11

The Lornoxicam orodispersible tablets (F1-F8) were tested for post-compression parameters such as weight variation, thickness, hardness, friability, drug content uniformity, disintegration time, and wetting time.

The **hardness, thickness, and frability** of Lornoxicam tablets were examined in the study. Batches F3 and F5 had the maximum hardness, indicating a stiff matrix. The thickness of the tablets varied slightly depending on the content of the excipient and the compression force, ranging from 2.99 ±1.2 mm to 3.22 ±0.07 mm. Good mechanical strength and abrasion resistance were demonstrated by friability readings that were below the 1% threshold. With drug content uniformity ranging from 97.24 ±1.3% to 99.64 ±1.1%, all formulations met USP requirements.

The study discovered that orodispersible tablets' disintegration time is important; F4 had the quickest disintegration time (22.14 ±3.11 sec), which may have been caused by the higher content of LHPC (15 mg), which enhances porosity and water absorption.

The most promising batch, according to the study, was Formulation F4 (LHPC 15 mg), which balanced high drug content homogeneity, rapid disintegration, and mechanical strength. Without affecting other physical characteristics, LHPC at greater concentrations markedly improved the Lornoxicam orodispersible tablets' disintegration and wetting behavior. Effective performance was also demonstrated by other superdisintegrants.

Table 3: Post Compression parameters of Orodispersible Tablets of Lornoxicam

Batch	Weight Variation (mg)	Thickness (mm)	Hardness (Kg/Cm2)	Friability (%)	Drug Content Uniformity (%)	Disintegration Time (sec)	Wetting Time (Sec)
F1	152.14 ±1.56	3.18±0.05	4.5±0.60	0.79±1.1	97.74±1.1	40.32 ±2.14	46.8 ±1.07
F2	151.52 ±1.30	3.22±0.07	4.5±0.55	0.81±0.9	97.82±1.2	32.10 ±2.18	36.0 ±0.95
F3	149.48 ±1.83	3.10±0.07	5.0±1.30	0.75±0.12	99.30±1.1	37.36±2.61	42.4 ±1.65
F4	150.24 ±2.10	3.08±1.8	4.5±0.80	0.65±0.18	99.64±1.1	22.14±3.11	26.0 ±1.85
F5	152.16 ±1.66	2.99±1.2	5.0±0.58	0.78±0.27	97.24±1.3	38.16±3.25	38.0 ±2.35
F6	153.21 ±1.40	3.11±1.2	4.5±0.85	0.80±0.16	98.11±0.4	30.62±3.12	36.4 ±1.480
F7	151.89 ±2.19	3.04±1.3	4.5±1.26	0.91±0.31	98.31±1.0	44.37±2.36	50.8 ±0.35
F8	153.10 ±1.74	3.04±1.4	4.5±1.16	0.88±0.24	97.31±0.9	34.55±1.23	37.7 ±1.45

(SD ± Mean of n=3)

In-Vitro Dissolution Study

The study assessed how the drug release profile of Lornoxicam orodispersible tablets was affected by various superdisintegrants and their concentrations. Two concentration levels of four different superdisintegrants—Ac-Di-Sol, LHPC, Sodium Starch Glycolate, and Kollidon CL—were employed. The most effective and quick drug release was demonstrated by LHPC at 15 mg (F4), which was closely followed by Ac-Di-Sol, Kollidon CL, and Sodium Starch Glycolate at the same concentration. According to the study's findings, the kind and quantity of superdisintegrant significantly affect how well Lornoxicam orodispersible pills dissolve.

Stability study

For stability tests, the Lornoxicam Orodispersible tablet formulation F4 was chosen because it demonstrated encouraging outcomes in terms of a short disintegration time and increased drug release. Hardness, drug content, disintegration time, and in vitro drug release did not significantly change after three months.

Conclusion

Lornoxicam orodispersible tablets were effectively prepared and assessed in this study employing a variety of superdisintegrants. With 15 mg of LHPC, formulation F4 showed the most promise in terms of quick disintegration, improved drug release, and outstanding mechanical characteristics. According to the study, LHPC works well as a superdisintegrant for Lornoxicam ODTs, especially when used in larger quantities. The overall findings support the

idea that creating a patient-friendly, fast-disintegrating oral dosage form of Lornoxicam with dependable therapeutic efficacy and stability requires careful consideration of the kind and concentration of superdisintegrants. Other poorly soluble medications that need a quick onset of action should benefit from this formulation approach, which would improve patient compliance, particularly in pediatric and elderly populations.

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