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Formulation and Evaluation of Fast Disintegrating Tablet of Lornoxicam

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ABSTRACT:

This research focused on the development and assessment of Lornoxicam Fast Disintegrating Tablets (FDTs), intended to deliver a faster onset of therapeutic action, improved bioavailability, and better patient adherence—especially for those who experience difficulty swallowing conventional tablets. Lornoxicam, a nonsteroidal anti-inflammatory drug (NSAID) known for its strong analgesic and anti-inflammatory effects, was chosen as the active pharmaceutical ingredient. The FDTs were manufactured using the direct compression technique, which is recognized for being both cost-effective and suitable for large-scale production.

A range of excipients—including microcrystalline cellulose, crospovidone, sodium starch glycolate, and magnesium stearate—were incorporated to enhance the formulation's disintegration rate, flow characteristics, and compressibility. Pre-compression evaluations such as bulk density, tapped density, Carr's index, angle of repose, and moisture content were conducted to assess the blend's suitability for tablet formation. These studies confirmed acceptable flow and compressibility properties.

Post-compression tests, including hardness, friability, disintegration time, and in vitro drug release, revealed that the developed tablets met the essential requirements for FDTs. The tablets disintegrated quickly in the presence of saliva, enabling rapid drug release. Overall, the formulated Lornoxicam FDTs demonstrated desirable characteristics in terms of mechanical strength, rapid disintegration, effective dissolution, and stability. Additionally, compatibility studies such as Fourier Transform Infrared Spectroscopy (FTIR) and in vitro dissolution of solid dispersions were employed to support the formulation's efficacy.

KEYWORDS: Lornoxicam, Fast Dissolving, Tablet

1. INTRODUCTION

The oral route remains the most commonly used method for drug administration because it is convenient, promotes better patient adherence, and is economically favorable. Nevertheless, standard oral forms such as tablets and capsules may not be appropriate for certain groups, including children, elderly individuals, and patients experiencing difficulty swallowing (dysphagia). To address this issue, Fast Disintegrating Tablets (FDTs) have been introduced. These are solid dosage forms that dissolve or disintegrate quickly in the mouth without requiring water, providing an efficient solution for such populations.

FAST DISINTEGRATING TABLETS (FDT)

Fast Disintegrating Tablets (FDTs) are attracting growing interest in both pharmaceutical research and manufacturing because of their user-friendly nature, swift onset of therapeutic effect, and ability to potentially increase drug bioavailability. Fast Disintegrating Tablets (FDTs) are engineered to break apart or dissolve swiftly within the oral cavity, often in a matter of seconds, enabling rapid drug release and absorption of the active pharmaceutical ingredient (API). The demand for dosage forms that offer enhanced bioavailability, faster therapeutic onset, and improved patient adherence has led to the development of innovative oral delivery systems. Among these, FDTs formulated with superdisintegrants and water-attracting (hydrophilic) excipients are becoming increasingly popular.

The origin of these technologies dates back to the late 1970s, when scientists began exploring alternatives to traditional solid dosage forms, particularly to assist elderly and pediatric patients who experience difficulty swallowing pills. FDTs represent one of the most recent advancements in oral drug delivery. Initially influenced by transdermal drug delivery approaches, these tablets disintegrate quickly upon contact with saliva and the moist environment of the oral mucosa. This process allows the drug to be released promptly and absorbed directly through the buccal mucosa into the bloodstream, ensuring fast systemic action.

5. Materials Used

- Lornoxicam (API)
- Superdisintegrants (Crospovidone, Croscarmellose Sodium, SSG)
- Excipients: MCC, mannitol, magnesium stearate, talc

S. No	Equipment Name	Source
1	Digital weighing machine	Contech Instruments Ltd. Mumbai, India
2	Tablet compression machine	Cemache, Ahmadabad
3	Monsanto hardness tester	Cintex Ind. Corporation, Mumbai
4	Friability tester	Electrolabpvt Ltd. India
5	Disintegration apparatus	Electrolabpvt Ltd. India
6	Infrared spectrophotometer	FTIR 8400 S

Experimental Work

PREPARATION OF CALIBRATION CURVE FOR LORNOXICAM

The calibration curve recorded in 6.8 pH buffer comprising 2/10M sodium hydroxide and 2/10M potassium di hydrogen ortho phosphste).

Preparation of 0.2 M NaOH

8gm of NaOH dissolved in minimum water and made upto mark in 1000ml standard flask

Preparation of 0.2 M KH2PO4

27.218 gm potassium di hydrogen ortho phosphate dissolved in water and made upto mark in 1000ml standard flask.

Preparation of Lornoxicam standard solution Preparation of stock I

0.01g drug dissolved in 6.8 pH buffer and made upto mark in 100 ml standard flask with to give 1000 mcg/ml concentration.

Preparation of stock II

0.01ml of above solution transferred to a 100 ml standard flask and made upto volume using buffer to get 100 mcg/ml concentration.

PLOTTING OF STANDARD CURVE FOR LORNOXICAM (Dixit and

Puthil,2009;Arya et al., 2014)

Aliquots of 0.2, 0.4, 0.6, 0.8, 1ml withdrawn for Stock II and made up to 10ml using 6.8pH buffer to obtain concentration of 2, 4, 6, 8, 10 mcg/ml solutions. All the samples analyzed spectrophotometrically at 369 nm.

PRELIMINARY SOLUBILITY STUDIES OF LORNOXICAM

The solubility of pure Lornoxicam was assessed following the procedure established by Higuchi and Connors in 1965. Excess Lornoxicam was added to 25 mL solutions containing various water-soluble carriers such as PEG 6000, Kollidon CL, PVP K-30, Soluplus, Aerosil 200, Poloxamer 127, HPMC,

and Urea. These mixtures were thoroughly mixed and kept at 25°C for 24 hours to reach equilibrium. Afterwards, the samples were filtered through Whatman filter paper No. 1. The filtrates were then diluted with methanol and the drug concentration was measured using UV spectrophotometry at a wavelength of 369 nm

Table : Composition of Lornoxicam

Ingredient	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)
Lornoxicam	8	8	8	8	8
Crospovidone	10	15	—	—	—
Croscarmellose Sodium	—	—	10	15	—
Sodium Starch Glycolate	—	—	—	—	15
Mannitol (diluent)	120	115	120	115	115
Microcrystalline Cellulose (MCC)	50	50	50	50	50
PVP K30 (binder)	5	5	5	5	5
Talc	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2
Total Weight	197	197	197	197	197

Result and Discussion

UV CALIBRATION CURVE

The UV spectra of Lornoxicam scanned between 200-400 nm denoted absorption maximum peak at 369 nm . The calibration curve exhibited good linearity within concentration of 2-10 mcg/ml with correlation coefficient value of 0.999.

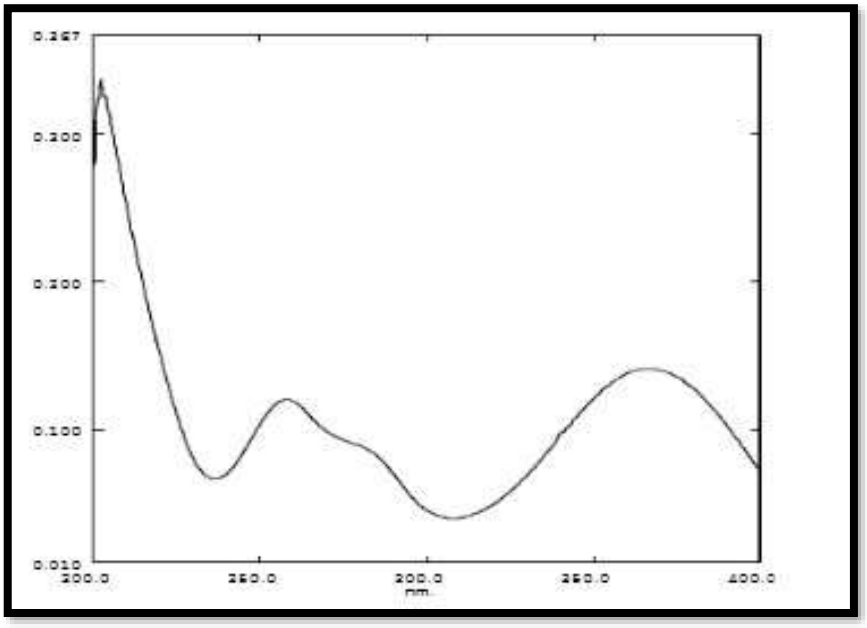


Figure :UV spectra of Lornoxicam pure drug

Table: Calibration curve of Lornoxicam

Concentration (mcg/ml)	Absorbance
0	0
2	0.196
4	0.388
6	0.601
8	0.82
10	0.996

Figure : Calibration curve for Lornoxicam

CHARACTERIZATION OF LORNOXICAM SD

The IR spectra are shown in Figure6.7-6.9. Pure Lornoxicam (A) exhibited peaks at 3126 cm^{-1} and 3088 cm^{-1} (NH and OH stretching), 1635 cm^{-1} (aromatic C=C), 1521 cm^{-1} and 1510 (Amide – C = O, C=N), 1440 cm^{-1} (C-H deformation), 1369 cm^{-1}(CH3 deformation). The optimized formulation of solid dispersion also exhibited the same characteristic peaks representing withholding of Lornoxicam chemical identity. Hence, there exists no interaction among drug and the carriers used in SD formulation.

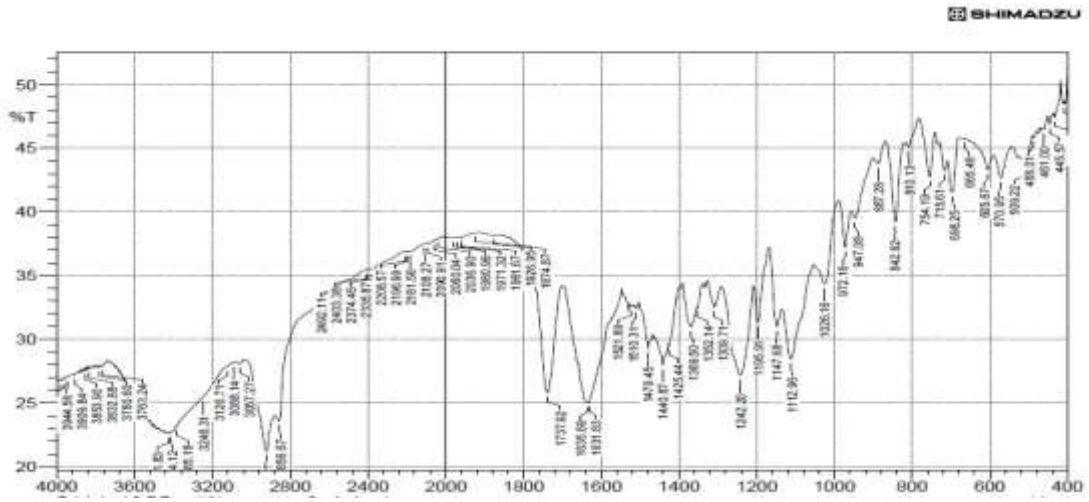


Figure: FTIR Spectrum of Lornoxicam pure drug

DSC studies

The DSC thermo grams of Lornoxicam displayed (Figure 6.12) sharp endothermic peak at 209 ^{0}C, demonstrating crystalline state of the drug. The nonappearance of this peak in SD9 thermo gram demonstrate amorphous form of drug. Crystallization inhibition is attributed to the entrapment of the drug molecules in the polymer matrix during solvent evaporation.

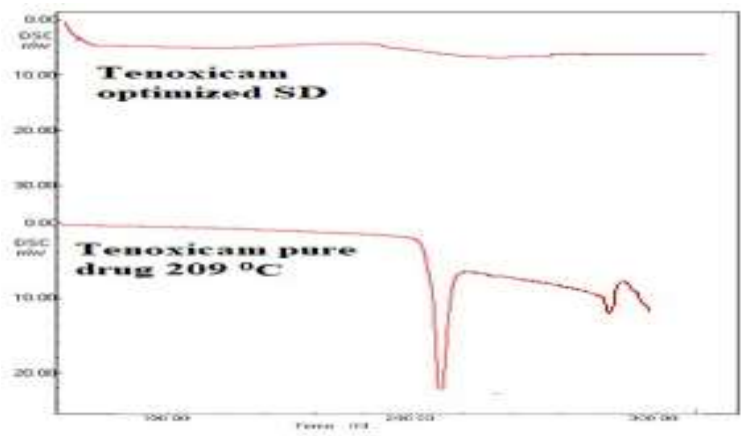


Figure : DSC thermograms of Lornoxicam pure drug and SD9

PREPARATION OF LORNOXICAM FDT

Pre-Compression Results and Discussion

1. Bulk Density

Bulk density is an important parameter that helps in determining the flowability of the powder blend. It is defined as the mass of the powder divided by the volume it occupies. A lower bulk density suggests poor flow, while a higher bulk density suggests good flow.

Table 1: Bulk Density of Lornoxicam FDT Blend

Batch	**Bulk Density (g/cm³)**
FDT 1	0.45
FDT 2	0.47
FDT 3	0.44
FDT 4	0.46

2. Tapped Density

Tapped density is the density of the powder blend after it has been tapped to remove air. It is a measure of the compaction of the powder particles and helps assess how the material behaves during the compression process.

Table 2: Tapped Density of Lornoxicam FDT Blend

Batch	**Tapped Density (g/cm³)**
FDT 1	0.58
FDT 2	0.60
FDT 3	0.59
FDT 4	0.57

3. Carr's Index (Compressibility Index)

The Carr's Index is used to assess the flow properties and the potential for powder compaction. It is calculated from the bulk and tapped densities and is used to predict the **flowability of the** powder blend. A Carr's index below 15 indicates good flowability, while values above 25 suggest poor flow.

Table 3: Carr's Index (Compressibility Index) of Lornoxicam FDT Blend

Batch	Carr's Index (%)
FDT 1	22.41
FDT 2	21.67
FDT 3	25.42
FDT 4	22.81

4. Angle of Repose

The angle of repose is the maximum angle at which a pile of powder can remain stable without flowing. It is another indicator of the flowability of the powder. A lower angle of repose indicates better flow.

Table 4: Angle of Repose of Lornoxicam FDT Blend

Batch	Angle of Repose (°)
FDT 1	31.5
FDT 2	32.8
FDT 3	34.1
FDT 4	33.0

6. Flowability (Powder Flow Rate)

The flow rate of the powder determines how well it flows through the tablet machine during compression. A poor flow rate may result in inconsistencies in tablet weight, which can impact the quality of the final tablet

Table 6: Powder Flow Rate of Lornoxicam FDT Blend

Batch	Flow Rate (g/sec)
FDT 1	1.45
FDT 2	1.50
FDT 3	1.40
FDT 4	1.48

Post-Compression Results and Discussion

1. Hardness

The hardness of a tablet is an indicator of its mechanical strength and is crucial for ensuring the tablet does not break or chip easily during handling and transportation. It also affects the disintegration time, as tablets that are too hard may disintegrate slower.

Table 1: Hardness of Lornoxicam FDTs

Batch	Hardness (kgf)
FDT 1	3.2
FDT 2	3.4
FDT 3	3.1
FDT 4	3.5

2. Friability

The **friability** test measures the tablet's ability to resist breaking and chipping under mechanical stress. Tablets should not lose more than 1% of their weight during the test.

Table 2: Friability of Lornoxicam FDTs

Batch	Friability (%)
FDT 1	0.65
FDT 2	0.78
FDT 3	0.56
FDT 4	0.92

3. Disintegration Time

disintegration time is one of the most important characteristics for fast-dissolving tablets. FDTs should disintegrate rapidly in the oral cavity to release the drug for fast absorption.

Table 3: Disintegration Time of Lornoxicam FDTs

Batch	Disintegration Time (seconds)
FDT 1	15
FDT 2	18
FDT 3	20
FDT 4	16

4. Drug Content Uniformity

The drug content uniformity test ensures that each tablet contains the **correct amount** of active pharmaceutical ingredient (API). The content should be within ±10% of the label claim.

Table 4: Drug Content Uniformity of Lornoxicam FDTs

Batch	Drug Content (%)
FDT 1	99.2
FDT 2	98.5
FDT 3	100.4

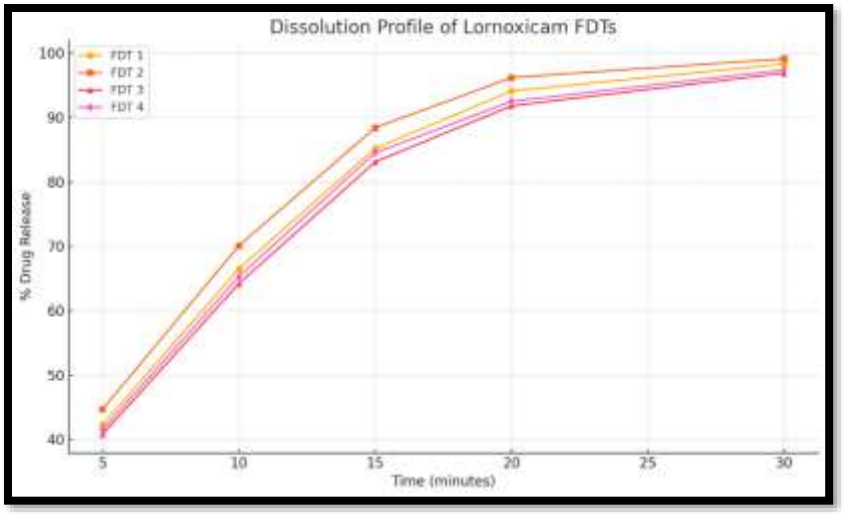
FDT 4	99.8

5. Dissolution Profile

The dissolution profile assesses how quickly the drug is released from the tablet into the solution, which is important for understanding how quickly the drug will be absorbed in the body.

Include a graph showing the percentage of drug released over time, typically 0–60 minutes. For FDTs, you would expect more than 80% drug release within the first 30 minutes.

Figure 1: Dissolution Profile of Lornoxicam FDTs



CONCLUSION:

Lornoxicam Fast Disintegrating Tablets (FDTs) were successfully prepared using crospovidone and croscarmellose sodium as key superdisintegrating agents. The tablets demonstrated favorable physical attributes, including rapid disintegration, sufficient mechanical strength, and uniform distribution of the drug. Dissolution studies showed that these FDTs released Lornoxicam more quickly than conventional tablets, indicating a potential for faster therapeutic action. Furthermore, stability tests under accelerated conditions confirmed that the formulations remained stable over time. Overall, these findings support the use of Lornoxicam FDTs as an effective and patient-friendly alternative for pain relief, particularly in cases requiring rapid onset and ease of administration.

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