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Development and Evaluation of Fast Dissolving Oral Film of Meloxicam

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Abstract: *The present study aimed to formulate and evaluate fast dissolving oral films of Meloxicam using the solvent casting method with suitable film-forming polymers such as methyl cellulose and hydroxypropyl methyl cellulose. Preformulation studies confirmed the physicochemical properties of the drug, while FTIR analysis indicated compatibility between the drug and excipients. Six formulations (F1–F6) were developed and evaluated for various parameters including physical appearance, thickness, folding endurance, weight variation, surface pH, drug content, disintegration time, and in vitro drug release.*

Among all formulations, F5 was identified as the optimized formulation based on its superior mechanical properties, rapid disintegration (38 ± 2 seconds), and maximum drug release (99.10% within 10 minutes). Stability studies of the optimized formulation showed no significant changes in physicochemical properties under accelerated conditions. The study concluded that fast dissolving oral films of Meloxicam provide a promising alternative to conventional dosage forms by offering rapid onset of action, improved bioavailability, and better patient compliance.

Keywords: Meloxicam, Fast dissolving oral films, Solvent casting method, Buccal drug delivery, Polymer films, Bioavailability enhancement, NSAIDs, Oral thin films

I. INTRODUCTION

Oral drug delivery is one of the most preferred and convenient routes for administering therapeutic agents because of its ease of administration, stability, accurate dosing, and simple manufacturing process. In recent years, advanced technologies have introduced several novel oral dosage forms suitable for pediatric, geriatric, nauseous, and non-compliant patients. Among these, polymeric films designed for drug delivery through the buccal cavity have gained considerable attention.[1]

Fast dissolving films (FDFs) represent an advanced oral solid dosage form offering improved flexibility, convenience, and patient comfort. These films rapidly dissolve within a few minutes after coming into contact with saliva, leading to quick hydration and disintegration in the oral cavity. As a result, the drug is released for oromucosal and intragastric absorption without the need for chewing or water intake. The large surface area of the oral mucosa, ease of swallowing, and painless administration make this route highly attractive for systemic drug delivery. In addition, FDFs improve patient compliance and provide significant commercial advantages.[2]

Fast dissolving films are generally prepared as thin strips using techniques such as solvent casting, hot-melt extrusion, and rolling methods. Due to their thin structure, these films exhibit rapid disintegration; however, the amount of drug incorporated is usually limited to approximately 60 mg. Compared with lyophilized dispersible tablets, FDFs are less brittle and more resistant to humidity. This dosage form is suitable for a variety of drugs including analgesics, antihistamines, cardiovascular agents, antiasthmatics, neuroleptics, and drugs used in erectile dysfunction. They are also beneficial when local action is required, such as in the treatment of oral ulcers, toothache, and cold sores.

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Furthermore, FDFs are particularly advantageous for drugs undergoing extensive first-pass metabolism, as they can improve bioavailability.[3]

Meloxicam (MLX) was selected as the model drug for the present study. Meloxicam is a Biopharmaceutics Classification System (BCS) class II drug belonging to the oxicam class of non-steroidal anti-inflammatory drugs (NSAIDs). It possesses anti-inflammatory, analgesic, and antipyretic properties and is commonly used in the treatment of osteoarthritis, rheumatoid arthritis, and other joint disorders in both adults and children. However, Meloxicam exhibits poor aqueous solubility, resulting in low oral bioavailability. Therefore, improving its solubility and dissolution rate is therapeutically important.[4]

Among the various approaches used to enhance the dissolution of poorly water-soluble drugs, the solid dispersion technique has proven to be highly effective. Several methods such as solid dispersion systems, co-solvency techniques, cyclodextrin complexation, and rapid disintegrating formulations have been investigated to improve the solubility and dissolution behavior of Meloxicam.[5]

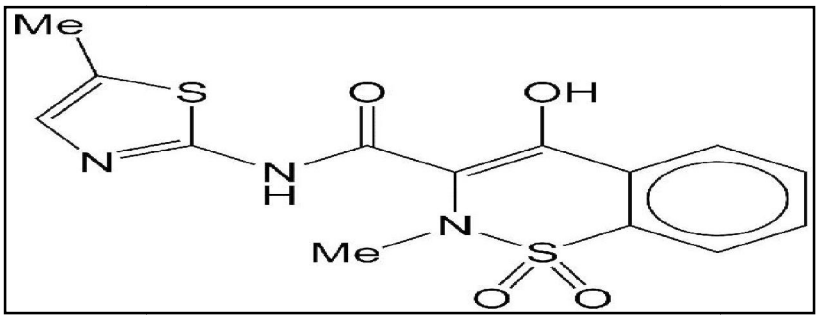

Figure 1: Chemical Structure of Meloxicam

Materials

All the materials used in the present study were of analytical grade. Meloxicam was obtained as an active pharmaceutical ingredient (API) from Dhamtec Pharma. Polymers such as Methyl Cellulose and Hydroxypropyl Methyl Cellulose (HPMC), plasticizers including PEG 400 and Glycerin, surfactant Tween 80, Citric Acid as a saliva stimulating agent, Sodium Saccharin as a sweetening agent, and Isopropyl Alcohol as solvent were procured from Ozone International. All chemicals and reagents used during the study were suitable for pharmaceutical and analytical applications.

Table: Composition of Fast Dissolving Oral Film of Meloxicam

Ingredients	F1	F2	F3	F4	F5	F6
Meloxicam	80 mg	80 mg	80 mg	80 mg	80 mg	80 mg
MC	50 mg	100 mg	120 mg	180 mg	200 mg	250 mg
HPMC	250 mg	200 mg	180 mg	120 mg	100 mg	50 mg
Citric Acid	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
Sodium saccharin	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
PEG 400	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Isopropyl alcohol	q.s	q.s	q.s	q.s	q.s	q.s
Distill water	q.s	q.s	q.s	q.s	q.s	q.s

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EXPERIMENTAL WORK

Pre-formulation Studies

Preformulation studies were conducted to evaluate the physicochemical properties and excipient compatibility of Meloxicam for the development of fast dissolving oral films. The drug was identified as a yellow, odourless crystalline powder. Solubility studies indicated that Meloxicam is practically insoluble in water but soluble in methanol and slightly soluble in ethanol, highlighting the need for solubility enhancement. The melting point was found to be 254–256°C, confirming the purity of the drug. FTIR compatibility studies showed characteristic functional group peaks without significant changes in the drug–excipient mixture, indicating no chemical interaction and confirming excipient compatibility. Overall, the studies demonstrated that Meloxicam is suitable for formulation into a stable and effective fast dissolving oral film. [6]

Determination of Solubility

The solubility study of Meloxicam was carried out in different solvents such as distilled water, ethanol, methanol, and phosphate buffer pH 6.8. An excess amount of the drug was added separately to each solvent in stoppered conical flasks and shaken continuously using a mechanical shaker for 24 hours at room temperature to attain equilibrium. The solutions were then filtered through Whatman filter paper to remove undissolved particles. The filtrates were suitably diluted and analysed spectrophotometrically to determine the concentration of dissolved drug. [7]

Determination of Melting Point

The melting point of Meloxicam was determined using the capillary method to assess the purity and identity of the drug sample. A small quantity of the drug was filled into a sealed capillary tube and placed in a melting point apparatus. The temperature was gradually increased, and the point at which the drug started to melt and completely liquefied was recorded. The sharp melting range indicates the purity of the drug and confirms the absence of significant impurities or degradation products. [8]

Organoleptic Properties

The organoleptic properties of Meloxicam were evaluated to assess its physical characteristics, which are important for identification and handling during formulation. The drug was observed visually for colour, Odor, and appearance. [9]

UV Spectroscopy

UV spectroscopic analysis was performed to determine the λmax of Meloxicam, which was found to be approximately:

$$\lambda_{max} \approx 362 \text{ nm}$$

The calibration curve showed good linearity according to Beer-Lambert's law. [10]

Preparation of Standard Calibration Curve

A standard calibration curve of Meloxicam was prepared in phosphate buffer pH 6.8 using concentrations of 2–16 µg/mL. Absorbance was measured at 362 nm, and the drug showed linearity within the selected range. [11]

Drug–Excipient Compatibility Study (FTIR)

FTIR studies were carried out to identify possible interactions between the drug and excipients. The characteristic peaks of the drug remained unchanged, indicating compatibility. [12]

Formulation Design of Fast Dissolving Oral Film

The oral film area was fixed at 6 cm² containing 7.5 mg of drug. The total drug required per Petri dish was calculated as:

$$10.6 \times 7.5 = 80 \text{ mg}$$

Formulation of Fast Dissolving Oral Film

Fast dissolving oral films of Meloxicam were prepared by solvent casting method using Methyl Cellulose and HPMC as film-forming polymers, PEG 400 and Glycerin as plasticizers, Sodium Saccharin as sweetener, and Isopropyl Alcohol as solvent. The prepared solution was cast into Petri dishes, dried, and cut into uniform films. [13]

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Table: Evaluation parameter [14]

Sr. No.	Evaluation Parameter	Purpose/Significance
1	Weight Variation	To determine uniformity of film weight and drug distribution
2	Thickness	To ensure uniform thickness and consistency of films
3	Folding Endurance	To evaluate flexibility and mechanical strength of the film
4	Tensile Strength	To measure the mechanical resistance of the film against breaking
5	Percent Elongation	To determine elasticity and stretching ability of the film
6	Transparency	To assess clarity and appearance of the film
7	Content Uniformity	To determine uniform distribution of Meloxicam in films
8	Surface pH	To ensure compatibility with buccal mucosa and avoid irritation
9	Moisture Content	To determine the amount of moisture present in the film
10	Disintegration Time	To measure the time required for complete disintegration of the film
11	In Vitro Dissolution Study	To evaluate the drug release profile from the film formulation

Percent Elongation

$$\% \text{ Elongation} = \frac{L \times 100}{L_0}$$

Moisture Content

$$\% \text{ Moisture Content} = \frac{(\text{Initial Weight} - \text{Final Weight}) \times 100}{\text{Initial Weight}}$$

In Vitro Dissolution Study

The dissolution study was performed using USP paddle apparatus in phosphate buffer pH 6.8 at 37 ± 0.5°C and 50 RPM. Samples were analyzed at 362 nm. [15]

Stability Study

Stability studies were carried out according to ICH guidelines by storing the films at 40 ± 2°C and 75 ± 5% RH for three months. The films were evaluated for physical appearance, drug content, and drug release after storage. [16]

RESULT AND DISCUSSION

Preformulation Study

Organoleptic Properties

Meloxicam was observed as a pale yellow, odorless crystalline powder with a bitter taste and smooth texture, confirming its identity and suitability for formulation.

Table: Organoleptic Properties

Property	Observation
Appearance	Crystalline powder
Odor	Odorless
Taste	Bitter
Color	Pale yellow
Texture	Fine and smooth

Solubility Study

Meloxicam was slightly soluble in water and phosphate buffer pH 6.8, soluble in ethanol, freely soluble in methanol and 0.1 N NaOH, and very slightly soluble in 0.1 N HCl.

Table: Solubility of Meloxicam

Solvent	Solubility
Water	Slightly soluble
Ethanol	Soluble

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Methanol	Freely soluble
Phosphate buffer pH 6.8	Slightly soluble
0.1 N HCl	Very slightly soluble
0.1 N NaOH	Freely soluble

Melting Point Determination

The melting point of Meloxicam was found to be 254–256°C, indicating purity of the drug sample.

UV Spectroscopy

The λmax of Meloxicam was observed at:

$$\lambda_{max} = 362 \text{ nm}$$

Standard Calibration Curve of Meloxicam

The calibration curve of Meloxicam in the concentration range of 2–16 µg/mL showed a linear relationship between concentration and absorbance, confirming Beer–Lambert's law.

Table: Standard Calibration Curve of Meloxicam

Concentration (µg/ml)	Absorbance
2	0.078
4	0.205
6	0.309
8	0.44
10	0.526
12	0.642
14	0.736
16	0.848

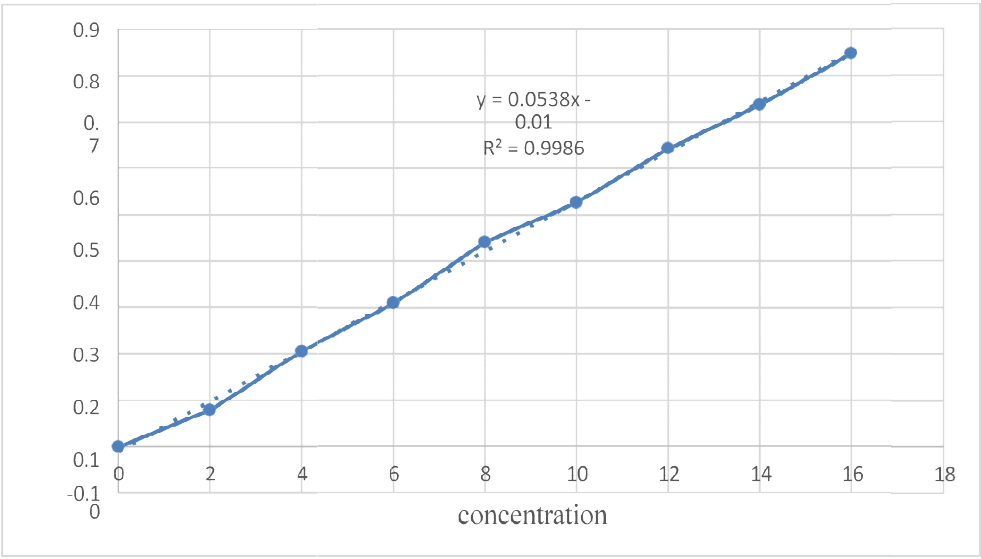

Figure: Standard Calibration Curve of Meloxicam

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Compatibility Study (FTIR)

The FTIR spectrum of Meloxicam (Figure 7.2) showed all characteristic peaks of the drug, confirming its identity and purity. Important functional group peaks such as N–H stretching (3283 cm^{-1}), C–H stretching (2987 cm^{-1}), aromatic C=C stretching (1522 cm^{-1}), and S=O stretching (1154 cm^{-1}) were observed clearly.

No significant shift or disappearance of peaks was found, indicating no drug–excipient interaction. Thus, the drug is compatible with the selected excipients.

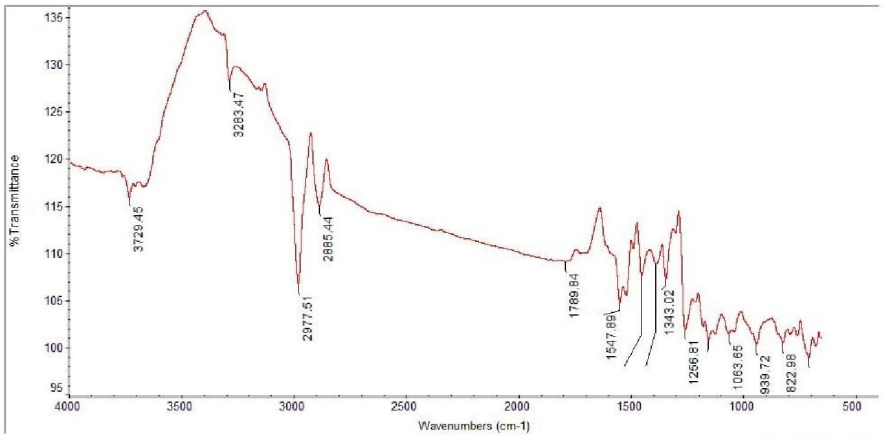

Figure: IR Spectra of Pure Drug Meloxicam

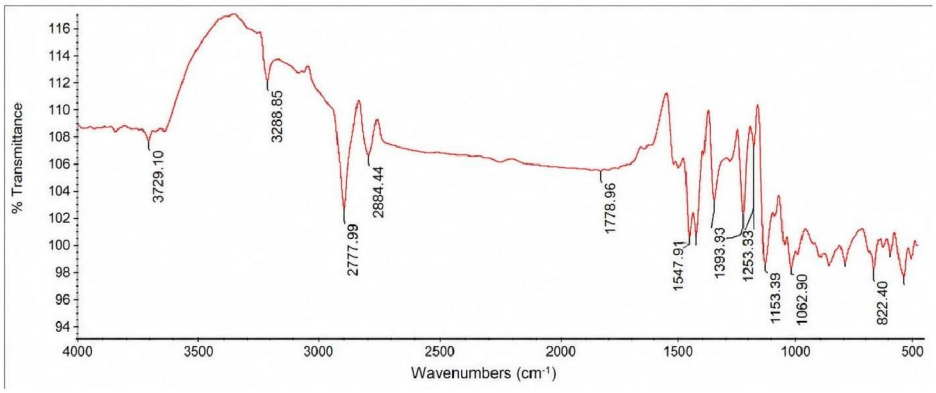

Figure: IR Spectra of Combination of Meloxicam+ MC+HPMC

Evaluation of Fast Dissolving Oral Film

Physical Appearance

All formulations of Meloxicam fast dissolving oral films were uniform, flexible, and smooth. Most films were transparent, while some showed slight translucency and stickiness due to polymer and plasticizer variation. Among all, formulation **F5**showed the best appearance (transparent, smooth, non-sticky, and flexible), indicating optimum formulation.

Table : Physical Evaluation of FDOFs

Formulation	Observation
F1	Transparent, smooth, flexible
F2	Transparent, slightly smooth, flexible
F3	Transparent, slightly sticky

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F4	Translucent, smooth, flexible
F5	Transparent, smooth, non-sticky, flexible
F6	Slightly translucent, smooth, flexible

Thickness

The film thickness ranged from **0.20 ± 0.01 to 0.24 ± 0.03 mm**, showing uniform casting. Formulation **F5** showed optimum thickness with good handling properties.

Table : Thickness of Meloxicam FDOFs

Formulation	Thickness (mm) ± SD
F1	0.20 ± 0.01
F2	0.22 ± 0.02
F3	0.24 ± 0.03
F4	0.23 ± 0.01
F5	0.21 ± 0.01
F6	0.22 ± 0.02

Folding Endurance

Folding endurance values ranged from **210 ± 5 to 290 ± 6**, indicating good flexibility of all films. The highest value was observed in **F5 (290 ± 6)** due to optimized polymer ratio, providing better mechanical strength and flexibility.

Table : Folding Endurance of Meloxicam FDOFs

Formulation	Folding Endurance ± SD
F1	210 ± 5
F2	235 ± 4
F3	255 ± 5
F4	270 ± 6
F5	290 ± 6
F6	265 ± 5

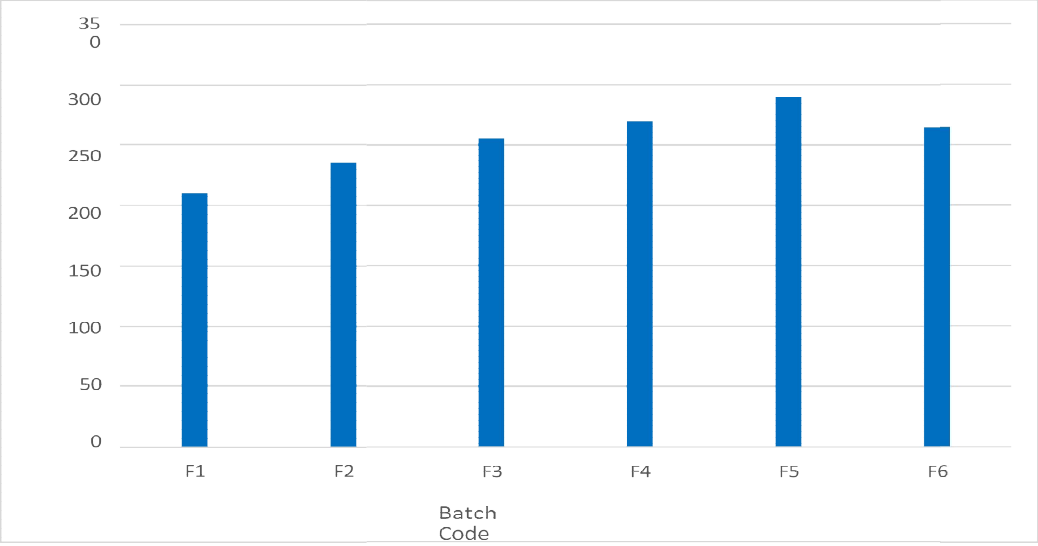

Figure: Folding Endurance Values of Batch Formulation F1 to F6

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Weight Variation

The weight of Meloxicam oral films ranged from **70 ± 2 mg to 110 ± 3 mg**, indicating uniform distribution of drug and excipients. All formulations showed acceptable and consistent weight. F3 and F5 showed similar weight (**80 ± 2 mg**) indicating good reproducibility.

Table : Weight Variation

Formulation	Weight (mg) ± SD
F1	100 ± 2
F2	70 ± 2
F3	80 ± 2
F4	110 ± 3
F5	80 ± 2
F6	90 ± 2

Surface pH

The surface pH of Meloxicam films ranged from **6.34 ± 0.08 to 6.72 ± 0.08**, close to salivary pH, indicating no risk of oral irritation. F5 showed the most favorable near-neutral pH.

Table: Surface pH

Formulation	Surface pH ± SD
F1	6.34 ± 0.08
F2	6.40 ± 0.07
F3	6.48 ± 0.09
F4	6.41 ± 0.06
F5	6.72 ± 0.08
F6	6.60 ± 0.10

Drug Content

Drug content was found to be within **95.5 ± 1.4% to 98.4 ± 1.0%**, confirming uniform drug distribution in all formulations. F5 showed the highest drug content (**98.4 ± 1.0%**), indicating better formulation uniformity.

Table : Drug Content

Formulation	Drug Content (%) ± SD
F1	96.8 ± 1.2
F2	95.5 ± 1.4
F3	97.2 ± 1.1
F4	96.0 ± 1.3
F5	98.4 ± 1.0
F6	97.0 ± 1.2

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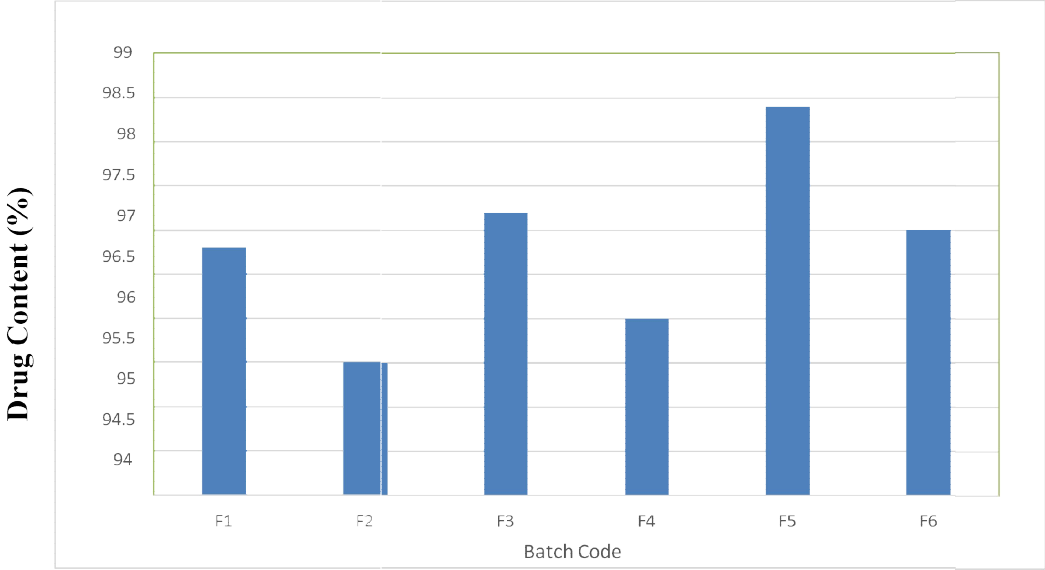

Figure: Drug Content (%) of all Batches of Meloxicam

Disintegration Time

The disintegration time of Meloxicam fast dissolving oral films ranged from **38 ± 2 to 56 ± 3 seconds**, showing rapid disintegration suitable for fast drug release. Among all formulations, **F5 showed the fastest disintegration (38 ± 2 s)**, indicating superior performance and faster onset of action.

Table: Disintegration Time

Formulation	Disintegration Time (sec) ± SD
F1	56 ± 3
F2	50 ± 2
F3	46 ± 3
F4	42 ± 2
F5	38 ± 2
F6	40 ± 3

In Vitro Dissolution Study

The in vitro drug release of Meloxicam films showed rapid and sustained release for all formulations (F1–F6). Drug release increased steadily with time, confirming fast dissolving behavior.

At 5 minutes, F5 showed the highest release (**96.20%**), while at 10 minutes it reached **99.10%**, indicating almost complete drug release and best performance among all batches. Hence, **F5 was selected as the optimized formulation**.

Table : In Vitro Drug Release (%)

Time (min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	18.20	26.12	27.45	31.35	40.20	34.20
2	34.50	39.48	46.98	49.56	60.28	53.30

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3	49.35	57.65	59.13	66.36	75.55	68.08
4	63.51	69.34	74.21	79.80	88.61	81.80
5	76.68	84.36	87.37	91.25	96.20	90.50
10	89.20	94.51	96.30	98.60	99.10	97.50

Conclusion: F5 showed the best disintegration and highest drug release, making it the optimized formulation.

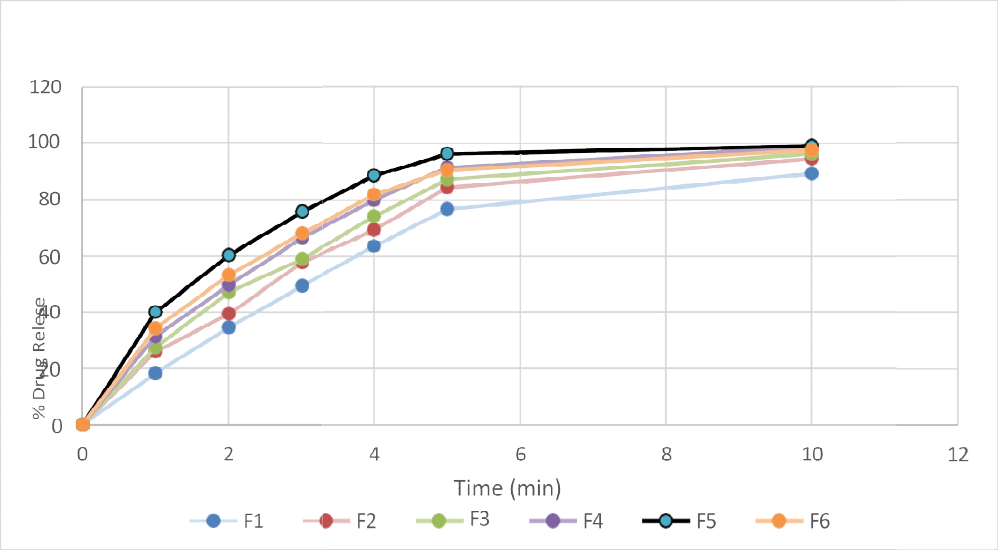

Figure: Comparative In-Vitro Dissolution Profile of Fast Dissolving Oral Film Formulation of Formulation F1 to F6

Stability Study

The stability study of optimized formulation **F5** of Meloxicam was conducted at **40 ± 2°C and 75 ± 5% RH for 90 days**to evaluate its physicochemical stability.

After storage, no significant changes were observed in key parameters such as folding endurance, drug content, drug release, and disintegration time. Only minor variations were noted, indicating good stability of the formulation.

Table : Stability Data of Optimized F5

Parameter	Before Storage	After Storage (3 months)
Folding Endurance	290 ± 4	289 ± 3
Drug Content (%)	98.4 ± 1.0	98.0 ± 0.8
% Drug Release	99.10 ± 1.5	98.30 ± 1.2
Disintegration Time (sec)	38 ± 2	39 ± 2

Conclusion: The optimized formulation F5 remained stable under accelerated conditions, showing no significant deterioration in performance.

II. CONCLUSION

The present study successfully developed fast dissolving oral films of Meloxicam using the solvent casting method with suitable polymers. Preformulation and FTIR studies confirmed drug suitability and compatibility with excipients.

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All formulations showed acceptable physicochemical properties with rapid disintegration and satisfactory drug release. Among them, **F5 was the optimized formulation**, showing the fastest disintegration, best mechanical properties, and highest drug release.

Stability studies confirmed that F5 remained stable without significant changes in its characteristics. Overall, the study concluded that fast dissolving oral films of Meloxicam are an effective alternative to conventional dosage forms, offering improved dissolution, faster onset of action, and better patient compliance.

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