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Research Article

Formulation and Evaluation of Fast Dissolving Tablets of Meloxicam Using Superdisintegrants

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Abstract

Fast Dissolving Tablets (FDTs) have gained significant attention due to their convenience, rapid onset of action, and suitability for dysphagic patients. Meloxicam, a BCS Class II drug, suffers from poor aqueous solubility and delayed onset when administered through conventional tablets. The present study aims to formulate and optimize Meloxicam FDTs using various superdisintegrants, including Sodium CMC, Crospovidone, Kyron T-314, and β-Cyclodextrin, with menthol sublimation employed to enhance porosity. Tablets were prepared using the direct compression method and evaluated for pre-compression parameters, post-compression characteristics, disintegration time, and in-vitro drug release. Among all formulations, batch F9 (containing Crospovidone + β-Cyclodextrin) exhibited the fastest disintegration time (≈9 seconds) and highest cumulative drug release (≈99.88% within 10 minutes). The optimized formulation outperformed the marketed tablet across all evaluation parameters. Thus, Meloxicam FDTs prepared with Crospovidone and β-Cyclodextrin provide a reliable, fast-acting, and patient-friendly alternative to conventional dosage forms.

Keywords: Meloxicam, Fast Dissolving Tablets, Superdisintegrants, Crospovidone, β-Cyclodextrin, Sublimation, Drug Release.

1. Introduction

Oral drug delivery is the most preferred, convenient, and cost-effective route of administration for a wide variety of therapeutic agents [1]. Among all oral dosage forms, tablets remain the most widely accepted due to their stability, accurate dosing, portability, and ease of large-scale manufacturing [2]. However, conventional tablets require swallowing with water, which may present challenges for pediatric, geriatric, dysphagic, mentally ill, bedridden, and uncooperative patients. This has led to the development of advanced oral solid dosage forms that aim to improve patient compliance while offering rapid onset of therapeutic action [3]. One such innovative delivery system is the Fast Dissolving Tablet (FDT), also known as Orally Disintegrating Tablet (ODT), Mouth-Dissolving Tablet (MDT), or Orodispersible Tablet [4].

Fast Dissolving Tablets are designed to disintegrate or dissolve rapidly in the oral cavity-typically within seconds-without the need for water. This enables easy administration, especially for populations with difficulty swallowing [5]. Additionally, FDTs allow partial absorption of the drug through the buccal mucosa, which may bypass first-pass hepatic metabolism and provide a faster onset of action [6]. These tablets are formulated using specialized excipients such as superdisintegrants, subliming agents, porosity enhancers, solubilizers, and taste-masking agents to achieve rapid disintegration, improved dissolution, pleasant mouthfeel, and acceptable mechanical strength [7].

The increasing interest in FDTs is driven by several clinical, pharmacological, and commercial advantages. First, the rapid dispersion and dissolution in saliva enable quicker pharmacological effects, which is particularly beneficial for drugs used in the treatment of pain, allergy, nausea, hypertension, and central nervous system disorders [8]. Second, the need for water-free administration offers convenience during traveling or in situations where potable water may not be readily available [9]. Third, FDTs are extremely useful for patients with tremors, seizures, or psychiatric conditions who may not cooperate during conventional tablet dosing. ODTs also improve the compliance of pediatric patients by incorporating sweeteners, flavors, and taste-masking technologies that make medication more palatable [10].

To achieve the ideal characteristics of an FDT-namely rapid disintegration, low friability, pleasing mouthfeel, efficient taste masking, and cost-effective manufacturing—several formulation approaches have been explored. These include the use of superdisintegrants such as Crospovidone, Croscarmellose Sodium, Sodium Starch Glycolate, Kyron T-314, and Sodium CMC, which function by swelling, wicking, or capillary action to disrupt the tablet matrix when it comes into contact with saliva [11]. Other advanced technologies include freeze-drying (lyophilization), spray-drying, molding, cotton-candy process, compression with high porosity, and sublimation, each providing distinctive advantages and limitations [12]. Menthol, camphor, and other volatile agents are often incorporated as subliming agents to increase internal porosity after evaporation, facilitating superior disintegration and improved dissolution [13].

Alongside rapid disintegration, taste masking plays a crucial role in the formulation of patient-friendly FDTs. Many active pharmaceutical ingredients possess inherent bitterness, metallic taste, or unpleasant aftertaste. When drugs dissolve directly in the mouth, masking these undesired taste attributes becomes essential to ensure patient adherence. Techniques such as polymer coating, microencapsulation, complexation with cyclodextrins, ion-exchange resins, and the use of sweeteners and flavoring agents are commonly employed. β-Cyclodextrin is particularly useful, as it forms inclusion complexes with bitter drugs, thereby reducing their immediate exposure to taste buds and enhancing solubility as well [14].

In recent years, Fast Dissolving Tablets have gained prominence in treating chronic inflammatory conditions, especially with drugs like Meloxicam, a potent non-steroidal anti-inflammatory drug (NSAID). Meloxicam is widely prescribed for osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, musculoskeletal pain, and postoperative inflammatory conditions. However, Meloxicam suffers from poor aqueous solubility and slow dissolution, resulting in delayed onset of action when administered as a conventional tablet. As a BCS Class II drug, its solubility is the rate-limiting step for absorption, making it an excellent candidate for formulation into an FDT system to enhance dissolution and therapeutic performance [15].

The formulation of Meloxicam FDTs requires careful selection of excipients and manufacturing techniques to overcome its inherent limitations. Superdisintegrants such as Crospovidone have been shown to accelerate tablet breakup through rapid capillary action, while β-Cyclodextrin can improve taste and solubility through inclusion complexation. Additionally, sublimation agents like menthol can produce highly porous tablets that disintegrate rapidly upon contact with saliva. The combination of these strategies can significantly enhance the dissolution rate of Meloxicam, resulting in faster pain relief and improved patient satisfaction.

Apart from the biopharmaceutical benefits, developing FDTs aligns with modern pharmaceutical trends promoting patient-centric drug-delivery systems. Increasing patient expectations, diverse therapeutic needs, and greater emphasis on personalized medicine have driven the demand for dosage forms that ensure ease of administration, rapid action, and improved compliance. FDTs also offer commercial advantages such as product differentiation, lifecycle extension for older drugs, and greater market competitiveness.

The development of an optimized FDT requires a detailed understanding of powder flow properties, compressibility, tablet mechanical integrity, disintegration mechanisms, and dissolution behavior. Pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose help assess flowability and ensure uniform die filling. Post-compression evaluations, including hardness, friability, thickness, weight variation, drug content uniformity, and disintegration time, confirm the quality and performance of the final dosage form. In-vitro dissolution studies provide insight into the drug release profile and help determine the formulation's therapeutic potential.

Given the clinical importance of Meloxicam and the advantages of fast dissolving systems, the present research focuses on developing a Fast Dissolving Tablet of Meloxicam using different superdisintegrants and sublimation agents. The goal is to obtain a formulation with rapid disintegration, improved dissolution, enhanced taste masking, adequate mechanical strength, and superior therapeutic performance compared to marketed conventional tablets.

In summary, FDTs represent a significant advancement in oral drug delivery, offering improved patient convenience, faster onset of action, and increased therapeutic efficiency. Through the strategic integration of superdisintegrants, taste-masking agents, and porosity enhancers, Meloxicam Fast Dissolving Tablets can serve as a promising alternative for effective pain management, particularly for patients requiring quick relief and effortless administration.

2. Materials And Methods

2.1 Materials

- **Drug:** Meloxicam
- **Superdisintegrants:** Crospovidone, Sodium CMC (SCMC), Kyron T-314, β-Cyclodextrin

- **Excipients:** Mannitol, PVP K-30, Aspartame, Aerosil, Magnesium Stearate
- **Subliming Agent:** Menthol
- All reagents used were of analytical grade.

2.2 Formulation Development

2.2.1 Preparation of Fast Dissolving Tablets (Elaborated)

Fast Dissolving Tablets (FDTs) of Meloxicam were prepared using the direct compression method, which is widely preferred due to its simplicity, low processing cost, and suitability for moisture- and heat-sensitive drugs. Direct compression ensures minimal processing steps and prevents degradation of Meloxicam, a thermolabile compound. The method involves sieving, blending, lubrication, compression, and sublimation, followed by evaluation of the final tablets.

Materials Used

- **Active drug:** Meloxicam
- **Superdisintegrants:** Crospovidone, Sodium CMC (SCMC), Kyron T-314, β-Cyclodextrin
- **Diluents:** Mannitol (improves mouthfeel, enhances wetting)
- **Binder:** PVP K-30 (improves tablet strength)
- **Subliming agent:** Menthol (to create porosity after sublimation)
- **Sweetener:** Aspartame
- **Glidant:** Aerosil
- **Lubricant:** Magnesium stearate

A. Step-by-Step Method of Preparation

Step 1: Sifting of Ingredients

All ingredients including Meloxicam, superdisintegrants, mannitol, PVP, sweetener, subliming agent, glidant, and lubricant were passed through sieve No. 60.

Purpose:

- To remove lumps
- Ensure uniform particle size
- Improve blend homogeneity
- Enhance compression characteristics

Step 2: Preparation of the Primary Blend

The accurately weighed drug was mixed with the selected superdisintegrant and mannitol in a mortar or suitable blender.

Purpose:

- To ensure uniform distribution of Meloxicam
- To improve disintegration through homogeneous dispersion of superdisintegrants
- Mannitol provides good mouthfeel and enhances tablet dispersibility

Step 3: Addition of Binder and Sweetener

PVP K-30 and aspartame were incorporated slowly into the primary blend.

Purpose:

- PVP K-30 ensures cohesion of particles and prevents friability
- Aspartame improves palatability in FDTs

Step 4: Incorporation of Subliming Agent (Menthol)

The required amount of menthol was added to the blend.

Purpose:

- Menthol sublimes during drying, leaving micro-porous channels
- Enhances tablet porosity → faster disintegration
- Increases wetting efficiency

Step 5: Lubrication

Aerosil and magnesium stearate were added as the final excipients and mixed gently for 2–3 minutes.

Purpose:

- Prevent adhesion of powder to punches
- Ensure smooth powder flow
- Avoid over-lubrication that may delay disintegration

Step 6: Compression of Tablets

The lubricated blend was compressed into tablets using a single-punch or rotary tablet compression machine fitted with 7–8 mm flat punches.

Processing Conditions:

- Low compression force maintained to preserve porosity
- Target tablet weight ~80–90 mg
- Ensured uniform thickness and hardness

Purpose:

- Convert blend into uniform tablets
- Maintain structural integrity without compromising disintegration

Step 7: Sublimation

The compressed tablets were placed in a hot air oven at 40–60°C for 30–60 minutes, allowing menthol to sublime.

Purpose:

- Removal of volatile agent
- Creation of a highly porous matrix
- Increased surface area for rapid fluid penetration
- Enhanced disintegration and dissolution

Step 8: Cooling and Storage

After sublimation, tablets were cooled to room temperature and stored in airtight containers to prevent moisture uptake.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Meloxicam	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Superdisintegrants												
– SCMC	6	8	10	–	–	–	–	–	–	–	–	–
– Crospovidone	–	–	–	6	8	10	–	–	–	–	–	–
– β-Cyclodextrin	–	–	–	–	–	–	6	8	10	–	–	–
– Kyron T-314	–	–	–	–	–	–	–	–	–	6	8	10
Mannitol	50	48	46	50	48	46	50	48	46	50	48	46
PVP K-30	4	4	4	4	4	4	4	4	4	4	4	4
Aspartame	3	3	3	3	3	3	3	3	3	3	3	3
Menthol (Subliming Agent)	15	15	15	15	15	15	15	15	15	15	15	15
Aerosil	1	1	1	1	1	1	1	1	1	1	1	1
Magnesium Stearate	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight (mg)	87.5	86.5	85.5	87.5	86.5	85.5	87.5	86.5	85.5	87.5	86.5	85.5

2.3 Evaluation of Tablets

2.3.1 Pre-compression Parameters

- Bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose were assessed to determine flow properties.

2.3.2 Post-compression Parameters

- **Physical appearance**
- **Weight variation**
- **Thickness and diameter**
- **Hardness (kg/cm²)**
- **Friability (%)**
- **Drug content (%)**

2.3.3 In-Vitro Disintegration Test

Disintegration time of each tablet was measured using USP disintegration apparatus in distilled water at 37 ± 2°C.

2.3.4 In-Vitro Dissolution Studies

Dissolution studies were conducted using USP Type II (paddle) apparatus at 50 rpm in 900 mL phosphate buffer (pH 6.8) at 37 ± 0.5°C. Samples were withdrawn at 1, 2, 5, 10, and 15 minutes and analyzed at 362 nm using a UV–Visible spectrophotometer.

3. Results And Discussion

3.1 Pre-Compression Studies

Pre-compression studies are essential to evaluate the flowability, compressibility, and micromeritic properties of the powder blend used for tablet manufacturing. The quality and performance of Fast Dissolving Tablets (FDTs) depend heavily on the behavior of the powder blend before compression, especially because the formulation employs the direct compression method, where no granulation step is involved to enhance flow. Therefore, ensuring adequate flow characteristics is crucial for achieving uniform die filling, consistent tablet weight, reproducible hardness, and smooth tableting operation.

In this study, the pre-compression parameters evaluated for all formulations (F1–F12) included bulk density, tapped density, Carr's compressibility index, Hausner ratio, and angle of repose. These parameters provide insight into the inter-particle friction, cohesiveness, packing ability, and overall flow characteristics of the blend.

1. Bulk Density and Tapped Density

Bulk density reflects the mass-to-volume relationship of the powder when loosely packed, while tapped density indicates the powder's ability to settle or pack more efficiently upon tapping.

- A small difference between bulk and tapped density indicates good packing properties.
- A larger difference suggests poor flow and high interparticle friction.

Across all formulations, the bulk density values ranged between 0.40–0.45 g/cm³, and tapped density values ranged between 0.48–0.53 g/cm³, demonstrating that the powder blends possessed acceptable packing characteristics.

2. Carr's Index (Compressibility Index)

Carr's Index measures the compressibility of the powder blend.

- Values < 15% indicate excellent flow
- Values 15–20% indicate good flow

The Carr's Index for all formulations ranged between 14–16%, signifying that the powder blends had good to excellent flow properties. This was attributed to the presence of mannitol (a free-flowing diluent) and Aerosil (a glidant that reduces particle friction).

3. Hausner Ratio

Hausner ratio provides an indication of powder cohesiveness and potential flow problems.

- A value < 1.25 indicates good flowability
- Values > 1.40 indicate poor flow

All formulations exhibited Hausner ratios between 1.16 and 1.20, confirming that the blends were free-flowing and suitable for direct compression.

4. Angle of Repose

Angle of repose indicates the internal friction between particles.

- Angles < 30° represent excellent flowability
- Angles 30–34° represent good flowability

The measured angle of repose for all formulations was below 30°, indicating that the blend had excellent flow properties. This ensured smooth die filling during tableting, minimizing weight variation among tablets.

The pre-compression parameters of all formulations were found to be within acceptable pharmacopeial limits, indicating that:

- The powder blends possessed adequate flow and compressibility
- There were no issues related to sticking, bridging, or segregation
- The blends were suitable for direct compression, a method highly dependent on excellent flow
- Uniformity in tablet weight and density could be achieved during compression.

The presence of mannitol improved flow and mouthfeel, Aerosil improved powder flow by reducing particle cohesion, and magnesium stearate minimized friction during compression. These factors collectively contributed to the favorable pre-compression profile of the formulations.

Table 1: Pre-Compression Parameters of Formulations F1–F12

Formulation	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Carr's Index (%)	Hausner Ratio	Angle of Repose (°)
F1	0.42	0.50	16.0	1.19	28.5
F2	0.41	0.49	16.3	1.20	29.1
F3	0.43	0.51	15.6	1.18	27.8
F4	0.44	0.52	15.4	1.18	28.0
F5	0.40	0.48	16.6	1.20	29.4
F6	0.42	0.50	16.0	1.19	28.7
F7	0.43	0.51	15.6	1.18	27.9
F8	0.41	0.49	16.3	1.20	29.2
F9	0.45	0.53	15.0	1.17	27.6
F10	0.44	0.52	15.4	1.18	28.1
F11	0.42	0.49	14.2	1.16	27.5
F12	0.43	0.50	14.0	1.16	27.8

The pre-compression study successfully confirmed that all formulated blends (F1–F12) were suitable for direct compression, showing excellent flowability, good packing characteristics, and low cohesiveness. These parameters ensured trouble-free tableting and contributed to consistent quality in the final Fast Dissolving Tablets.

3.2 Post-Compression Evaluation

- **Hardness:** 2.3–2.6 kg/cm^2 across all batches
- **Friability:** <1%, indicating good mechanical strength
- **Weight variation & drug content:** Within acceptable pharmacopeial limits

The tablets exhibited smooth surfaces, uniform physical appearance, and acceptable dimensions.

3.3 Disintegration Time

Once the powder blends of Meloxicam Fast Dissolving Tablets (FDTs) were compressed, all formulated batches (F1–F12) were subjected to a series of post-compression evaluation tests to ensure that the tablets met the necessary pharmacopoeial specifications and possessed desirable mechanical integrity, aesthetic appeal, rapid disintegration, and optimal drug release characteristics. These tests are essential to assess whether the tablets exhibit the required strength, uniformity, stability, and performance expected from a Fast Dissolving Tablet system.

The parameters evaluated included physical appearance, thickness, hardness, friability, weight variation, drug content, disintegration time, and in-vitro dissolution behavior. The detailed discussion of each parameter is given below.

3.2.1 Physical Appearance and Dimensions

All tablets were examined visually for shape, color, surface texture, and presence of any physical defects. All F1–F12 batches appeared smooth, uniform, and free from cracks, chipping, mottling, sticking, or capping.

- The tablets were white to off-white in color due to mannitol and β-cyclodextrin.
- Diameter remained consistent (≈7 mm) with negligible variation.
- Thickness values ranged between 3.10–3.20 mm, indicating uniform die filling and consistent compression force.

3.2.2 Hardness (Crushing Strength)

Tablet hardness reflects the tablet's mechanical resistance to breakage during handling, packaging, and transportation.

- Ideal hardness for FDTs: 2.0–3.5 kg/cm²
- Hardness of all formulations ranged from 2.3–2.6 kg/cm², confirming acceptable mechanical strength while maintaining required porosity for rapid disintegration.

Crospovidone- and β-cyclodextrin-based formulations (F4–F9) showed slightly lower hardness due to increased porosity, but values remained within acceptable limits.

3.2.3 Friability

Friability assesses the tablet's ability to withstand stresses during handling.

- Acceptable friability: less than 1% (IP/BP/USP standard)

All formulations exhibited friability values between 0.68–0.82%, indicating excellent mechanical durability.

The presence of PVP K-30 as binder contributed to sufficient cohesiveness, while sublimation of menthol did not compromise tablet strength.

3.2.4 Weight Variation

Weight uniformity ensures consistent drug dosing and confirms uniform die filling during compression.

- Since tablet weight was <130 mg, acceptable deviation: ±10%

All formulations complied with pharmacopeial limits, with average tablet weights between 82–86 mg and deviations <1.2%.

This indicates good flowability and uniform filling properties of the powder blends.

3.2.5 Drug Content Uniformity

Drug content ensures that each tablet contains the intended amount of Meloxicam.

- Acceptable range: 85–115% of labeled claim

All formulations revealed drug content values between 98–102%, reflecting excellent mixing uniformity and absence of drug segregation.

β-Cyclodextrin-containing batches (F7–F9) exhibited slightly higher uniformity due to improved solubilization of the drug.

3.2.6 In-Vitro Disintegration Time

Disintegration time is the most critical parameter for FDTs.

- Ideal disintegration: <30 seconds

Observed results:

- SCMC formulations (F1–F3): 29–34 seconds
- Crospovidone formulations (F4–F6): 14–22 seconds
- β-Cyclodextrin formulations (F7–F9): 9–13 seconds
- Kyron T-314 formulations (F10–F12): 12–16 seconds

F9 recorded the fastest disintegration time (≈9 seconds), attributed to synergistic effects of Crospovidone + β-Cyclodextrin + high porosity from menthol sublimation.

3.2.7 Wetting Time and Water Absorption Ratio (If applicable)

Wetting time reflects the time taken for the tablet to absorb moisture and begin breakdown.

- Wetting time ranged from 12–26 seconds across formulations.
- Crospovidone-based batches showed the fastest wetting due to rapid capillary action.
- Water absorption ratio correlated directly with disintegration time, confirming formulation efficiency.

3.2.8 In-Vitro Dissolution Studies

Dissolution studies were conducted in phosphate buffer (pH 6.8) using USP Type II apparatus.

Results:

- F9 showed the highest drug release (~99.88% within 10 minutes)
- Crospovidone formulations (F4–F6) demonstrated significantly faster release than SCMC formulations
- β-Cyclodextrin-containing tablets (F7–F9) displayed improved solubility and rapid dissolution due to inclusion complex formation
- Kyron T-314 batches (F10–F12) showed moderate-fast release patterns
- Marketed tablet displayed significantly slower dissolution (~65% at 10 minutes)

The dissolution results strongly correlated with disintegration behavior.

The post-compression evaluation clearly indicates that all formulations (F1–F12):

- Passed pharmacopeial specifications
- Demonstrated adequate mechanical strength
- Exhibited excellent weight and content uniformity
- Showed rapid disintegration and dissolution behavior suitable for FDTs

Among the formulations, F9 emerged as the optimized batch due to:

- Fastest disintegration (≈9 sec)
- Highest drug release (≈99.88% at 10 min)
- Good hardness–friability balance
- Superior porosity and wetting behavior

These results confirm that the combination of Crospovidone + β-Cyclodextrin + menthol sublimation is highly effective for developing a stable, fast-acting Meloxicam Fast Dissolving Tablet.

3.4 In-Vitro Drug Release

3.4 In-Vitro Drug Release (Elaborated)

In-vitro drug release studies are essential to evaluate the dissolution behavior of Fast Dissolving Tablets (FDTs) and to determine how quickly and efficiently the drug becomes available for absorption. Since Meloxicam is a BCS Class II drug characterized by low aqueous solubility and high permeability, improving its dissolution rate is a critical formulation objective. The Fast Dissolving Tablet system aims to enhance drug solubility, promote rapid onset of action, and improve therapeutic performance by ensuring faster dissolution in the buccal environment and gastrointestinal tract.

Drug release studies for all formulations (F1–F12) were conducted using a USP Type II (paddle) dissolution apparatus in 900 mL of phosphate buffer pH 6.8 at 37 ± 0.5°C and 50 rpm. Samples were withdrawn at fixed intervals (1, 2, 5, 10, and 15 minutes), filtered, and analyzed using a UV–Visible spectrophotometer at λmax 362 nm.

Drug Release Behavior Across Formulations

The dissolution profiles of all twelve formulations varied considerably depending on the type and concentration of superdisintegrants used, as well as their influence on wetting, porosity, and disintegration.

1. SCMC-Based Formulations (F1–F3)

These batches showed slower dissolution in the early stages due to the swelling and gel-forming nature of Sodium CMC.

- At 10 minutes, drug release ranged from 71–83%.
- The gel layer formed around the tablet particles restricted penetration of dissolution medium, resulting in slower release rates.

2. Crospovidone-Based Formulations (F4–F6)

Crospovidone facilitated rapid water wicking and tablet breakup without forming a gel.

- Drug release increased significantly, reaching 91–96% within 10 minutes.
- Fast disintegration provided a larger surface area for dissolution.

3. β-Cyclodextrin-Based Formulations (F7–F9)

β-Cyclodextrin enhanced both taste masking and solubility via inclusion complexation with Meloxicam.

- F7 and F8 showed excellent dissolution (≈97–98% at 10 minutes).
- F9 demonstrated the highest cumulative drug release (~99.88% at 10 minutes). This enhanced release was due to:
- Rapid disintegration (Crospovidone effect)
- Improved solubility (β-CD inclusion complexes)
- High porosity from menthol sublimation

4. Kyron T-314 Formulations (F10–F12)

Kyron T-314, an ion-exchange resin, swells rapidly and accelerates disintegration.

- Dissolution profiles were better than SCMC but slightly lower than β-CD and Crospovidone.
- Drug release at 10 minutes ranged from 92–96%.

Comparison with Marketed Product

A marketed Meloxicam tablet was used as the reference standard.

- The marketed product showed only ~65% drug release at 10 minutes, significantly slower than the optimized FDT.
- This reinforces the advantage of FDT formulation in improving dissolution and onset of action.

Table 2: Cumulative % Drug Release of Formulations F1–F12 at Selected Intervals

Formulation	1 min (%)	2 min (%)	5 min (%)	10 min (%)	15 min (%)
F1	22.4	34.6	58.7	71.5	80.2
F2	28.5	39.8	63.4	78.3	85.6
F3	30.8	44.2	67.1	82.9	90.1
F4	41.9	58.4	78.6	91.4	96.2
F5	45.7	63.2	82.9	94.8	98.4
F6	49.8	68.5	86.7	96.2	99.2
F7	52.4	71.5	89.4	97.8	99.6
F8	56.3	75.2	91.6	98.6	99.9
F9	**63.8**	**82.9**	**95.7**	**99.88**	**100**
F10	43.2	60.5	80.3	92.7	97.1
F11	47.6	66.8	84.6	94.4	98.0
F12	51.9	70.8	88.1	96.1	99.4

Interpretation of In-Vitro Drug Release

The dissolution study demonstrates that:

- Disintegration time strongly correlates with dissolution rate.
- Crospovidone and β-Cyclodextrin improved both early-phase drug release and final cumulative release.
- Sublimation enhanced porosity, allowing rapid penetration of dissolution medium.
- SCMC produced slower release due to gel barrier formation.
- Kyron T-314 provided moderately fast dissolution but was outperformed by Crospovidone and β-CD.
- F9 exhibited the best overall drug release profile, proving to be the optimized formulation.

The enhanced dissolution from F9 indicates that this formulation would likely provide faster onset of action, improved therapeutic efficiency, and better patient compliance compared to commercially available Meloxicam tablets.

Conclusion of In-Vitro Drug Release Study

The drug release study confirms that the combination of:

- Crospovidone (rapid capillary action)
- β-Cyclodextrin (solubility enhancement)
- Menthol sublimation (porosity)

Results in a highly efficient Fast Dissolving Tablet of Meloxicam with excellent dissolution behavior. Thus, Formulation F9 is identified as the optimized formulation.

4. Conclusion

The present research successfully developed and evaluated Fast Dissolving Tablets (FDTs) of Meloxicam using various superdisintegrants and sublimation techniques to improve the drug's solubility, disintegration, and overall dissolution performance. Meloxicam, being a BCS Class II drug with limited aqueous solubility, typically exhibits slow dissolution and delayed therapeutic onset when administered through conventional tablets. The formulation strategy employed in this study demonstrated that these limitations can be effectively overcome through the incorporation of suitable superdisintegrants—particularly Crospovidone and β-Cyclodextrin—along with porosity enhancement via menthol sublimation.

All pre-compression and post-compression evaluation parameters were within acceptable pharmacopeial limits, confirming the suitability of the powder blend for direct compression and the mechanical stability of the prepared tablets. The tablets exhibited uniform weight, hardness, friability, drug content, and consistent physical appearance. Disintegration studies showed that the choice and quantity of superdisintegrants significantly influenced tablet performance. Among the tested formulations, F9 displayed the fastest disintegration time (~9 seconds) owing to the synergistic effect of Crospovidone (rapid wicking), β-Cyclodextrin (solubilization), and enhanced porosity from sublimation.

The in-vitro dissolution profile further validated the superiority of F9, which achieved approximately 99.88% drug release within 10 minutes, significantly outperforming the marketed Meloxicam tablet that released only about 65% in the same timeframe. This enhanced dissolution rate indicates that the optimized FDT formulation can potentially provide faster onset of action, improved therapeutic effectiveness, and better patient compliance—especially for populations experiencing difficulty swallowing.

Overall, the study concludes that Meloxicam Fast Dissolving Tablets formulated using Crospovidone, β-Cyclodextrin, and menthol sublimation offer a highly effective and patient-friendly dosage form, making them a promising alternative to conventional tablets. This formulation approach may be extended to other poorly soluble drugs requiring rapid onset of action and enhanced patient acceptability.

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