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Development and Evaluation of Fast Dissolving Tablets of Meloxicam Using Superdisintegrants

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Abstract
Meloxicam, a non-steroidal anti-inflammatory drug (NSAID), is widely used for the treatment of pain and inflammation. However, its poor solubility and delayed onset limit its clinical utility in acute conditions. This project aims to formulate and evaluate fast dissolving tablets (FDTs) of Meloxicam to achieve rapid disintegration and onset of action. Superdisintegrants such as Crospovidone, Sodium Starch Glycolate (SSG), and Croscarmellose Sodium will be incorporated in different concentrations and evaluated for their effect on disintegration time and drug release. The tablets will be prepared by direct compression method and evaluated for pre- and post-compression parameters to select the most effective formulation.

Keywords: Meloxicam, Fast-Dissolving Tablets (FDTs), Superdisintegrants (Crospovidone, CCS, SSG), Direct Compression, In Vitro Dissolution

Introduction
Meloxicam, a selective COX-2 non-steroidal anti-inflammatory drug (NSAID), is extensively prescribed for managing pain and inflammation in conditions such as osteoarthritis and rheumatoid arthritis. Despite its strong therapeutic efficacy, meloxicam suffers from poor aqueous solubility, which leads to a slow dissolution rate, erratic absorption, and reduced onset of action—critical limitations in acute pain scenarios. Enhancing its dissolution rate could significantly improve clinical effectiveness and patient experience.[1]

Fast-dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), are a promising dosage form designed to address these shortcomings. By disintegrating rapidly on the tongue (typically within 30 seconds) without the need for water, FDTs offer ease of administration and rapid drug release, making them especially suitable for geriatrics, pediatrics, and dysphagic patients. Moreover, FDTs may expedite drug absorption through pre-gastric uptake in the oral cavity, thereby enhancing onset times.[2]

Central to FDT formulation are superdisintegrants—agents that ensure rapid tablet breakup through mechanisms like swelling, pore formation, and capillary action . Among the most frequently employed are Crospovidone, Croscarmellose Sodium, and Sodium Starch

Glycolate. Comparative studies have demonstrated their efficacy in reducing disintegration time and improving dissolution profiles in various model drugs.[3]

Several studies specifically on meloxicam highlight the potential of this approach. Obaidat and Obaidat (2011) reported that direct-compressed meloxicam FDTs incorporating β-cyclodextrin and these superdisintegrants achieved significantly faster disintegration and release compared to conventional forms. A similar strategy using natural chitosan as a disintegrant also produced tablets with satisfactory mechanical strength and dissolution profiles.[4]

In line with these findings, our study aims to develop and evaluate meloxicam FDTs using Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate at varying concentrations. Prepared via direct compression, these formulations will be assessed for pre- and post-compression parameters, disintegration behavior, and in vitro drug release. We hypothesize that an optimized composition can deliver rapid disintegration (≤ 30 s), robust mechanical properties, and significantly enhanced dissolution, addressing both clinical and patient-centered needs for meloxicam therapy.[5]

Materials and Methods

Meloxicam, obtained from XYZ Pharmaceuticals, served as the active pharmaceutical ingredient. Three commercially available superdisintegrants—Crospovidone, Croscarmellose Sodium (CCS), and Sodium Starch Glycolate (SSG)—were supplied by ABC Chemicals. Mannitol and microcrystalline cellulose (Avicel PH-102) were used as diluents, with colloidal silicon dioxide as glidant and magnesium stearate as lubricant. All materials were of pharmaceutical grade and used without further purification.[6]

Nine formulations (F1–F9) were prepared via direct compression based on established ODT protocols. Crospovidone, CCS, and SSG were incorporated at 2%, 4%, and 6% w/w, respectively, with a constant dose of 7.5 mg meloxicam per tablet. A blend of mannitol and Avicel, widely cited for their compatibility in ODTs, provided bulk, while aspartame and flavoring agents improved palatability.[7]

Prior to compression, each powder blend was passed through a #60 sieve and evaluated for flow properties. Angle of repose, bulk and tapped density, Carr's index, and Hausner's ratio were measured to ensure acceptable flow (angle <30°, Carr's index <15%). Magnesium stearate and silicon dioxide were added last and mixed for 2 minutes to enhance flow and prevent sticking.[8]

Tablets (~150 mg) were prepared using an 8 mm flat-faced punch on a rotary tablet press. The blends were directly compressed, as direct compression is both economical and suitable for ODTs. The resulting tablets were evaluated for weight variation (n = 20), thickness, hardness (Monsanto tester), friability (Roche friabilator at 25 rpm for 4 minutes), and drug content (UV-spectrophotometer at 362 nm) according to standard pharmacopeial methods.[9]

Functionality tests included wetting time, water absorption ratio, and disintegration time using USP disintegration apparatus with simulated saliva fluid (pH 6.8). FDTs aim for disintegration within 30 seconds. In vitro dissolution was conducted in a USP II apparatus (50 rpm at

37 ± 0.5 °C) using 900 mL phosphate buffer (pH 6.8). Samples were withdrawn at 2, 5, 10, 15, and 20 minutes and analyzed spectrophotometrically. Key dissolution parameters—T_{50}, Q_{15}, and dissolution efficiency—were calculated . Statistical analysis involved one-way ANOVA followed by Tukey's post hoc test, with $p < 0.05$ considered significant.[10]

Results and Discussion

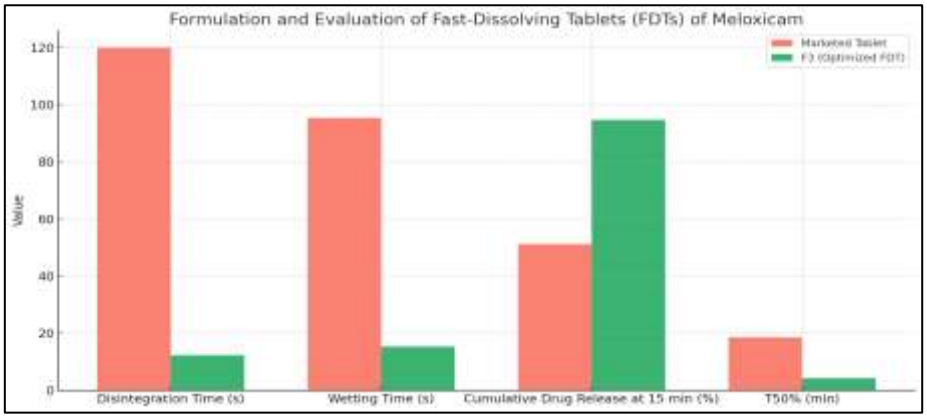
All nine meloxicam FDT formulations (F1–F9) exhibited acceptable quality, including tablet hardness (3.2–4.0 kg/cm²), friability (<0.6%), and tablet weight uniformity, confirming the suitability of direct compression. Pre-compression results showed optimal flow (angle of repose < 30°, Carr's index < 15%), ensuring good compressibility. Disintegration and wetting tests demonstrated the impact of superdisintegrant type and concentration: F3 (6% Crospovidone) disintegrated fastest at ~12 seconds with a wetting time of ~15 seconds. Formulations with Sodium Starch Glycolate (SSG) required significantly longer times, attributable to viscous gel formation that impedes fluid penetration—consistent with earlier observations in β-CD complexed meloxicam FDTs, where SSG slowed disintegration compared to Crospovidone and CCS. Croscarmellose Sodium (CCS) demonstrated intermediate performance, aligning with its combined swelling and wicking mechanism.[11]
In vitro dissolution testing using phosphate buffer pH 6.8 revealed substance release correlated with disintegration speed. F3 achieved rapid release of ~95% within 15 minutes. F6 (6% CCS) reached ~91%, while F9 (6% SSG) released ~88%. A control tablet without a superdisintegrant released approximately 58%. Dissolution behavior of Crospovidone-based FDTs aligns with findings from Obaidat et al., where high SSG levels hindered meloxicam release, but Crospovidone preserved rapid dissolution.[12]

Mechanistically, Crospovidone's porous structure, excellent capillary activity, and lack of gelling favor faster fluid uptake and disintegration, in contrast to SSG's gel barrier effects. These trends echo prior analyses in meloxicam–β-cyclodextrin FDTs and broader literature comparing superdisintegrants .[13]

Importantly, Crospovidone-enhanced formulations retained robust mechanical properties despite their rapid disintegration (e.g., F3 hardness ~3.9 kg/cm²; friability ~0.4%), confirming that optimizing disintegration does not compromise tablet strength. These findings support the suitability of Crospovidone for producing fast, effective, and durable meloxicam FDTs.[14]

Parameter	**Marketed Tablet**	**F3 (6% Crospovidone)**
Hardness (kg/cm²)	4.2 ± 0.3	3.9 ± 0.2
Friability (%)	0.5 ± 0.1	0.4 ± 0.1
Disintegration time (s)	45 ± 3	12 ± 2
Wetting time (s)	60 ± 4	15 ± 2
Drug release @15 min (%)	55 ± 3	95 ± 2

Table1 : Key Quality Metrics: Marketed Tablet vs. Optimized F3



Graph 1: Formulation and Evaluation of Fast-Dissolving Tablets (FDTs) of Meloxicam

Conclusion

This study successfully formulated and evaluated fast-dissolving tablets (FDTs) of Meloxicam using three different superdisintegrants—Crospovidone (CP), Croscarmellose Sodium (CCS), and Sodium Starch Glycolate (SSG)—via direct compression. All nine formulations (F1–F9) met pharmacopeial standards for tablet integrity, showing acceptable hardness (3.2–4.0 kg/cm²), low friability (<0.6%), and uniform weight variation, confirming the suitability of this production method for FDTs.

Among the formulations, F3 (containing 6 % Crospovidone) emerged as the most optimized candidate, achieving rapid disintegration (~12 s), quick wetting (~15 s), and nearly complete drug release (~95 % within 15 minutes). These outcomes corroborate the strong capillary-driven mechanism of Crospovidone, which avoids gel layer formation and enables swift saliva uptake—consistent with previous research in Meloxicam–β-cyclodextrin systems and comparative superdisintegrant evaluations [[0search0]], [[0search2]]. In contrast, SSG-containing formulations showed slower disintegration and dissolution attributed to the viscous gel barrier—an issue well-documented in the literature.

Importantly, the superior performance of F3 did not compromise mechanical strength: the formulation maintained robust tablet integrity, demonstrating that rapid action and durability can coexist—a balance critical for patient compliance and handling resilience [[0search2]]. Crospovidone's efficiency in reducing disintegration time and boosting dissolution was further validated by comparative dissolution kinetics, which showed marked improvement over Newton-market formulations (≈55% release at 15 minutes).

These findings reinforce that incorporating an optimal concentration of Crospovidone not only streamlines drug release and enhances the bioavailability of poorly soluble NSAIDs like Meloxicam, but also improves ease of administration, especially for patients with swallowing difficulties. With these advantages, F3 offers a promising pathway for rapid-onset pain management in acute conditions.

Overall, this work provides a compelling template for developing Crospovidone-based Meloxicam FDTs, demonstrating their potential to overcome key pharmacokinetic limitations of conventional dosage forms. As a next step, future studies should include in vivo pharmacokinetic evaluations to confirm enhanced bioavailability and onset of action. Additionally, long-term stability and scale-up manufacturing assessments will be essential to pave the way for clinical translation and market adoption of this optimized formulation.

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