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Original Research Article

FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF MELOXICAM USING B-CYCLODEXTRIN INCLUSION COMPLEX FOR ENHANCED DISSOLUTION AND PATIENT COMPLIANCE

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Name of Author:
[1]Shubham Saini, [2]Manmohan Sharma, [2]Anil Ahuja, [3]Ashok Kumar

Affiliation: *[1]Scholar, School of Pharmaceutical Studies, Dr. K. N. Modi University, Newai, Rajasthan*
[2]Professor, School of Pharmaceutical Studies, Dr. K. N. Modi University, Newai, Rajasthan
[3]Assistant Professor, School of Pharmaceutical Studies, Dr. K. N. Modi University, Newai, Rajasthan

Corresponding Author:
Shubham Saini

Abstract: Mouth dissolving tablets (MDTs) have emerged as an advanced oral drug delivery system offering rapid disintegration, improved patient compliance, and enhanced bioavailability, particularly for drugs with poor aqueous solubility and unpleasant taste. Meloxicam, a selective COX-2 inhibitor widely used in the management of inflammatory and arthritic conditions, suffers from poor solubility and bitter taste, limiting its patient acceptability. The present research aimed to develop and evaluate mouth dissolving tablets of meloxicam by incorporating a β-cyclodextrin (β-CD) inclusion complex to improve solubility, dissolution rate, and palatability. Inclusion complexes were prepared using the solvent evaporation method and characterized by FTIR and DSC to confirm complex formation and compatibility. Mouth dissolving tablets were formulated by direct compression employing two techniques: super-disintegrant addition and effervescent method. The prepared formulations were evaluated for pre-formulation parameters, physicochemical characteristics, mechanical strength, disintegration behavior, drug content uniformity, wetting time, water absorption ratio, in-vitro dispersion time, and dissolution profile. The optimized formulation (SDDC1) exhibited rapid disintegration (72 seconds), high drug release (91.39% within 30 minutes), acceptable mechanical strength, and superior wetting behavior compared to the effervescent formulation and marketed product. The study concludes that the super-disintegrant based MDTs of meloxicam using β-cyclodextrin inclusion complex offer a promising approach for fast onset of action, improved dissolution, and enhanced patient compliance.

Keywords: Meloxicam, Mouth dissolving tablets, β-Cyclodextrin, Inclusion complex, Super-disintegrants

INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, cost-effectiveness, and ease of formulation. However, conventional oral solid dosage forms such as tablets and capsules often pose challenges related to swallowing difficulty, delayed onset of action, poor bioavailability, and patient non-compliance, especially among paediatric, geriatric, dysphagic, and bedridden patients. These limitations have prompted the development of alternative oral dosage forms that can overcome such drawbacks while maintaining therapeutic efficacy1.

Mouth dissolving tablets (MDTs), also referred to as orally disintegrating tablets, are solid dosage forms designed to disintegrate or dissolve rapidly in the oral cavity, usually within seconds, without the need for water. Once placed on the tongue, MDTs undergo rapid disintegration, releasing the drug into saliva, which is then swallowed or absorbed partially through the oral mucosa. This dosage form offers several advantages including rapid onset of action, improved bioavailability, enhanced patient compliance, ease of administration, and reduced choking risk2,3.

Despite these advantages, formulation of MDTs presents several challenges, particularly when the active pharmaceutical ingredient possesses poor aqueous solubility, unpleasant taste, or low dissolution rate. Taste masking and solubility enhancement are therefore critical formulation considerations in MDT development3.

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) belonging to the oxicam class and acts as a selective cyclooxygenase-2 (COX-2) inhibitor. It is widely prescribed for the management of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and other inflammatory disorders. Although meloxicam exhibits good therapeutic efficacy, its poor aqueous solubility, bitter taste, and relatively slow dissolution rate limit its oral bioavailability and patient acceptance. Meloxicam is classified as a BCS Class II drug, where dissolution is the rate-limiting step for absorption4,5.

To overcome these limitations, cyclodextrin-based inclusion complexation has gained considerable attention. Cyclodextrins are cyclic oligosaccharides with a hydrophilic outer surface and a hydrophobic inner cavity, capable of forming inclusion complexes with poorly soluble drugs. Among them, β-cyclodextrin is widely used due to its optimal cavity size, availability, safety profile, and ability to improve solubility, dissolution rate, stability, and taste masking of drugs6.

In the present study, β-cyclodextrin was employed to form an inclusion complex with meloxicam using the solvent evaporation method. The prepared inclusion complex was further formulated into mouth dissolving tablets using direct compression by two approaches: super-disintegrant technique and effervescent technique. Super-disintegrants such as sodium starch glycolate and crospovidone promote rapid tablet breakup by swelling and wicking mechanisms, whereas effervescent agents facilitate rapid disintegration through carbon dioxide generation upon contact with saliva7.

The research focuses on systematic formulation, characterization, and evaluation of meloxicam MDTs to identify an optimized formulation with rapid disintegration, enhanced dissolution, acceptable mechanical strength, and superior patient-friendly characteristics.

2. Objectives of the Research

- To prepare and characterize a meloxicam–β-cyclodextrin inclusion complex for solubility and taste enhancement.
- To formulate mouth dissolving tablets of meloxicam using super-disintegrant and effervescent techniques.
- To evaluate pre- and post-formulation parameters including flow properties, disintegration behavior, and dissolution profile.
- To compare the optimized formulation with a marketed meloxicam tablet.

3. Materials Required

Meloxicam was obtained as a gift sample from Akum Drugs and Pharmaceuticals Ltd., Delhi. β-Cyclodextrin, sodium starch glycolate, crospovidone, sodium bicarbonate, citric acid, microcrystalline cellulose, mannitol, magnesium stearate, aerosil, sodium saccharin, talc, and camphor were procured from CDH, India. All chemicals used were of analytical grade.

MATERIAL AND METHODS

4.1 Preparation of Meloxicam–β-Cyclodextrin Inclusion Complex

The inclusion complex was prepared using the solvent evaporation technique in a 1:1 molar ratio. Meloxicam was dissolved in ethanol, and an aqueous solution of β-cyclodextrin was added gradually with continuous stirring. The mixture was stirred for 24 hours to allow complex formation, followed by solvent removal under reduced pressure using a rotary evaporator at 50°C. The resulting solid mass was dried, pulverized, and stored in a desiccator8.

4.2 Characterization of Inclusion Complex

The inclusion complex was characterized using FTIR spectroscopy to assess drug–carrier compatibility and DSC to study thermal behavior and confirm complex formation8.

4.3 Formulation of Mouth Dissolving Tablets

Mouth dissolving tablets were prepared by direct compression using two techniques:

- Super-disintegrant technique: Mouth dissolving tablets of meloxicam were prepared by direct compression using the super-disintegrant technique. Sodium starch glycolate and crospovidone were incorporated in varying concentrations to promote rapid tablet disintegration. Sodium starch glycolate facilitated disintegration by rapid swelling,

while crospovidone enhanced water uptake through wicking action. Accurately weighed ingredients were passed through a 60-mesh sieve, blended uniformly, lubricated, and compressed into tablets. The formulations were evaluated for flow properties, disintegration time, and dissolution behavior910.

- Effervescent technique: In the effervescent technique, sodium bicarbonate and citric acid were used as effervescent agents to achieve rapid tablet disintegration through carbon dioxide generation upon contact with saliva. Mannitol was used as a diluent and sweetening agent. The effervescent components were preheated to remove residual moisture, sieved, and blended with the drug and other excipients. The prepared blends were compressed by direct compression and evaluated for disintegration time, wetting behavior, and drug release profile11.

All ingredients were passed through a 60-mesh sieve, blended uniformly, lubricated, and compressed using a 16-station rotary tablet punching machine.

4.4 Evaluation Studies

A. Pre-Formulation Studies

- Bulk Density: A known quantity of powder blend was gently poured into a graduated cylinder, and the initial volume was recorded. Bulk density was calculated by dividing the weight of powder by the bulk volume12.
- Tapped Density: The same cylinder containing the powder was tapped repeatedly until no further volume change was observed. Tapped density was calculated by dividing the powder weight by the tapped volume.
- Carr's Index: Carr's index was calculated using bulk and tapped density values to assess compressibility and flow property of the powder blend13.
- Hausner's Ratio: Hausner's ratio was calculated as the ratio of tapped density to bulk density. Values less than 1.25 indicated good flow.
- Angle of Repose: The powder blend was allowed to flow freely through a funnel to form a cone. The height and radius of the powder heap were measured, and the angle of repose was calculated to assess flow behavior13.

B. Post-Formulation Studies

- General Appearance: Tablets were visually examined for color, shape, surface texture, presence of cracks, and overall appearance.
- Weight Variation: Twenty tablets from each batch were weighed individually, and the average weight was calculated. Percentage deviation of individual tablets from the average weight was determined according to pharmacopoeial limits14.
- Hardness: Tablet hardness was measured using a Pfizer hardness tester. Five tablets from each batch were tested, and the average hardness was recorded.
- Friability: Twenty tablets were weighed and rotated in a Roche friabilator at 25 rpm for 4 minutes. Tablets were reweighed, and percentage weight loss was calculated14.
- Thickness and Diameter: Thickness and diameter of tablets were measured using a digital vernier caliper. Measurements were taken for five tablets, and the average values were recorded.
- Wetting Time: A tablet was placed on tissue paper soaked with water in a petri dish. The time required for complete wetting of the tablet surface was recorded14.
- Water Absorption Ratio: The tablet was weighed before and after wetting. Water absorption ratio was calculated using the difference in weight to assess hydration capacity15.
- Disintegration Time: Six tablets were placed in the disintegration test apparatus containing phosphate buffer at 37 ± 0.5°C. The time taken for complete disintegration was recorded.
- In-Vitro Dispersion Time: A tablet was placed in a beaker containing phosphate buffer (pH 7.5), and the time required for complete dispersion was noted14,15.
- Drug Content Uniformity: Tablets were crushed, and an amount equivalent to the drug dose was dissolved in a suitable solvent. The solution was filtered, diluted, and analyzed using UV spectrophotometry. Drug content was calculated16.
- Percent Assay: The assay was performed by analyzing a diluted tablet solution at the drug's λmax using a UV spectrophotometer. Percent assay was calculated based on the labeled claim17.
- In-Vitro Dissolution Study: Dissolution studies were performed using USP type II (paddle) apparatus containing phosphate buffer at 37 ± 0.5°C and 50 rpm. Samples were withdrawn at predetermined time intervals, filtered, and analyzed spectrophotometrically to determine percent drug release17.

RESULT AND DISCUSSION

5.1 Characterization of Drug and Inclusion Complex

Meloxicam was identified as a yellow crystalline, bitter, odorless powder with a particle size of 21.97 µm. FTIR spectra confirmed the presence of characteristic functional groups of meloxicam and β-cyclodextrin without chemical interaction. DSC thermograms showed disappearance of the sharp melting peak of meloxicam in the inclusion complex, confirming successful complexation.

5.2 Pre-Formulation Studies

Pre-Formulation Studies: Pre-formulation studies were carried out to evaluate the flow and compressibility properties of powder blends prior to compression. The results are summarized based on

bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose.

The bulk density of the selected formulations EFDC1 and SDDC1 was found to be 404.97 mg/ml and 336.65 mg/ml, respectively, while tapped density values were 467.27 mg/ml and 395.20 mg/ml. The Carr's index values for EFDC1 (13.33%) and SDDC1 (14.81%) indicated good compressibility. Hausner's ratio values for both formulations were below 1.25, confirming satisfactory flow properties. The angle of repose values were found to be less than 25°, indicating excellent flow behavior suitable for direct compression. These results confirmed that the powder blends possessed adequate flow and packing characteristics for tablet formulation.

5.3 Post-Formulation Evaluation

Post-Formulation Studies

- General Appearance: All prepared mouth dissolving tablets were found to be uniform in shape, light yellow in color, round, flat, smooth surfaced, and free from visible defects such as cracks or mottling, indicating good aesthetic quality and acceptable appearance.
- Weight Variation: Weight variation studies showed that the average tablet weights of EFDC1 (251.49 ± 12.57 mg) and SDDC1 (253.6 ± 12.68 mg) were within the permissible pharmacopoeial limits. Individual tablet weights showed minimal deviation, confirming uniform die filling and consistent tablet mass.
- Hardness: The hardness of tablets prepared by direct compression was found to be 5.2 ± 0.38 kg/cm² for EFDC1 and 5.09 ± 0.29 kg/cm² for SDDC1. These values indicate that the tablets possessed sufficient mechanical strength to withstand handling while still allowing rapid disintegration.
- Friability: Friability values for both EFDC1 and SDDC1 were found to be 0.43%, which is well below the acceptable limit of 1%. This indicates good mechanical resistance and minimal tablet abrasion during handling and transportation.
- Thickness and Diameter: The thickness of EFDC1 and SDDC1 tablets was found to be 3.51 ± 0.08 mm and 3.52 ± 0.05 mm, respectively, while the diameter for both formulations was approximately 9.09 mm. Minimal variation in thickness and diameter reflects uniform compression and consistent tablet size.
- Wetting Time: Wetting time studies revealed that SDDC1 tablets showed faster wetting (135 seconds) compared to EFDC1 tablets (240 seconds). The reduced wetting time of SDDC1 can be attributed to the combined action of sodium starch glycolate and crospovidone, which enhanced water uptake and rapid tablet hydration.
- Water Absorption Ratio: The water absorption ratio was found to be higher for SDDC1 (91.74 ± 0.41) than EFDC1 (88.70 ± 0.04), indicating superior hydration capacity and supporting faster disintegration behavior of the super-disintegrant formulation.
- Disintegration Time: Disintegration time studies showed a significant difference between the two formulations. EFDC1 tablets disintegrated in 178 seconds, whereas SDDC1 tablets disintegrated rapidly within 72 seconds. The faster disintegration of SDDC1 is attributed to the swelling and wicking action of super-disintegrants.
- In-Vitro Dispersion Time: In-vitro dispersion time for EFDC1 and SDDC1 tablets was found to be 41.00 ± 1.39 seconds and 40.33 ± 1.35 seconds, respectively. Both formulations demonstrated rapid dispersion, making them suitable for mouth dissolving applications.
- Drug Content Uniformity: Drug content uniformity studies revealed that EFDC1 tablets contained 15.6 ± 0.499 mg of meloxicam, while SDDC1 tablets contained 15.3 ± 0.616 mg. All values were within the acceptable pharmacopoeial range of 85–115% of the labeled claim, indicating uniform drug distribution.
- Percent Assay: The percent assay values were found to be 104% for EFDC1 and 102% for SDDC1. These results confirm accurate drug loading and compliance with official assay limits (90–110%).
- In-Vitro Dissolution Studies: In-vitro dissolution studies demonstrated enhanced drug release from mouth dissolving tablets compared to pure drug and marketed formulation. At the end of 30 minutes, EFDC1 showed 88.70% drug release, while SDDC1 exhibited the highest release of 91.39%. The improved dissolution profile of SDDC1 is attributed to rapid disintegration, improved wetting, and increased surface area available for dissolution. The dissolution performance followed the order:

SDDC1 > EFDC1 > Marketed product

The results indicates that both formulation approaches successfully produced mouth dissolving tablets of meloxicam with acceptable quality attributes. However, the super-disintegrant based formulation (SDDC1) demonstrated superior performance in terms of disintegration time, wetting behavior, water absorption, and dissolution rate, making it the optimized formulation.

6. Conclusion

The present study successfully developed mouth dissolving tablets of meloxicam using β-cyclodextrin inclusion complex to enhance dissolution and patient compliance. The super-disintegrant based formulation (SDDC1) emerged as the optimized batch due to rapid disintegration, superior wetting behavior, improved dissolution rate, and acceptable mechanical properties. The developed MDTs offer a promising alternative to conventional meloxicam tablets, particularly for patients requiring rapid onset of action and ease of administration.

7. Acknowledgement
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8. Conflict of Interest
The authors declare no conflict of interest.

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