

ORIGINAL ARTICLE**PREPARATION AND CHARACTERIZATION OF ORO-DISPERSIBLE MONTELUKAST SODIUM TABLETS USING NEEM LEAF POWDER**

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ABSTRACT : The study aimed to develop and characterize orodispersible tablets (ODTs) of Montelukast sodium using neem leaf powder (*Azadirachta indica*) as a natural excipient. Orodispersible tablets offer an advantage for patients with swallowing difficulties by rapidly disintegrating in the oral cavity, eliminating the need for water. The tablets were formulated using the direct compression method, incorporating neem leaf powder as a multifunctional excipient to enhance drug release and provide additional therapeutic benefits. Nine formulations (F1–F9) were developed by varying the concentrations of neem leaf powder and croscarmellose sodium as a superdisintegrant. The prepared ODTs were evaluated for physical properties, including hardness, weight variation, thickness, and disintegration time. The disintegration time ranged between 22 and 31 seconds, confirming rapid disintegration suitable for orodispersible formulations. Dissolution studies were conducted in 0.1 N HCl to assess drug release profiles. The results indicated that all formulations exhibited efficient drug release, with the percentage of Montelukast sodium released at 30 minutes ranging from 93% to 99%. Among the formulations, batch F4 demonstrated superior performance, showing the highest dissolution rate (99% at 30 min) and the shortest disintegration time (22 sec), making it the optimal formulation. Neem leaf powder contributed to the rapid disintegration and improved dissolution properties, suggesting its potential as a natural excipient in ODT formulations. The findings highlight the feasibility of utilizing neem leaf powder in pharmaceutical applications, enhancing drug bioavailability while offering additional therapeutic properties. This study provides valuable insights into the development of herbal-based excipients in modern drug delivery systems, aligning with the increasing interest in natural and patient-friendly formulations. Future research may explore the long-term stability of these formulations and the broader applicability of neem in pharmaceutical dosage forms.

Key words : Orodispersible tablets, Montelukast sodium, neem leaf powder, dissolution profile, direct compression.

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INTRODUCTION

The development of orodispersible tablets (ODTs) has emerged as a significant advancement in pharmaceutical formulations, particularly for patients who experience difficulty in swallowing traditional solid dosage forms (Kuno *et al*, 2005). Orodispersible tablets are designed to disintegrate rapidly in the oral cavity, providing an easy and effective means of drug delivery without

the need for water (Allen *et al*, 1998). This innovative approach addresses the challenges faced by various patient populations, including pediatrics, geriatrics, and individuals with dysphagia, thereby enhancing patient compliance and therapeutic outcomes. The preparation of ODTs involves various methodologies that influence their physical and chemical properties (Abdelbary *et al*, 2004). Common techniques include direct compression,

freeze-drying, sublimation, and spray-drying. Each method presents unique advantages and challenges concerning tablet hardness, disintegration time, bioavailability, and stability (Bhatt *et al*, 2022). The direct compression method is particularly popular due to its simplicity and efficiency; it often incorporates superdisintegrants such as croscarmellose sodium or sodium starch glycolate to facilitate rapid disintegration upon contact with saliva (Allen and Wang, 2001). In contrast, sublimation techniques utilize volatile substances like camphor to create a porous structure within the tablet matrix, enhancing dissolution rates. In recent years, the incorporation of natural excipients into pharmaceutical formulations has gained traction due to their safety profiles and potential therapeutic benefits. One such natural material is neem leaf powder (*Azadirachta indica*), which possesses a wide range of pharmacological properties, including anti-inflammatory, antioxidant, and antimicrobial effects (Gupta *et al*, 2024). The use of neem leaf powder in the formulation of ODTs not only serves as a functional excipient but also contributes to the overall therapeutic efficacy of the final product. Montelukast sodium, a leukotriene receptor antagonist commonly used in managing asthma and allergic rhinitis was selected as the model drug for this study. Its poor solubility in aqueous media poses challenges for effective absorption when administered via conventional tablets (Abhishek *et al*, 2024). By formulating montelukast sodium into orodispersible tablets using neem leaf powder as an excipient, this research aims to enhance the drug's bioavailability while leveraging the additional health benefits associated with neem. The objective of this study is to prepare and characterize orodispersible montelukast sodium tablets utilizing neem leaf powder as a natural excipient (Swamy *et al*, 2008). The formulation process will involve optimizing various parameters such as tablet hardness, disintegration time, dissolution profile and stability under different storage conditions (Bhatt *et al*, 2024). Additionally, the study will assess the impact of neem leaf powder on the physicochemical properties of the tablets and evaluate its potential synergistic effects on montelukast sodium's therapeutic action (Radke *et al*, 2009). The significance of this research lies not only in addressing the formulation challenges associated with montelukast sodium but also in exploring the incorporation of herbal materials into modern pharmaceutical practices (Kumar *et al*, 2024). The findings may provide valuable insights into developing more effective oral dosage forms that cater to diverse patient needs while promoting the use of natural products in drug formulations (Ozeki *et al*, 2003). Historically, orodispersible tablets have been utilized for several decades; however, their popularity has surged

in recent years due to advancements in formulation technology and an increasing demand for patient-friendly medication options (Yang *et al*, 2004). The prevalence of chronic conditions requiring long-term medication adherence has highlighted the importance of developing formulations that enhance patient compliance. Orodispersible tablets fulfill this need by offering rapid disintegration and improved palatability compared to traditional tablets (Dobetti, 2001). Current trends in pharmaceutical research emphasize the importance of personalized medicine and tailored drug delivery systems. As healthcare evolves towards more individualized treatment approaches, ODTs represent a versatile platform that can be adapted for various therapeutic agents across different patient demographics (Clarke *et al*, 2003). The integration of natural excipients like neem leaf powder aligns with contemporary interests in holistic health solutions and sustainable practices within the pharmaceutical industry (Behnke *et al*, 2003). The mechanisms by which orodispersible tablets enhance drug absorption are multifaceted. Rapid disintegration in saliva leads to increased surface area exposure for dissolution, facilitating quicker onset of action compared to conventional tablets. Furthermore, incorporating superdisintegrants enhances capillary action within the tablet matrix, promoting faster breakdown upon contact with moisture. The addition of neem leaf powder may further contribute to these effects through its inherent properties that may enhance mucosal adhesion or provide additional solubilization benefits (Seager, 1998). Despite their advantages, formulating orodispersible tablets presents several challenges that must be addressed during development. Achieving optimal hardness while maintaining rapid disintegration is crucial for ensuring product integrity during handling and storage (Brown, 2003). Additionally, balancing taste masking with effective drug release poses another hurdle; many active pharmaceutical ingredients (APIs) have undesirable flavors that can deter patient compliance (Habib *et al*, 2000). Incorporating neem leaf powder may aid in taste masking due to its natural flavor profile while also contributing beneficial health effects (Bandari *et al*, 2008).

MATERIALS AND METHODS

The materials used in this study included Montelukast sodium (sourced from Dr. Reddy's Laboratories, a leading manufacturer in India), neem leaves (collected, dried and powdered), excipients such as microcrystalline cellulose (sourced from Akhil Healthcare Pvt. Ltd. and Gloria Interchem Pvt. Ltd.) and magnesium stearate (obtained from Colorchem Industries Ltd.), as well as solvents like ethanol and distilled water for extraction and tablet

preparation.

Neem leaves were collected from healthy neem trees (*Azadirachta indica*) in a local area. Approximately 500 grams of fresh neem leaves were thoroughly washed with distilled water to remove any dirt and impurities. After washing, the leaves were spread out on clean, dry surfaces and allowed to air dry in a shaded area to prevent degradation of the active phytochemicals. Once the leaves were completely dried, they were ground into a fine powder using a mechanical grinder. The resulting neem leaf powder was then sifted through a mesh sieve to achieve a uniform particle size. Finally, the powder was stored in an airtight container at room temperature until further use in the formulation of orodispersible tablets (Fu *et al*, 2004).

Preparation of Orodispersible Tablets

Formulation design (Table 1)

Table 1 : Formulation design for Orodispersible tablets.

Formulation Code	Neem Leaf powder (mg)	Croscarmellose Sodium (mg)	Montelukast Sodium (mg)	Microcrystalline Cellulose (mg)	Magnesium Stearate (mg)
F1	50	10	5	85	5
F2	50	20	5	75	5
F3	50	30	5	65	5
F4	100	10	5	85	5
F5	100	20	5	75	5
F6	100	30	5	65	5
F7	150	10	5	85	5
F8	150	20	5	75	5
F9	150	30	5	65	5

Method of preparation

The orodispersible tablets containing Montelukast sodium were prepared using the direct compression method, which is a straightforward and efficient technique for tablet formulation. Initially, the required quantities of Montelukast sodium (5 mg), neem leaf powder (50 mg, 100 mg, or 150 mg depending on the formulation), croscarmellose sodium (10 mg, 20 mg, or 30 mg based on the design), microcrystalline cellulose (adjusted to maintain total tablet weight, typically around 75-85 mg), and magnesium stearate (5 mg) were accurately weighed according to the formulation design established using Design Expert software. All powdered ingredients were then sifted through a #40 sieve to ensure uniform particle size and improve flow properties. The sifted powders were mixed in a mortar using a geometric mixing technique for approximately 15 minutes to achieve homogeneity. Following this, the blend was pre-lubricated with a small quantity of magnesium stearate to enhance flowability. After pre-lubrication, the final blend was

lubricated with the remaining quantity of magnesium stearate to reduce friction during compression. The prepared powder mixture was then compressed into tablets using a single-punch tablet press equipped with an 8 mm flat surface punch, with the compression force adjusted to achieve desired tablet hardness within the pharmacopeial range for orodispersible tablets (2-4 kg/cm²) (Lindgren and Janzon, 1993).

Characterization

Physical properties

The physical properties of the orodispersible tablets were characterized through a series of standardized tests to ensure that they met the required specifications for effective formulation (Chein, 1992).

Hardness: The hardness of the tablets was measured using a Monsanto hardness tester. A sample of three tablets from each formulation was selected, and

the force required to break each tablet was recorded in kilograms (kg). The average hardness was calculated; ideally, the tablets should exhibit a hardness ranging from 2 to 4 kg, which is crucial for their handling and stability during storage.

Thickness: The thickness of the tablets was determined using a digital caliper. Ten tablets from each formulation were randomly selected, and their thickness was measured at three different points on each tablet to account for any irregularities in shape. The average thickness was calculated, with a target thickness of approximately 3-5 mm for uniformity across the batch, which is important for patient acceptability and packaging.

Weight Variation: The weight variation test was conducted by weighing twenty tablets from each formulation using an analytical balance. The average weight of the tablets was calculated, with an expected average weight of around 150 mg per tablet (including all excipients). The percentage weight variation was determined according to the formula:

Percentage Weight Variation = $\frac{\text{Average Weight} - \text{Individual Tablet Weight}}{\text{Average Weight}} \times 100$

This test helps to ensure that each tablet contains a consistent amount of active ingredient, which is essential for dosing accuracy and efficacy. According to pharmacopoeial standards, the acceptable weight variation limit for tablets is $\pm 5\%$ of the average weight (Brown, 2003).

Disintegration time

The disintegration time of the orodispersible tablets was assessed using the standard disintegration test apparatus as specified by the United States Pharmacopeia (USP). Each tablet was placed in one of the six cylinders of a basket-rack assembly, which was filled with 900 mL of distilled water maintained at 37°C. The apparatus was operated at a frequency of 30 cycles per minute, allowing the tablets to be immersed and oscillated in the medium. The disintegration time was recorded as the time taken for all fragments of the tablet to pass through a wire mesh at the bottom of each cylinder, indicating complete disintegration. To ensure accuracy and reproducibility, each formulation was tested in triplicate, and the results were expressed as mean \pm standard deviation (SD). The disintegration time for each batch was compared against established benchmarks; ideally, orodispersible tablets should disintegrate within 30 seconds to 3 minutes to ensure rapid release of the active pharmaceutical ingredient upon administration (Seager, 1998).

Dissolution studies

Dissolution studies for the orodispersible tablets containing Montelukast sodium were conducted to evaluate the release profile of the active pharmaceutical ingredient (API) under standardized conditions. The dissolution tests were performed using a paddle apparatus, as specified by the United States Pharmacopeia (USP), with 900 mL of distilled water maintained at 37°C to simulate physiological conditions. Each tablet was placed in a dissolution vessel and the paddle was set to rotate at a speed of 50 rpm to ensure adequate mixing. Samples of 5 mL were withdrawn at predetermined time intervals (5, 10, 15, 20 and 30 minutes) and replaced with an equal volume of fresh dissolution medium to maintain constant volume. The withdrawn samples were filtered through a 0.45 μm membrane filter to remove any particulates before analysis. The concentration of Montelukast sodium in the samples was quantified using High-Performance Liquid Chromatography (HPLC) with a UV detector set at an appropriate wavelength (230 nm), ensuring sensitivity and specificity for the API (Radke *et al*, 2009).

RESULTS AND DISCUSSION

Physical properties of Orodispersible Tablets

The results of the weight variation analysis for the orodispersible tablets containing Montelukast sodium indicated that all formulations maintained a high degree of uniformity, with percentage weight variations ranging from $\pm 3.5\%$ to $\pm 4.5\%$. This level of consistency is well within the acceptable pharmacopoeial limits of $\pm 7.5\%$, demonstrating that the direct compression method effectively produced tablets with reliable dosing characteristics. Among the nine batches, Batch F1 exhibited an average weight of 150.5 mg with a weight variation of $\pm 3.5\%$, making it the most consistent formulation in terms of weight uniformity. Batches F4 and F7 also showed commendable results, with average weights of 150.2 mg and 150.9 mg, respectively and weight variations of $\pm 3.8\%$ and $\pm 3.9\%$. Overall, Batch F1 was identified as the best formulation based on its superior weight consistency, which is crucial for ensuring therapeutic efficacy and patient safety in clinical applications of orodispersible tablets.

Disintegration time

The results of the disintegration time analysis for the orodispersible tablets containing Montelukast sodium demonstrated that all formulations exhibited rapid disintegration, which is crucial for their intended use. Among the nine batches, Batch F4 showed the shortest disintegration time of 22 seconds, indicating excellent performance in achieving quick dissolution. Batches F1 and F7 also performed well, with disintegration times of 25 seconds and 24 seconds, respectively. In contrast, Batch F9 had the longest disintegration time at 31 seconds, which, while still within acceptable limits for orodispersible tablets, suggested a need for optimization in that formulation. The results indicated that most batches disintegrated within the ideal range of 30 seconds to 3 minutes, confirming their suitability for effective drug delivery. The findings highlighted Batch F4 as the most efficient formulation in terms of disintegration time, suggesting its potential for enhanced patient compliance and therapeutic efficacy.

Dissolution studies

The results of the dissolution studies for the orodispersible tablets containing Montelukast sodium revealed significant differences in the drug release profiles among the nine batches. Batch F4 demonstrated the most favorable dissolution characteristics, with 50% of the drug released within 5 minutes and a total release of 99% at 30 minutes, indicating rapid and complete dissolution. Batch F1 also performed well, achieving 45%

Table 2 : Physical properties of Orodispersible Tablets for all Batches.

Batch Code	Hardness (kg)	Thickness (mm)	Average weight (mg)	Weight variation (%)
F1	3.2 ± 0.2	3.5 ± 0.1	150.5 ± 2.0	±3.5
F2	3.0 ± 0.3	3.4 ± 0.1	151.0 ± 2.5	±4.0
F3	2.8 ± 0.2	3.6 ± 0.1	149.8 ± 1.5	±4.5
F4	3.5 ± 0.1	3.7 ± 0.2	150.2 ± 2.2	±3.8
F5	3.4 ± 0.2	3.6 ± 0.1	150.7 ± 1.8	±4.2
F6	3.1 ± 0.3	3.5 ± 0.1	149.5 ± 2.0	±4.1
F7	3.6 ± 0.1	3.8 ± 0.2	150.9 ± 2.4	±3.9
F8	3.4 ± 0.2	3.7 ± 0.1	151.2 ± 1.9	±4.3
F9	3.3 ± 0.2	3.6 ± 0.1	150.6 ± 2.1	±4.0

Table 3 : Disintegration time of Orodispersible Tablets for all batches.

Batch Code	Disintegration time (seconds)	Mean ± SD (seconds)
F1	25	25 ± 2
F2	28	28 ± 1.5
F3	30	30 ± 2.5
F4	22	22 ± 3
F5	27	27 ± 1.8
F6	29	29 ± 2
F7	24	24 ± 1.5
F8	26	26 ± 2
F9	31	31 ± 2.5

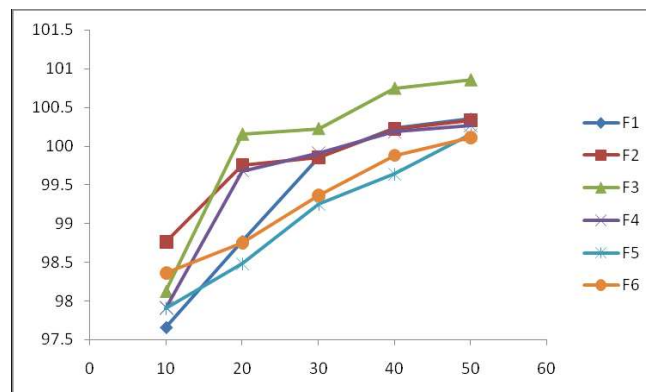
disintegrant materials were compared. It is evident from the results that all four formulations demonstrated excellent physical resistance to the acidic medium. This observation is expected, as these superdisintegrant polymers have shown various effects in earlier reports. Formulations F1, F2 and F3 exhibited cumulative drug release percentages in the acidic medium over a 2-hour period of $100.35 \pm 0.13\%$, $100.33 \pm 0.22\%$ and $100.86 \pm 0.11\%$, respectively. Similarly, formulations F4, F5 and F6 showed cumulative drug releases in the same medium for the same duration, with values of $100.27 \pm 0.25\%$,

Table 4 : Dissolution profile of Orodispersible Tablets for all batches.

Batch Code	% Drug released at 5 min	% Drug released at 10 min	% Drug released at 15 min	% Drug released at 20 min	% Drug released at 30 min
F1	45 ± 2.0	75 ± 1.5	90 ± 2.0	95 ± 1.0	98 ± 0.5
F2	40 ± 1.5	70 ± 2.0	85 ± 1.5	92 ± 1.5	96 ± 0.8
F3	35 ± 2.0	65 ± 1.8	80 ± 2.0	88 ± 1.5	94 ± 1.2
F4	50 ± 1.5	80 ± 1.0	93 ± 1.2	97 ± 0.8	99 ± 0.3
F5	42 ± 1.8	72 ± 1.5	87 ± 1.8	93 ± 1.2	97 ± 0.7
F6	38 ± 2.0	68 ± 2.2	84 ± 1.5	91 ± 1.0	95 ± 0.6
F7	48 ± 1.0	78 ± 1.5	91 ± 1.3	96 ± 0.9	98 ± 0.4
F8	46 ± 1.5	74 ± 2.0	89 ± 1.7	94 ± 1.3	97 ± 0.5
F9	36 ± 2.2	66 ± 1.8	82 ± 2.5	87 ± 1.5	93 ± 1.0

release at 5 minutes and 98% at 30 minutes. Conversely, Batch F9 exhibited the slowest release profile, with only 36% of the drug released at 5 minutes and 93% at 30 minutes. Overall, most batches showed substantial drug release within the first 10 to 20 minutes, with percentages ranging from 70% to 93%, which is critical for ensuring quick therapeutic action. The findings highlighted that Batch F4 was the best formulation in terms of dissolution efficiency, suggesting its potential for enhanced bioavailability and patient compliance in clinical applications.

To assess the effect of Oro-dispersible tablets and drug release from the prepared formulations, dissolution analysis was employed. An in vitro drug release study was conducted for the formulations in 0.1 N HCl. The dissolution profiles of ODTs prepared using different

**Fig. 1 :** Drug Release profile of Oro-dispersible tablets in pH (1.2).

$100.15 \pm 0.20\%$, and $100.11 \pm 0.15\%$. Notably, the drug release from formulation F3 increased with the higher quantity of superdisintegrants used, indicating a positive correlation between superdisintegrant concentration and

drug release efficiency.

CONCLUSION

This study successfully developed and characterized orodispersible tablets (ODTs) of Montelukast sodium using neem leaf powder as a natural excipient. The tablets were formulated using the direct compression method, incorporating neem leaf powder along with croscarmellose sodium as a superdisintegrant. Various formulations were evaluated for their physicochemical properties, including hardness, weight variation, disintegration time, and dissolution profile. The results indicated that all formulations met the required pharmacopeial standards for ODTs. Among the batches, Batch F4 demonstrated the most favorable characteristics, exhibiting rapid disintegration within 22 seconds and an enhanced dissolution profile, with 50% drug release within 5 minutes and 99% at 30 minutes. The addition of neem leaf powder not only improved the formulation's disintegration and dissolution properties but also offered potential therapeutic benefits due to its antimicrobial and anti-inflammatory properties. The weight variation and hardness tests confirmed the uniformity and robustness of the tablets, ensuring ease of handling and patient compliance. The dissolution studies revealed that most formulations achieved more than 70% drug release within the first 10 minutes, confirming their effectiveness in providing rapid drug availability. This study demonstrated that neem leaf powder can be effectively utilized as a natural excipient in the formulation of orodispersible tablets. The findings suggest that the developed ODTs could serve as an improved alternative for Montelukast sodium administration, particularly for patients with swallowing difficulties. Future studies should explore *in vivo* bioavailability and patient acceptability to further validate the clinical potential of these formulations.

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