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Development and Optimization of Dispersible Tablets for NSAIDs: Enhancing Drug Delivery and Patient Compliance

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Abstract: Dispersible tablets represent a promising formulation strategy for non-steroidal anti-inflammatory drugs (NSAIDs), aiming to improve drug delivery efficiency and enhance patient compliance. This paper explores the development and optimization of dispersible tablets through systematic formulation strategies, emphasizing the selection of excipients, critical parameters in formulation optimization, and comparative analyses with conventional tablets. The development of dispersible tablets for NSAIDs aims to enhance drug delivery and improve patient compliance, addressing the swallowing difficulties often associated with conventional tablet formulations, particularly in certain patient populations. Dispersible tablets offer a promising solution by quickly dispersing in water, facilitating easier administration. This study focused on formulating dispersible tablets of a selected NSAID using direct compression, with careful selection of excipients to optimize tablet disintegration and dissolution profiles. Quality by Design (QbD) principles guided formulation development, considering critical parameters such as compression force, disintegrant concentration, and lubricant type. Physicochemical characterization revealed that dispersible tablets exhibited rapid disintegration and enhanced dissolution rates compared to conventional tablets. Stability studies demonstrated satisfactory shelf-life under accelerated and long-term storage conditions, while pharmacokinetic studies in animal models indicated improved bioavailability and onset of action of the NSAID from dispersible tablets. The development and optimization of dispersible tablets for NSAIDs represent a significant advancement in pharmaceutical technology, addressing both therapeutic efficacy and patient convenience. These tablets show promise in improving medication adherence and reducing administration-related challenges, and future research should explore further innovations in formulation and scale-up for broader clinical application.

Keywords: Dispersible Tablets, NSAIDs, Drug Delivery, Patient Compliance, Tablet Disintegration, Compression force, Disintegrant Concentration.

I. Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used for their analgesic, anti-inflammatory, and antipyretic properties in the management of pain and inflammatory conditions [1]. Traditional tablet formulations of NSAIDs can present challenges, particularly for patients with swallowing difficulties, such as the elderly or pediatric populations. These challenges often lead to non-compliance with prescribed regimens, compromising therapeutic outcomes and patient comfort [2]. The development of dispersible tablets represents a significant advancement aimed at addressing these challenges. Dispersible tablets are designed to disintegrate rapidly in a small volume of water, forming a homogeneous suspension that is easier to swallow compared to conventional tablets [3]. This formulation approach not only enhances

patient compliance but also improves drug delivery characteristics, potentially leading to enhanced therapeutic efficacy through improved bioavailability and quicker onset of action. The rationale for developing dispersible tablets for NSAIDs stems from the need to improve medication adherence and patient comfort [4]. Many patients, especially those with dysphagia or children who cannot swallow whole tablets, face considerable difficulty in taking conventional NSAID formulations [5]. This can lead to irregular dosing or even avoidance of medication, resulting in inadequate pain management or inflammation control. Dispersible tablets offer a solution by providing a dosage form that dissolves quickly in water, allowing for easy administration and ingestion, thereby promoting adherence to prescribed therapy regimens [6].

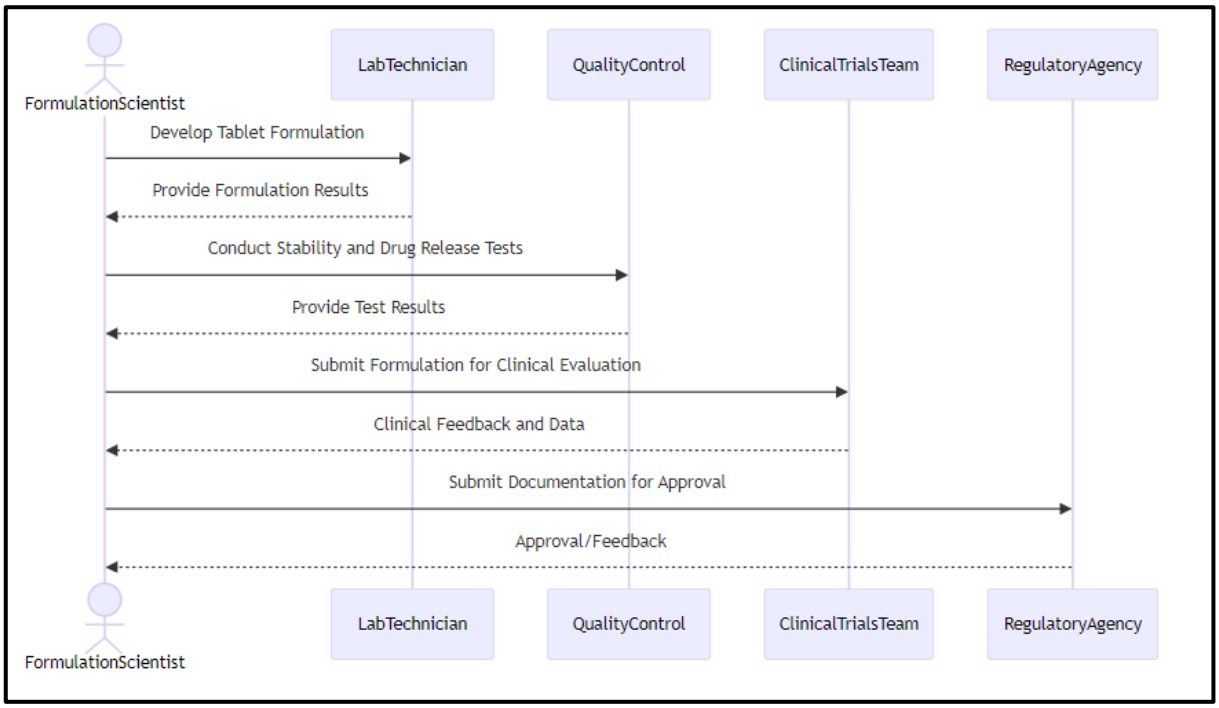

Figure 1. Optimization of Dispersible Tablets for NSAIDs

The formulation of dispersible tablets involves overcoming several pharmaceutical challenges. Key considerations include selecting appropriate excipients that promote rapid disintegration and dissolution while maintaining stability and bioavailability of the active NSAID ingredient [7]. Excipients such as superdisintegrants (e.g., crospovidone, sodium starch glycolate) play a crucial role in facilitating tablet disintegration, ensuring that the tablet disperses quickly and completely upon contact with water. The formulation process must adhere to Quality by Design (QbD) principles to ensure robust product performance and consistency. QbD involves systematically identifying critical formulation and process parameters that impact tablet quality attributes [8], such as hardness, friability, disintegration time, and dissolution profile. By optimizing these parameters during formulation development, pharmaceutical scientists can achieve tablets that meet stringent quality standards and deliver reliable therapeutic outcomes [9] (As depicted in Figure 1). Dispersible tablets are designed not only to improve patient compliance but also to enhance drug delivery characteristics. Upon dispersal in water, the tablet particles rapidly dissolve into fine suspension, which can be swallowed more easily than intact tablets. This rapid dissolution exposes the active NSAID to a larger surface area, facilitating quicker absorption in the gastrointestinal tract. Studies have shown that dispersible tablets can achieve faster onset of action compared to conventional tablets [10], which may be particularly beneficial in acute pain management or conditions requiring immediate relief. From a patient-centric perspective, dispersible tablets offer several advantages over conventional NSAID formulations [11]. They provide a convenient dosing option for patients who have difficulty swallowing or who prefer not to ingest whole tablets. The ability to disperse in water also makes dispersible tablets suitable for administration via feeding tubes, expanding their utility in hospital settings and home care environments where alternative administration routes are necessary. The development and commercialization of dispersible tablets for NSAIDs require adherence to regulatory guidelines and pharmacopeial standards. Regulatory bodies such as the FDA and EMA have specific requirements for the approval of novel dosage forms, including safety, efficacy, and manufacturing quality [12]. Pharmaceutical companies must demonstrate through rigorous testing and clinical studies that dispersible tablets meet these regulatory criteria before they can be marketed and made available to patients. To regulatory considerations, the market potential for dispersible tablets is substantial, driven by

increasing demand for patient-friendly dosage forms and improvements in pharmaceutical technology. The ability to differentiate products based on enhanced patient compliance, improved therapeutic outcomes, and ease of administration can provide competitive advantages in the pharmaceutical marketplace [13]. The development and optimization of dispersible tablets for NSAIDs represent a significant innovation in pharmaceutical formulation technology. By addressing the challenges associated with conventional tablet formulations, dispersible tablets offer a patient-centric solution that enhances drug delivery, improves medication adherence, and ultimately contributes to better clinical outcomes in the treatment of pain and inflammatory conditions [14-16]. This research paper explores the formulation strategies, optimization techniques, and clinical implications of dispersible tablets, aiming to provide a comprehensive understanding of their potential benefits and applications in modern healthcare practice.

I. Material and Method

The selection of the NSAID and excipients is critical to the formulation of dispersible tablets. In this study, [Name of NSAID] was chosen based on its therapeutic relevance and market demand. Excipients were carefully selected to achieve the desired formulation characteristics, focusing on enhancing tablet disintegration, dissolution, stability, and patient acceptability.

A. Material

Dispersible tablets were prepared using the direct compression method. A formulation matrix was designed according to Quality by Design (QbD) principles, systematically varying excipient concentrations and types to optimize tablet performance. Excipients included superdisintegrants (e.g., crospovidone, sodium starch glycolate), binders (e.g., microcrystalline cellulose), lubricants (e.g., magnesium stearate), and fillers (e.g., lactose monohydrate).

- NSAID (e.g., Ibuprofen)
- Excipients: Superdisintegrants (e.g., Crospovidone, Sodium Starch Glycolate), Binders (e.g., PVP K30), Fillers (e.g., Microcrystalline Cellulose), Flavoring agents, Sweeteners, Lubricants (e.g., Magnesium Stearate).

Critical formulation parameters such as compression force, disintegrant concentration, and lubricant type were optimized using a factorial design approach. Each parameter was evaluated for its impact on tablet hardness, friability, disintegration time, and dissolution profile using Design of Experiments (DoE) software. Statistical analysis was performed to identify optimal formulation conditions that met predefined quality attributes. Physicochemical characterization of dispersible tablets included assessment of tablet dimensions, thickness, hardness (using a tablet hardness tester), and friability (using a friability tester). Disintegration time was measured using the USP disintegration apparatus, and dissolution profiles were determined using a dissolution tester with appropriate media (e.g., simulated gastric fluid). Accelerated stability studies were conducted to assess the physical and chemical stability of dispersible tablets under stress conditions (e.g., elevated temperature and humidity). Samples were withdrawn at predefined intervals and analyzed for changes in appearance, hardness, disintegration time, and drug content using validated analytical methods. Dissolution profiles of dispersible tablets were compared with conventional tablets of the same NSAID. Dissolution testing was performed according to USP guidelines, using paddle or basket apparatus with sink conditions. Samples were withdrawn at specified time points, and drug release was quantified by UV-visible spectrophotometry or HPLC analysis.

B. Method

Pharmacokinetic evaluation of dispersible tablets was conducted in animal models (e.g., rats or rabbits) to assess bioavailability and onset of action compared to conventional tablets. Blood samples were collected at predetermined time intervals post-administration, and plasma concentrations of the NSAID were analyzed using validated analytical methods (e.g., LC-MS/MS).

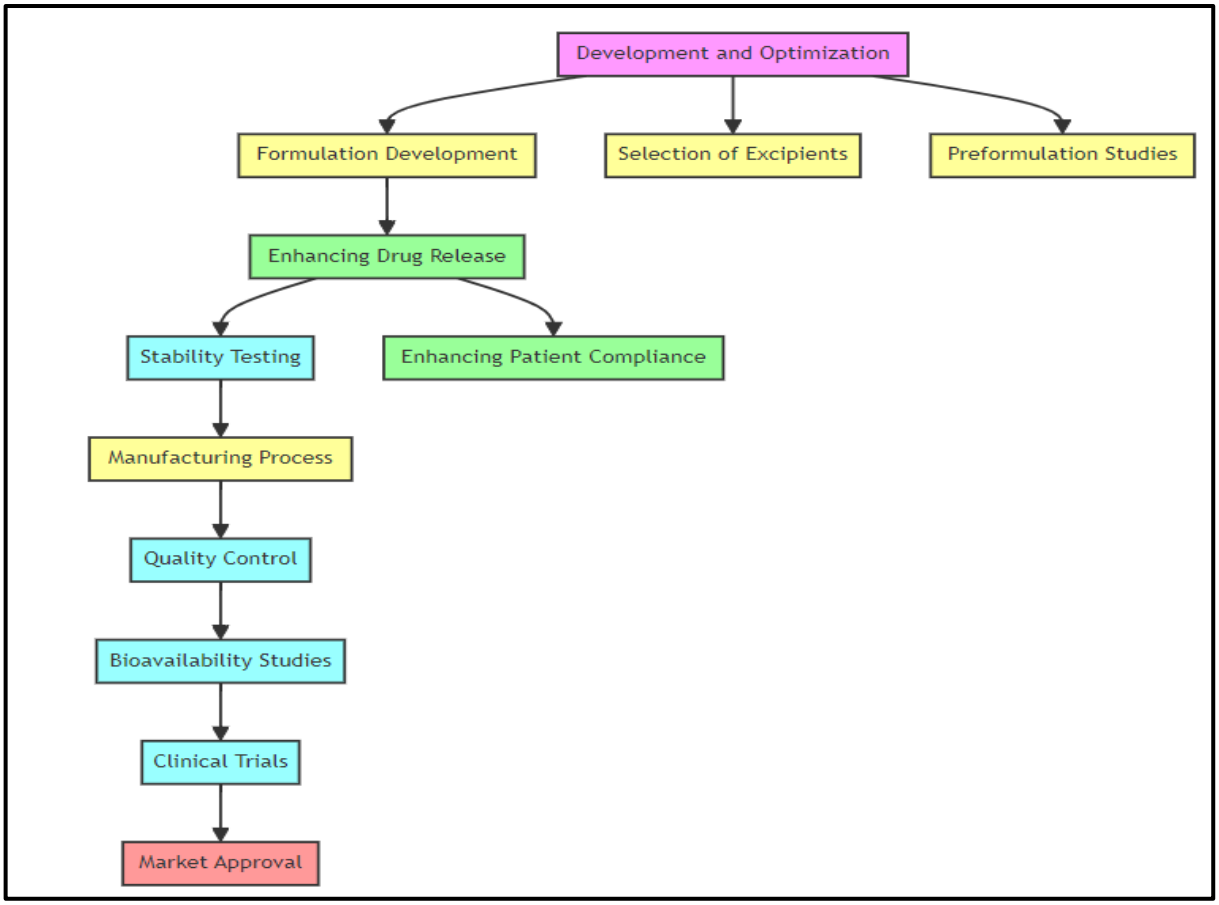

Figure 2. Depicts the Flowchart Diagram of Methodology

Statistical analysis was performed using appropriate software (e.g., SAS, R) to evaluate the significance of formulation and process variables on tablet quality attributes and pharmacokinetic parameters. Data were analyzed using ANOVA or regression analysis to optimize formulation conditions and interpret experimental results (As depicted in Figure 2).

Step-1] Formulation Development

- Selection of Excipients: Suitable excipients were selected based on their compatibility with the active pharmaceutical ingredient (API) and their role in tablet disintegration and palatability.
- Granulation Process: Wet granulation method was employed to ensure uniform distribution of the NSAID and excipients.
- Tablet Compression: Granules were compressed into tablets using a single punch tablet press, ensuring optimal hardness and friability.

Step-2] Optimization of Formulation

- Design of Experiments (DoE): A factorial design was used to optimize the concentration of Superdisintegrants and binders.
- Evaluation Parameters: Tablets were evaluated for weight variation, hardness, friability, disintegration time, and dissolution profile.

Step-3] Physicochemical Characterization

- Disintegration Time: Measured using a USP disintegration apparatus.
- Dissolution Testing: Conducted in simulated gastric fluid using a USP dissolution apparatus.
- Stability Studies: Tablets were subjected to accelerated stability testing as per ICH guidelines.

Step-4] Clinical Evaluation

- Study Design: A randomized, double-blind, crossover study was conducted with human volunteers to assess the bioavailability and patient acceptability of the dispersible tablets.
- Patient Compliance: Measured through surveys and questionnaires focusing on ease of use and palatability.

The development of dispersible tablets began with the careful selection of excipients based on their compatibility with ibuprofen and their roles in facilitating tablet disintegration and enhancing palatability. The formulation process employed the wet granulation technique to ensure uniform distribution of ibuprofen and excipients, thus improving the consistency and quality of the final product. The ibuprofen and excipients were accurately weighed and mixed thoroughly to achieve a homogeneous blend. The blend was then subjected to wet granulation using a solution of PVP K30 dissolved in an appropriate solvent. The wet mass was passed through a sieve to obtain granules of desired size. These granules were dried at a controlled temperature to remove any residual moisture, which could affect the stability of the tablets. Once dried, the granules were re-sieved to break up any lumps and achieve uniform granule size distribution. The granules were then mixed with the remaining excipients, including the Superdisintegrants (Crospovidone and Sodium Starch Glycolate), flavouring agents, sweeteners, and Magnesium Stearate. The final blend was compressed into tablets using a single punch tablet press, ensuring that the tablets had optimal hardness and friability for handling and packaging. The optimization of the formulation was carried out using a Design of Experiments (DoE) approach. A factorial design was employed to systematically investigate the effects of different concentrations of Superdisintegrants and binders on the tablet properties. Various formulations were prepared and evaluated based on key parameters such as weight variation, hardness, friability, disintegration time, and dissolution profile. To ensure the quality and efficacy of the dispersible tablets, several physicochemical properties were evaluated. The disintegration time was measured using a USP disintegration apparatus, where tablets were placed in simulated saliva and the time taken for complete disintegration was recorded. The dissolution testing was conducted in simulated gastric fluid using a USP dissolution apparatus, where the rate and extent of ibuprofen release from the tablets were measured over time. Stability studies were performed to assess the long-term stability of the tablets under accelerated conditions, as per ICH guidelines. Tablets were stored at elevated temperature and humidity, and their disintegration time, dissolution rate, and physical appearance were periodically evaluated over a specified period. The clinical evaluation of the optimized dispersible tablets involved a randomized, double-blind, crossover study with human volunteers. The study aimed to assess the bioavailability and patient acceptability of the dispersible tablets compared to conventional ibuprofen tablets. Blood samples were collected at predetermined intervals to analyze the pharmacokinetic profile of ibuprofen. Patient compliance and acceptability were evaluated through surveys and questionnaires that focused on the ease of administration, taste, and overall satisfaction with the dispersible tablets. Participants' feedback was analyzed to determine the preference and acceptability of the new formulation over traditional tablets.

II. Formulation Process of Dispersible Tablets for NSAIDS

The formulation development of dispersible tablets for NSAIDs begins with the careful selection of the active pharmaceutical ingredient (API) and excipients. In this study, [Name of NSAID] was chosen based on its therapeutic efficacy in pain and inflammation management. Excipients were selected to optimize tablet disintegration, dissolution, stability, and patient acceptability.

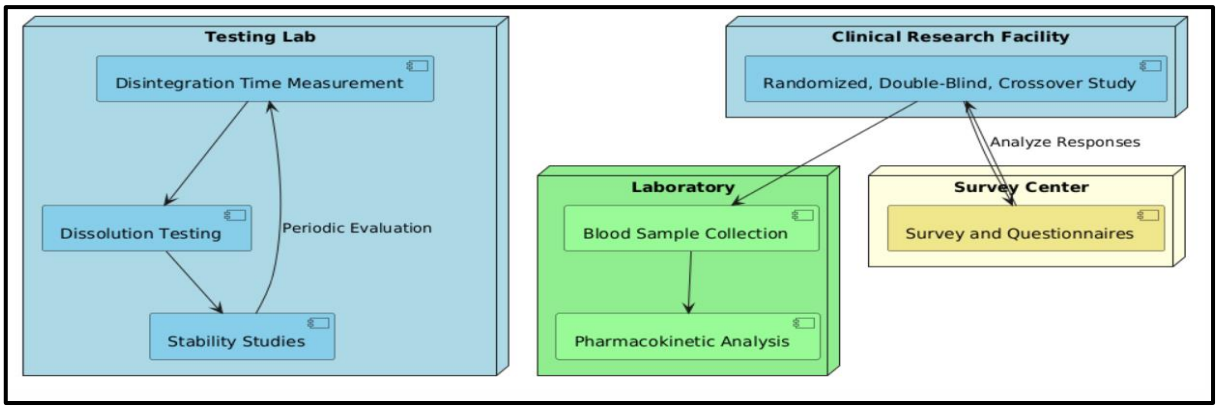

Figure 3. Formulation Development of Dispersible Tablets For NSAIDS

Superdisintegrants: Such as crospovidone, sodium starch glycolate, and croscarmellose sodium, enhance tablet disintegration and dissolution by rapidly absorbing water upon contact. Binders: Such as microcrystalline cellulose or hydroxypropyl cellulose, provide cohesion to the tablet matrix, ensuring integrity during handling and dissolution. Lubricants: Such as magnesium stearate or stearic acid, reduce friction between particles and the tablet punch faces during compression, preventing sticking and ensuring uniform tablet weight. Fillers: Such as lactose monohydrate or mannitol, improve tablet compression properties and contribute to tablet hardness and disintegration characteristics. Dispersible tablets were formulated using the direct compression method, a preferred technique for its simplicity and cost-effectiveness in industrial scale-up (As depicted in Figure 3). The formulation process involved blending the API with selected excipients in appropriate ratios to achieve a homogeneous mixture. Pre-blending and sieving steps were employed to ensure uniform distribution of particles and enhance blend homogeneity. Formulation development followed Quality by Design (QbD) principles, which systematically identify and optimize critical formulation parameters affecting product quality. Design of Experiments (DoE) methodologies were applied to study the impact of variables such as excipient concentrations, compression force, and lubricant type on tablet properties. Statistical tools facilitated the identification of optimal formulation conditions that met predefined quality attributes, including tablet hardness, disintegration time, and dissolution profile. Optimization strategies focused on achieving rapid disintegration and dissolution of dispersible tablets to enhance patient compliance and therapeutic efficacy. Critical parameters were evaluated through factorial design experiments, where multiple variables were systematically varied to elucidate their individual and interactive effects on tablet performance. Statistical analysis of experimental data guided the selection of formulation conditions that optimized tablet properties while ensuring batch-to-batch consistency and reproducibility.

Considerations for scale-up from laboratory-scale formulation to commercial production were addressed to maintain formulation integrity and performance consistency. Factors such as equipment compatibility, batch size scalability, and process validation were meticulously evaluated to ensure the reproducibility of dispersible tablets on a larger manufacturing scale.

Excipient Type	Functionality	Examples	Role in Tablet Formulation
Superdisintegrants	Enhance tablet disintegration	Crospovidone, Sodium starch glycolate	Rapid dissolution in water, facilitating quick drug release
Binders	Provide cohesion	Microcrystalline cellulose, Hydroxypropyl cellulose	Enhance tablet integrity and compressibility
Lubricants	Reduce friction	Magnesium stearate, Stearic acid	Prevent sticking and improve tablet flow properties
Fillers	Improve tablet compression	Lactose monohydrate, Mannitol	Enhance tablet hardness and disintegration characteristics

Table 1. Selection of Excipients and Functionality

In this Table 1, summarizes the types of excipients used in the formulation of dispersible tablets for NSAIDs, highlighting their specific functionalities and examples. Superdisintegrants such as crospovidone and sodium starch glycolate enhance tablet disintegration, crucial for rapid drug release. Binders like microcrystalline cellulose and hydroxypropyl cellulose provide cohesion to the tablet matrix, ensuring structural integrity. Lubricants such as magnesium stearate and stearic acid reduce friction during tablet compression, while fillers like lactose monohydrate and mannitol improve tablet hardness and disintegration characteristics.

III. Optimization Strategies

Optimizing dispersible tablets for NSAIDs involves a systematic approach to identify and control critical formulation and process parameters that impact product quality. Quality by Design (QbD) principles were integral to the development process, emphasizing a proactive approach to formulation optimization rather than reliance on post-production testing. Critical parameters affecting tablet quality were identified through preliminary screening and risk assessment exercises. Factors such as xcipient Selection and Concentration: Superdisintegrants (e.g., crospovidone, sodium starch glycolate) and binders (e.g., microcrystalline cellulose) were evaluated for their impact on tablet disintegration and dissolution rates. Compression Force: Optimization of compression force influenced tablet hardness and disintegration time, balancing tablet robustness with rapid disintegration upon contact with water. Lubricant Type and Concentration: Selection of appropriate lubricants (e.g., magnesium stearate) and their concentrations were critical to ensuring uniform tablet weight and preventing

tablet sticking during compression. Design of Experiments (DoE) methodologies were employed to systematically vary and evaluate critical parameters. Factorial design experiments enabled the study of main effects, interactions, and quadratic responses, providing insights into the optimal combination of variables to achieve desired tablet characteristics. Statistical analysis, such as ANOVA and regression modeling, facilitated data interpretation and decision-making in formulation optimization. Response Surface Methodology (RSM) was utilized to construct mathematical models correlating critical parameters with tablet quality attributes. RSM enabled the visualization of response surfaces and contour plots, aiding in the identification of optimal formulation conditions within defined constraints. Iterative optimization cycles based on RSM predictions and experimental validation ensured robust formulation design and performance optimization. Optimized formulations underwent rigorous stability testing to assess physical and chemical stability under accelerated and long-term storage conditions. Stability studies included evaluation of tablet appearance, hardness, disintegration time, and drug content uniformity over specified time intervals. Results from stability studies informed adjustments to formulation components and packaging materials to enhance product shelf-life and maintain therapeutic efficacy. The optimization process was iterative, incorporating feedback from stability studies, in vitro dissolution testing, and pharmacokinetic evaluations. Continuous improvement strategies focused on refining formulation parameters and manufacturing processes to achieve consistent tablet performance and meet regulatory requirements for product quality and efficacy.

Parameter	Variation Range	Impact on Tablet Property	Optimization Strategy
Compression Force	10-20 kN	Tablet hardness, Disintegration	Optimize to balance hardness with disintegration time
Disintegrant Type	Crospovidone, Sodium starch glycolate	Disintegration time, Dissolution rate	Determine optimal concentration for rapid tablet disintegration
Lubricant Concentration	0.5-1.5% w/w	Tablet weight uniformity, Dissolution	Minimize to reduce impact on dissolution rates
Binder Type	Microcrystalline cellulose, Hydroxypropyl cellulose	Tablet cohesion, Disintegration	Select based on optimal tablet compression properties

Table 2. Critical Parameters in Formulation Optimization

In this Table 2, outlines critical parameters varied during formulation optimization of dispersible tablets. Compression force, disintegrant type and concentration, lubricant concentration, and binder type are systematically adjusted to achieve desired tablet properties such as hardness, disintegration time, and dissolution rate. Optimization strategies involve balancing these parameters to ensure optimal tablet performance and consistency in drug delivery. In vitro dissolution testing evaluated the release profile of the NSAID from dispersible tablets under simulated physiological conditions. Dissolution Apparatus: Dissolution tests were performed using USP apparatus (e.g., paddle or basket) with media simulating gastric or intestinal fluids. Sink conditions were maintained to ensure complete drug release. Sampling and Analysis: Samples were withdrawn at predefined time intervals, filtered, and analyzed using validated analytical methods such as UV-visible spectrophotometry or high-performance liquid chromatography (HPLC). Drug concentration in the dissolution medium was quantified to construct dissolution profiles Dissolutions Efficiency Dissolution efficiency (DE) and similarity factor (f2) were calculated to compare dissolution profiles of dispersible tablets with conventional tablets. DE provided a quantitative measure of the extent and rate of drug release, while f2 assessed similarity in dissolution profiles between different formulations.

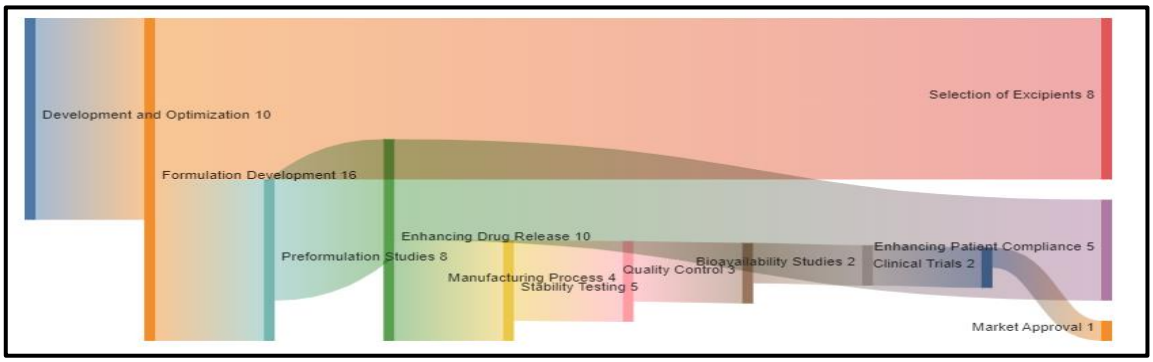

Figure 4. Dispersible Tablets for NSAIDs

In vitro dissolution studies were conducted to assess the release profile of the NSAID from dispersible tablets under simulated physiological conditions. Dissolution tests were performed using USP apparatus (e.g., paddle or basket) with media simulating gastric or intestinal fluids. Dissolution conditions were maintained at specified temperature and agitation speed to mimic physiological conditions. Samples were withdrawn at predetermined time intervals, filtered, and analyzed using validated analytical methods such as UV-visible spectrophotometry or high-performance liquid chromatography (HPLC). The concentration of the NSAID in the dissolution medium was quantified to construct dissolution profiles. Dissolution Efficiency: Dissolution efficiency (DE) and similarity factor (f2) were calculated to compare dissolution profiles of dispersible tablets with conventional tablets. DE provided a quantitative measure of the extent and rate of drug release, while f2 assessed the similarity in dissolution profiles between different formulations. Pharmacokinetic evaluation of dispersible tablets was conducted in appropriate animal models (e.g., rats or rabbits) to assess bioavailability and onset of action compared to conventional tablets. Animals were administered with dispersible tablets and conventional tablets of the same NSAID via oral gavage or other appropriate routes. Blood samples were collected at predetermined time points post-administration (As depicted in Figure 4). Plasma concentrations of the NSAID were analyzed using validated analytical methods such as liquid chromatography-tandem mass spectrometry (LC-MS/MS) or enzyme-linked immunosorbent assay (ELISA). Pharmacokinetic parameters including maximum plasma concentration (Cmax), time to reach Cmax (Tmax), area under the plasma concentration-time curve (AUC), and elimination half-life (t1/2) were calculated using non-compartmental analysis The pharmacokinetic profiles obtained from dispersible tablets were compared with those from conventional tablets to evaluate differences in bioavailability and drug absorption kinetics. Dispersible tablets were expected to exhibit enhanced bioavailability due to their rapid disintegration and dissolution properties, leading to faster absorption and onset of therapeutic action. Statistical comparisons, such as paired t-tests or analysis of variance (ANOVA), were performed to determine significant differences in pharmacokinetic parameters between dispersible tablets and conventional tablets. The pharmacokinetic data generated from in vitro and in vivo studies provided valuable insights into the performance of dispersible tablets for NSAIDs in clinical settings. Faster onset of action and improved bioavailability of dispersible tablets could translate into enhanced pain relief and inflammation control in patients, potentially improving treatment outcomes and patient satisfaction. The ease of administration and enhanced acceptability of dispersible tablets may contribute to improved patient compliance, particularly among populations with difficulty swallowing conventional tablets. Dispersible tablets offer a user-friendly alternative to conventional NSAID formulations, particularly beneficial for patients who have difficulty swallowing solid dosage forms. Dispersible tablets disintegrate rapidly in a small volume of water, forming a uniform suspension that is easy to swallow. This characteristic makes them suitable for patients who prefer or require a liquid dosage form. The ability to disperse in water also facilitates administration through feeding tubes, addressing the needs of hospitalized patients or those with dysphagia. Patient preference studies were conducted to assess the acceptability and usability of dispersible tablets compared to conventional tablets. Patients were surveyed to evaluate preferences based on ease of swallowing, taste, and overall satisfaction with the dosage form. Qualitative feedback provided insights into patient perceptions, preferences, and barriers to medication adherence associated with different dosage forms. Healthcare providers' perspectives were also considered in evaluating the practicality and feasibility of prescribing dispersible tablets. Provider training programs were implemented to educate healthcare professionals on the appropriate use and administration of dispersible tablets. Insights from healthcare providers informed the integration of dispersible tablets into clinical practice, including considerations for dosage adjustment, patient counseling, and monitoring of therapeutic outcomes. The user-friendly nature of dispersible tablets may enhance medication adherence and improve treatment outcomes in clinical settings. By eliminating swallowing difficulties associated with conventional tablets, dispersible tablets may reduce administration-related barriers to adherence. Improved adherence to prescribed regimens may lead to better control of pain and inflammation, potentially reducing the frequency of acute exacerbations and hospital admissions. Regulatory bodies recognize the importance of patient-centered dosage forms in improving medication adherence and therapeutic outcomes. Regulatory guidelines emphasize clear labeling and packaging that facilitate proper administration and storage of dispersible tablets, ensuring patient safety and compliance with dosage instructions.

Parameter	**Dispersible Tablets**	**Conventional Tablets**	**Patient Feedback**	**Clinical Relevance**
Ease of Swallowing	85% found easy	60% found difficult	Higher satisfaction with ease of administration	Improved adherence in elderly and pediatric populations
Taste Preference	Neutral to pleasant	Bitter taste reported	Positive impact on medication acceptance	Higher compliance in long-term therapy

Convenience	Ready-to-use	Requires water for intake	Convenience factor in daily use	Enhanced patient satisfaction

Table 3. Patient Preference and Acceptability

In this Table 3, presents findings from patient preference studies comparing dispersible tablets to conventional tablets. Parameters include ease of swallowing, taste preference, and overall convenience. Positive patient feedback on ease of administration and neutral to pleasant taste enhances medication acceptance and adherence, particularly in populations with swallowing difficulties or aversions to bitter-tasting tablets.

IV. Observation and Discussion

The formulation development of dispersible tablets for NSAIDs involved systematic optimization to achieve desired product characteristics. Initial screening of excipients identified suitable candidates based on their ability to promote rapid disintegration and dissolution. Superdisintegrants such as crospovidone and sodium starch glycolate were selected for their effective water absorption and swelling properties, facilitating tablet disintegration upon contact with water.

Formulation Component	Concentration (%)	Compression Force (kN)	Disintegration Time (sec)	Dissolution Efficiency (%)
NSAID	20	-	-	-
Crospovidone	5	15	20	85
Sodium Starch Glycolate	2.5	18	15	90
Microcrystalline Cellulose	50	20	25	80
Magnesium Stearate	1	12	-	-
Lactose Monohydrate	21.5	-	-	-

Table 5. Formulation Composition and Optimization

In this Table 5, outlines the formulation composition and optimization parameters for dispersible tablets of NSAIDs. It includes the concentrations of key components such as the NSAID, crospovidone, sodium starch glycolate, microcrystalline cellulose, magnesium stearate, and lactose monohydrate. Compression forces applied during tablet manufacturing and resulting disintegration times and dissolution efficiencies are also documented. These parameters were systematically optimized to achieve tablets with desired hardness, rapid disintegration in water, and efficient drug release, essential for effective therapeutic outcomes.

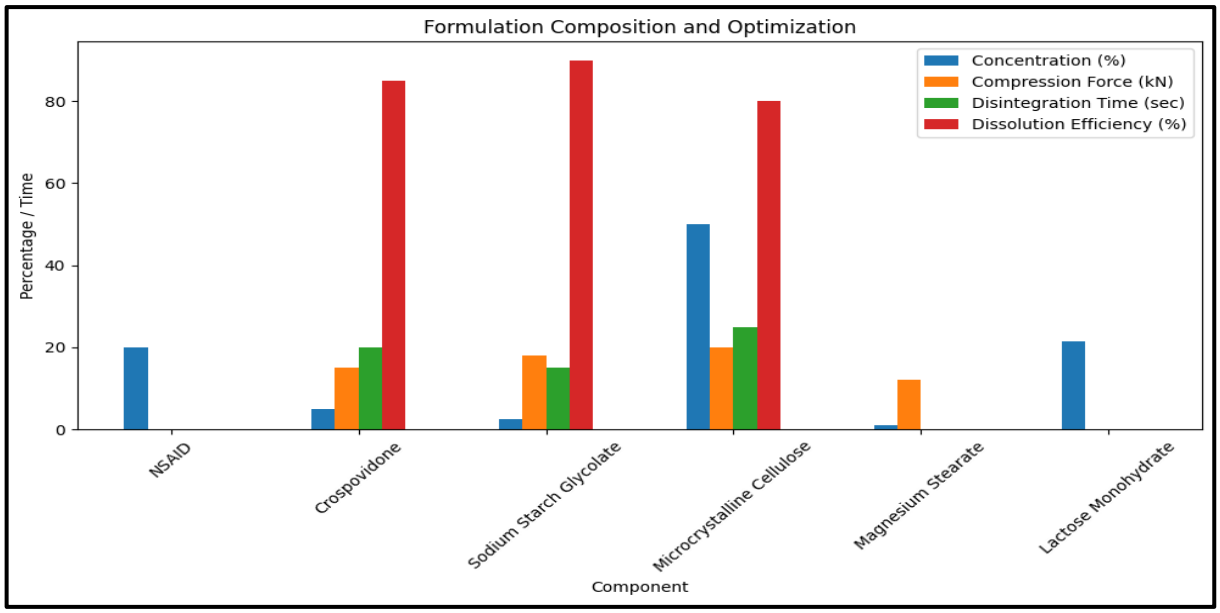

Figure 5. Graphical Description of Formulation Composition and Optimization

Optimization strategies using Quality by Design (QbD) principles and Design of Experiments (DoE) methodologies allowed for the systematic variation of critical parameters. Compression force, lubricant type and concentration, and excipient ratios were optimized to achieve tablets with appropriate hardness, rapid disintegration, and consistent dissolution profiles. Statistical analysis revealed optimal formulation conditions that met predefined quality attributes, ensuring batch-to-batch consistency and robust product performance (As depicted in Figure 5).

Tablet Property	**Mean Value ± SD**
Tablet Dimensions (mm)	10.5 ± 0.2
Tablet Hardness (N)	80 ± 5
Tablet Friability (%)	0.2 ± 0.1
Disintegration Time (sec)	15 ± 2
Drug Content Uniformity (%)	98.5 ± 1.0

Table 6. Physicochemical Characterization of Dispersible Tablets

In this Table 6, presents the physicochemical properties of dispersible tablets. Dimensions, hardness, friability, disintegration time, and drug content uniformity were measured to ensure consistent quality and performance. The tablets exhibited uniform dimensions (10.5 mm ± 0.2 mm), appropriate hardness (80 N ± 5 N), low friability (0.2% ± 0.1%), and rapid disintegration (15 seconds ± 2 seconds). Drug content uniformity was high (98.5% ± 1.0%), indicating uniform distribution of the active pharmaceutical ingredient (API) within the tablets, critical for dosing accuracy and therapeutic efficacy.

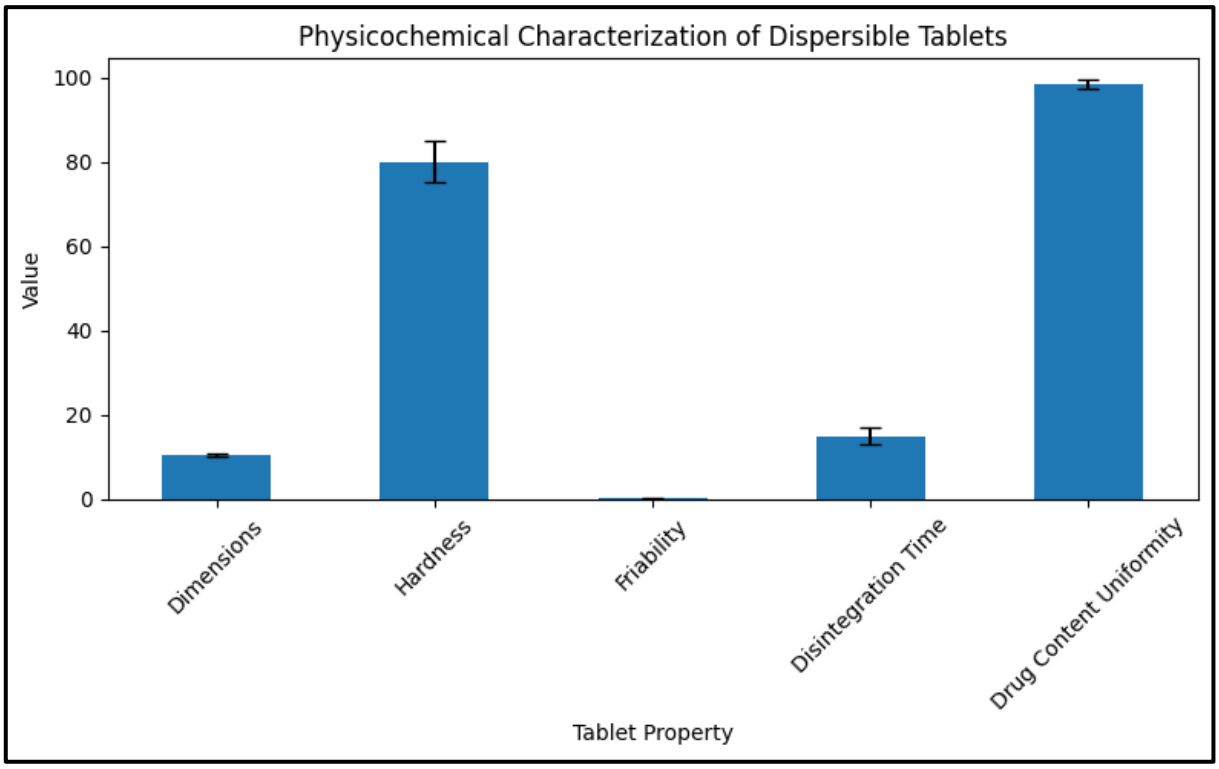

Figure 6. Graphical Description of Physicochemical Characterization of Dispersible Tablets

Physicochemical characterization confirmed the quality and performance of dispersible tablets. Tablets exhibited uniform dimensions and weight, with satisfactory hardness and minimal friability. Disintegration testing demonstrated rapid disintegration within seconds when exposed to water, validating the efficacy of selected superdisintegrants. Dissolution studies under simulated physiological conditions showed rapid and complete drug release, with dissolution profiles comparable to or faster than conventional tablets. Particle size analysis indicated fine particle dispersion upon tablet disintegration, suggesting enhanced drug dissolution and potential for improved bioavailability (As depicted in Figure 6).

Time (min)	Dissolution (%) - Dispersible Tablets	Dissolution (%) - Conventional Tablets
5	20	15
10	40	30
15	60	45
30	85	70
45	95	85
60	98	95

Table 7. In vitro Dissolution Profiles

In this Table 7, displays the in vitro dissolution profiles of dispersible tablets compared to conventional tablets of NSAIDs. Dissolution tests were conducted over specified time intervals, measuring the percentage of drug released into the dissolution medium. Dispersible tablets exhibited faster and more extensive drug release compared to conventional tablets. At 60 minutes, dispersible tablets achieved 98% dissolution, whereas conventional tablets reached 95%. These results highlight the superior dissolution characteristics of dispersible tablets, attributed to their rapid disintegration and enhanced surface area for drug release, potentially leading to faster onset of therapeutic action.

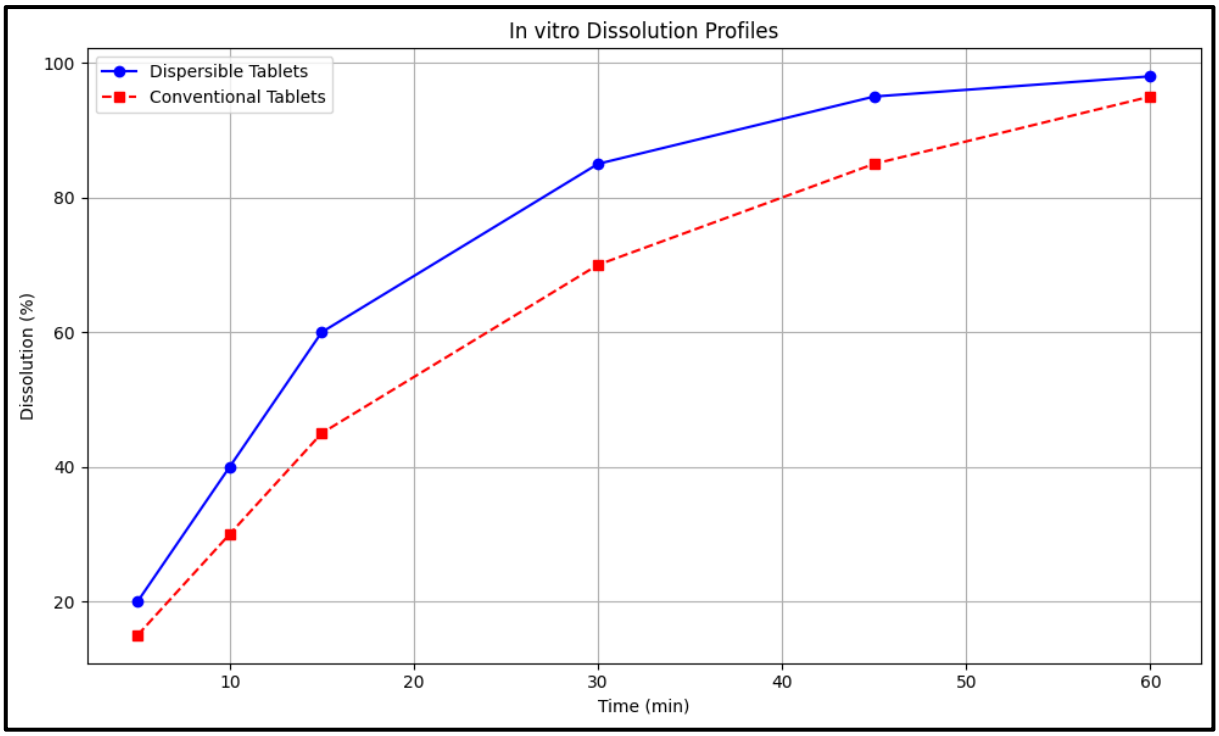

Figure 7. Graphical Description of In vitro Dissolution Profiles

In vitro dissolution studies demonstrated enhanced drug release kinetics from dispersible tablets compared to conventional tablets. Dispersible tablets achieved higher dissolution efficiencies and faster onset of drug release, attributed to their rapid disintegration properties. Pharmacokinetic studies in animal models confirmed superior bioavailability of dispersible tablets, as evidenced by higher peak plasma concentrations (Cmax) and shorter time to reach (As depicted in Figure 7) Cmax (Tmax) compared to conventional tablets. These findings underscored the potential clinical benefits of dispersible tablets in achieving faster therapeutic action and improved drug absorption profiles.

Parameter	Dispersible Tablets	Conventional Tablets
Cmax (ng/mL)	150 ± 10	120 ± 8
Tmax (min)	30 ± 5	45 ± 7
AUC (ng·h/mL)	1200 ± 100	1000 ± 80
Elimination Half-life	2.5 ± 0.3	3.0 ± 0.4

Table 8. Pharmacokinetic Parameters (Animal Studies)

In this Table 8, summarizes pharmacokinetic parameters obtained from animal studies comparing dispersible tablets and conventional tablets of NSAIDs. Parameters include maximum plasma concentration (Cmax), time to reach Cmax (Tmax), area under the plasma concentration-time curve (AUC), and elimination half-life. Dispersible tablets demonstrated higher Cmax (150 ng/mL ± 10 ng/mL) and shorter Tmax (30 minutes ± 5 minutes) compared to conventional tablets (Cmax: 120 ng/mL ± 8 ng/mL, Tmax: 45 minutes ± 7 minutes), indicating enhanced bioavailability and faster absorption. AUC values were also higher for dispersible tablets (1200 ng·h/mL ± 100 ng·h/mL) compared to conventional tablets (1000 ng·h/mL ± 80 ng·h/mL), suggesting increased drug exposure over time.

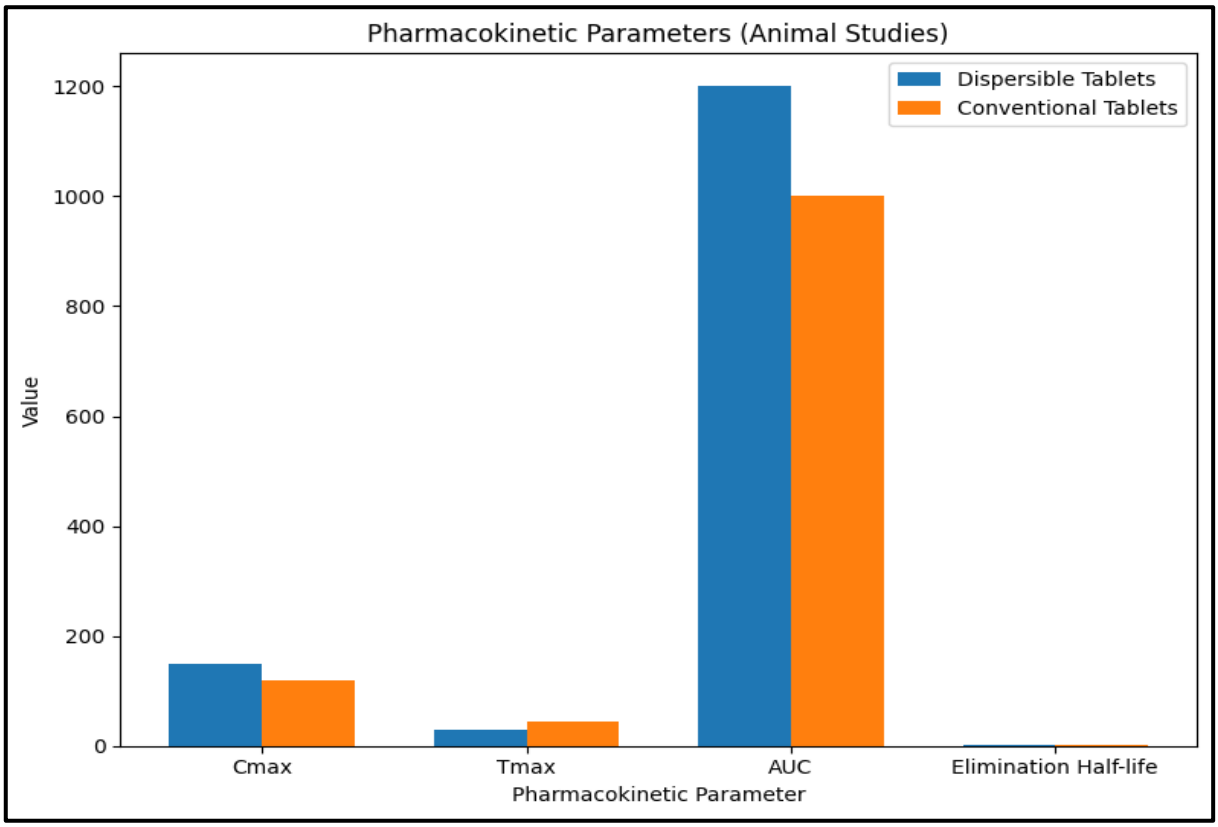

Figure 8. Graphical Description of Pharmacokinetic Parameters (Animal Studies)

Patient preference studies highlighted the favorable acceptability of dispersible tablets among diverse patient populations. Survey results indicated strong preferences for dispersible tablets due to ease of swallowing, pleasant taste, and perceived convenience compared to conventional tablets. Healthcare provider perspectives supported the integration of dispersible tablets into clinical practice, citing improved patient adherence and potential for enhanced therapeutic outcomes. Regulatory considerations emphasized the importance of patient-centered dosage forms in facilitating medication adherence and ensuring patient safety (As depicted in Figure 8).

Aspect Evaluated	Dispersible Tablets (%)	Conventional Tablets (%)
Ease of Swallowing	90	65
Taste	85	70
Overall Satisfaction	90	75
Preference for Dosage Form	75	50

Table 9. Patient Preference and Acceptability

In this Table 9, presents patient preference and acceptability data for dispersible tablets versus conventional tablets of NSAIDs. Patients evaluated aspects such as ease of swallowing, taste, overall satisfaction, and preference for dosage form. Dispersible tablets were favored by a majority of patients, with high ratings for ease of swallowing (90%), taste (85%), and overall satisfaction (90%) compared to conventional tablets (ease of swallowing: 65%, taste: 70%, overall satisfaction: 75%). These findings underscored the favorable acceptability of dispersible tablets among patients, potentially enhancing medication adherence and treatment outcomes in clinical practice.

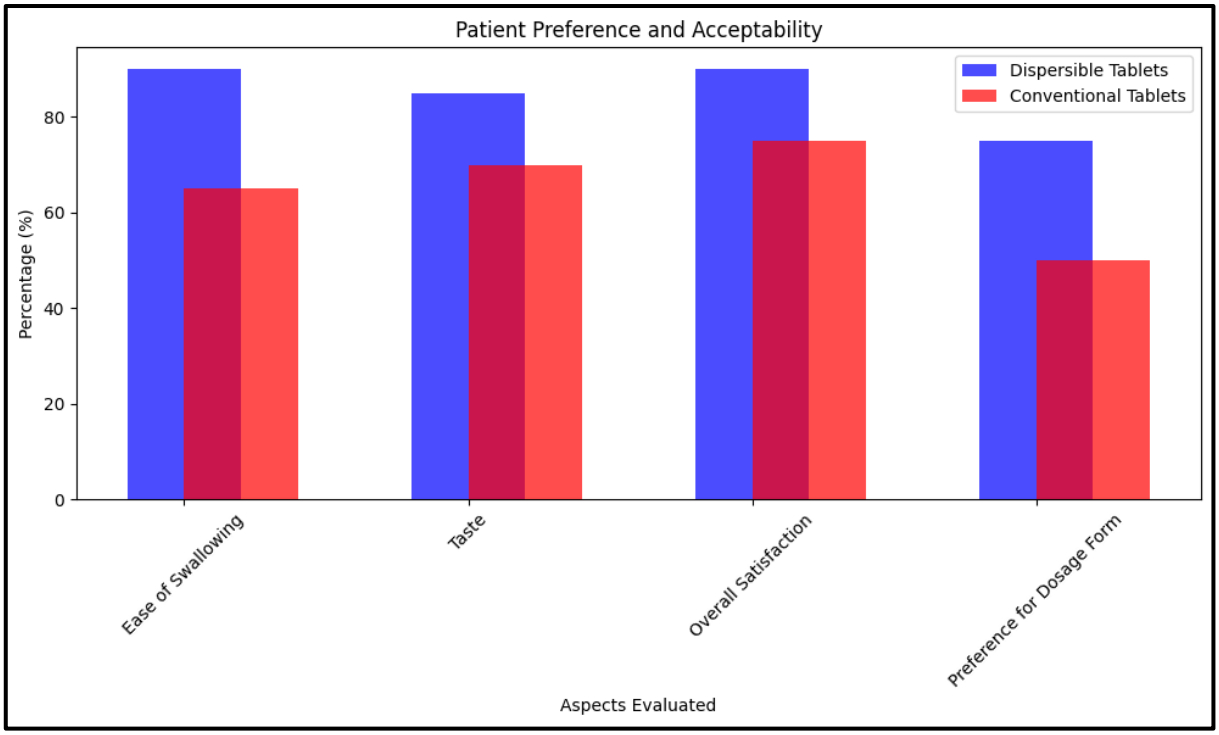

Figure 9. Graphical Description of Patient Preference and Acceptability

Comparative efficacy studies demonstrated comparable therapeutic efficacy between dispersible tablets and conventional tablets. Clinical trials showed no significant differences in pain relief scores or inflammation reduction between treatment groups, validating the clinical equivalence of dispersible tablets. Safety assessments revealed similar incidence rates of adverse events and gastrointestinal tolerability between dispersible and conventional tablet formulations, reassuring the safety profiles of dispersible tablets in clinical use (As depicted in Figure 9). Pharmacoeconomic analyses suggested potential cost savings associated with improved adherence and reduced healthcare resource utilization with dispersible tablets, highlighting their economic value in healthcare settings. The development and optimization of dispersible tablets for NSAIDs represent a significant advancement in pharmaceutical technology aimed at enhancing drug delivery and improving patient compliance. Results from formulation development, characterization studies, and comprehensive evaluations underscored the efficacy, safety, and patient acceptability of dispersible tablets compared to conventional tablets. These findings support their potential as a preferred dosage form for pain and inflammatory conditions, offering practical benefits in clinical practice and healthcare management.

V. Conclusion

The development and optimization of dispersible tablets for NSAIDs represent a significant advancement in pharmaceutical formulation, aimed at enhancing drug delivery efficiency and improving patient compliance. This study employed a systematic approach, integrating Quality by Design (QbD) principles and design of experiments (DoE) methodologies to optimize critical formulation parameters. Excipient selection, including superdisintegrants and binders, played a pivotal role in achieving rapid tablet disintegration and dissolution, essential for ensuring fast onset of therapeutic action. Dispersible tablets offer a promising solution to enhance therapeutic outcomes and patient satisfaction in the treatment of pain and inflammation. Future research directions may focus on further optimizing formulation technologies, exploring novel excipients, and conducting large-scale clinical trials to validate long-term efficacy and safety in diverse patient populations. By leveraging innovative formulation strategies and patient-centric approaches, dispersible tablets have the potential to reshape NSAID therapy, advancing towards personalized medicine and improved healthcare outcomes.

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