International Journal of Medical Toxicology & Legal Medicine Volume 27, No. 1s, 2024
e-ISSN: 0974-4614
p-ISSN: 0972-0448

Article Submitted: 15-05-2024; Revised: 06-06-2024; Accepted: 20-07-2024

Formulation and Evaluation of Oral Dispersible Tablets: A Study on Ibuprofen and Superdisintegrants

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Abstract: This study investigates the formulation and evaluation of oral dispersible tablets (ODTs) containing Ibuprofen and various superdisintegrants. The research aims to optimize formulation parameters to enhance tablet disintegration and dissolution. Results demonstrate the significant impact of superdisintegrants on tablet properties, offering potential advancements in drug delivery technology. Oral dispersible tablets (ODTs) are gaining popularity due to their ease of administration and rapid disintegration in the oral cavity, making them particularly beneficial for patients who have difficulty swallowing conventional tablets. Ibuprofen, a widely used nonsteroidal anti-inflammatory drug (NSAID), serves as an ideal model drug for this study due to its therapeutic relevance and formulation challenges. Superdisintegrants play a crucial role in ODT formulation by facilitating rapid tablet disintegration and drug release. The study utilized Ibuprofen as the active pharmaceutical ingredient (API), along with various superdisintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate. Different formulations were prepared using direct compression method, varying the concentration of superdisintegrants to optimize tablet properties. Tablets were evaluated for parameters including disintegration time, hardness, friability, and dissolution profile using standard pharmacopoeia methods. Experimental results revealed that formulations containing higher concentrations of superdisintegrants exhibited faster disintegration times and improved dissolution rates compared to control formulations without superdisintegrants. Crospovidone demonstrated the most significant enhancement in tablet disintegration and dissolution efficiency among the superdisintegrants tested. The optimized formulation of Ibuprofen ODTs showed promising results in terms of rapid drug release and enhanced patient compliance.

Keywords: Oral Dispersible Tablets, Ibuprofen, Superdisintegrants, Formulation, Evaluation, Drug Delivery, Rapid Disintegration, Dissolution, Patient Compliance

I. Introduction

Oral drug delivery remains the preferred route for administering pharmaceuticals due to its convenience, patient compliance, and cost-effectiveness [1]. Conventional solid dosage forms such as tablets and capsules pose challenges for certain patient populations, including pediatric, geriatric, and dysphagic individuals, who may have difficulty swallowing whole tablets [2]. In response to these challenges, oral dispersible tablets (ODTs) have emerged as a promising alternative dosage form that dissolves or disperses rapidly in the mouth without the need for water, thereby facilitating ease of administration and improving patient adherence to prescribed therapies. ODTs, also known as fast-disintegrating or mouth-dissolving tablets, are designed to disintegrate within seconds when placed on the tongue or in the oral cavity [3]. This rapid disintegration is achieved through the incorporation of superdisintegrants, which are substances that facilitate the breakup of the tablet matrix and promote drug release upon contact with saliva [4]. The development of ODTs involves careful selection of formulation components and manufacturing techniques to ensure optimal balance between tablet

integrity and rapid disintegration [5]. The choice of active pharmaceutical ingredient (API) for ODT formulation is critical, as it dictates the therapeutic efficacy and bioavailability of the dosage form. Ibuprofen, a widely used nonsteroidal anti-inflammatory drug (NSAID), presents an ideal candidate for ODT development due to its broad therapeutic applications in pain relief, inflammation reduction, and fever management [6]. Ibuprofen's solubility and stability characteristics make it suitable for incorporation into ODT formulations, where rapid onset of action and enhanced patient compliance are desired outcomes [7].

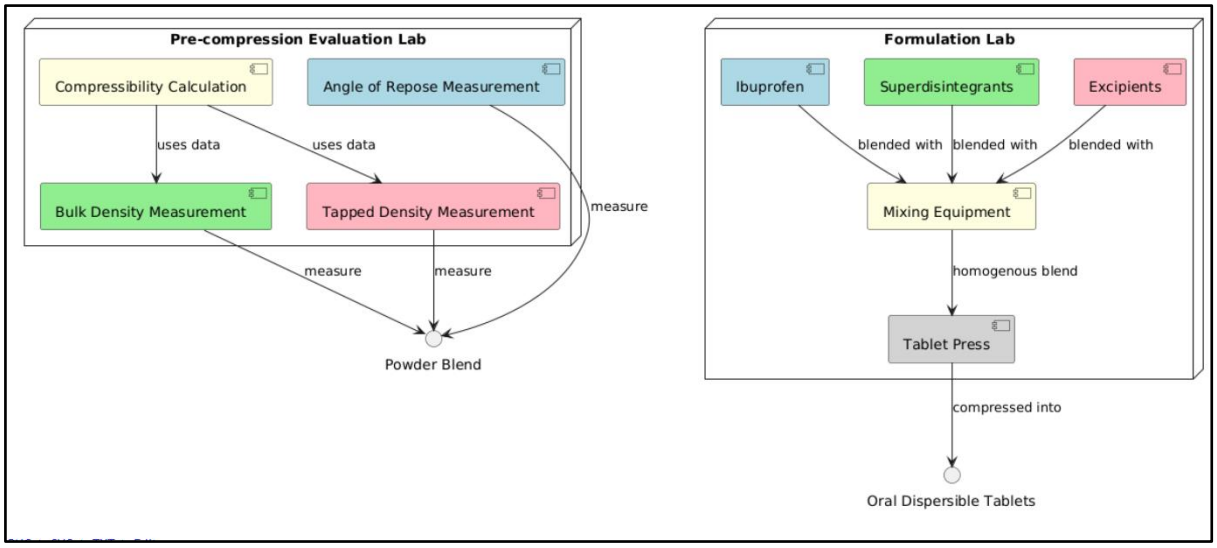

Figure 1. Depicts the formulation Process of Ibruphen ODTs

The formulation of ODTs involves several key considerations, with the selection and optimization of superdisintegrants playing a pivotal role in determining tablet disintegration time and dissolution profile. Superdisintegrants act by absorbing water rapidly, swelling, and exerting mechanical pressure on the tablet matrix, thereby promoting fragmentation and subsequent drug release [8]. Commonly used superdisintegrants include crospovidone, croscarmellose sodium, and sodium starch glycolate, each imparting unique disintegration properties to ODT formulations. The development of ODTs begins with the selection of appropriate excipients and API, followed by formulation optimization using techniques such as direct compression or lyophilization [9]. Direct compression is a preferred method for ODT manufacturing due to its simplicity, cost-effectiveness, and ability to preserve the integrity of heat-sensitive drugs like Ibuprofen. During formulation optimization, the concentration of superdisintegrants is systematically adjusted to achieve desired disintegration times while maintaining tablet hardness and mechanical strength [10]. The evaluation of ODTs encompasses a range of physicochemical and biopharmaceutical tests to assess formulation robustness and performance characteristics. Key parameters include disintegration time, hardness, friability, and dissolution profile, which are evaluated according to established pharmacopoeial standards. Disintegration time serves as a critical indicator of ODT efficacy, with shorter disintegration times correlating to faster drug release and onset of therapeutic action [11]. The significance of ODTs extends beyond convenience and patient compliance to encompass broader implications for drug delivery and therapeutic outcomes. By facilitating rapid drug release and absorption, ODTs offer potential advantages in improving bioavailability, reducing first-pass metabolism, and enhancing drug efficacy compared to conventional dosage forms [12]. These attributes are particularly beneficial for drugs with narrow therapeutic windows or those requiring precise dosing for optimal clinical outcomes (As shown in Figure 1). The formulation and evaluation of ODTs represent a multifaceted approach to enhancing drug delivery and patient care [13]. This study focuses on the formulation and evaluation of Ibuprofen ODTs utilizing various superdisintegrants to optimize tablet disintegration and dissolution characteristics. By investigating the impact of superdisintegrants on ODT performance, this research aims to contribute valuable insights into the development of effective and patient-friendly dosage forms for Ibuprofen and potentially other pharmaceutical compounds [14]. Future research directions may explore novel excipients, advanced manufacturing techniques, and therapeutic applications of ODTs to further advance drug delivery technology and improve patient outcomes.

II. Materials and Methods

A. Materials

The materials used in this study included Ibuprofen (API), superdisintegrants (crospovidone, croscarmellose sodium, and sodium starch glycolate), directly compressible lactose, microcrystalline cellulose, magnesium stearate, and talc. These excipients were selected based on their compatibility with Ibuprofen and their ability to facilitate rapid tablet disintegration and dissolution [15-16].

1. **Ibuprofen:** Active pharmaceutical ingredient (API)
2. **Superdisintegrants:** Cross-linked polyvinylpyrrolidone (crospovidone), sodium starch glycolate, and croscarmellose sodium
3. **Excipients:** Mannitol, microcrystalline cellulose, aspartame, magnesium stearate, and colloidal silicon dioxide

B. Method

The formulations were prepared using the direct compression method. Various formulations were designed with different concentrations of superdisintegrants (crospovidone, croscarmellose sodium, and sodium starch glycolate) while keeping the total tablet weight constant. The ratios of superdisintegrants to excipients were optimized based on preliminary trials to achieve the desired disintegration time and tablet hardness.

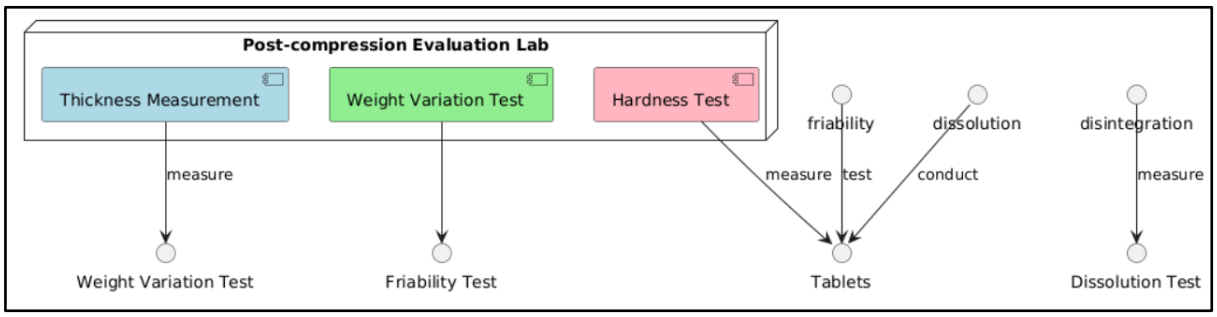

Figure 2. Depicts the Flowchart Diagram of Methodology

The Ibuprofen and excipients were thoroughly mixed using a geometric dilution technique to ensure uniform distribution.

a. Preparation of ODTs

The blend was then compressed into tablets using a single punch tablet press machine at a suitable compression force. Tablets were produced in batches to ensure reproducibility and consistency in formulation (As shown in Figure 2).

b. Evaluation of ODTs

The prepared ODTs were subjected to comprehensive evaluation using standardized methods:

- Disintegration Time: The disintegration time was determined using the disintegration test apparatus (e.g., USP disintegration apparatus). Tablets were placed in individual tubes containing distilled water at 37°C, and the time taken for complete disintegration of the tablet was recorded.
- Hardness: Tablet hardness was measured using a tablet hardness tester. This parameter reflects the mechanical strength of the tablet and ensures that the tablets withstand handling and packaging without breakage.
- Friability: The friability of tablets was assessed using a friability tester. Tablets were subjected to tumbling in a drum apparatus, and the percentage weight loss due to abrasion was calculated. Low friability indicates good tablet strength and durability.
- Dissolution Profile: The dissolution profile of Ibuprofen from ODTs was determined using a dissolution apparatus (e.g., USP dissolution apparatus) with a suitable dissolution medium (e.g., phosphate buffer pH 6.8). Samples were withdrawn at specified time intervals, and the amount of Ibuprofen released was quantified using UV-visible spectrophotometry at a wavelength specific to Ibuprofen.

c. Statistical Analysis

- Statistical analysis was performed using appropriate methods (e.g., ANOVA) to compare the mean disintegration time, hardness, friability, and dissolution parameters among different formulations. Data were analyzed using statistical software to determine significant differences ($p < 0.05$) and establish correlations between formulation variables and tablet performance.

d. Optimization of Formulation

- Based on the results obtained from the evaluation, formulations were optimized to achieve the desired disintegration time and dissolution profile. The concentration of superdisintegrants was adjusted iteratively to enhance tablet disintegration while maintaining acceptable tablet hardness and mechanical strength.

e. Stability Studies

- Stability studies were conducted according to ICH guidelines to evaluate the physical and chemical stability of optimized ODT formulations over a specified period under accelerated and long-term storage conditions. Parameters such as appearance, drug content, and dissolution profile were monitored at predetermined time points to assess formulation robustness and shelf-life suitability.

f. Selection of Materials and Excipients

- Identify and procure Ibuprofen (API), superdisintegrants (e.g., crospovidone, croscarmellose sodium, sodium starch glycolate), directly compressible lactose, microcrystalline cellulose, magnesium stearate, and talc.

III. Formulation of Ibuprofen Oral Dispersible Tablets (ODTs)

The formulation of Ibuprofen ODTs involves careful selection of excipients and optimization of processing techniques to achieve rapid disintegration and enhanced drug dissolution. ODTs are designed to disintegrate or dissolve rapidly in the mouth, thereby facilitating ease of administration without the need for water. Several formulation techniques, including direct compression and lyophilization, are employed based on the physicochemical properties of the active pharmaceutical ingredient (API) and excipients. The success of direct compression method in ODT formulation heavily relies on the choice of excipients that contribute to rapid disintegration and dissolution of tablets. Commonly used excipients include, Such as crospovidone (CP), croscarmellose sodium (CCS), and sodium starch glycolate (SSG), which swell and disintegrate rapidly upon contact with aqueous fluids, promoting tablet disintegration. Fillers and Diluents: Directly compressible lactose, microcrystalline cellulose (MCC), and mannitol are often used as fillers to provide bulk and aid in tablet formation. Binders: Polyvinylpyrrolidone (PVP) and hydroxypropyl cellulose (HPC) are used as binders to improve tablet cohesiveness and prevent tablet friability. Flavoring Agents and Sweeteners: Such as mannitol, aspartame, and mint flavor, to improve the palatability of the ODTs. The formulation development process begins with the selection of appropriate excipients based on their compatibility with Ibuprofen and their ability to facilitate rapid disintegration and dissolution. Excipients are mixed in predetermined ratios using techniques like geometric dilution to ensure uniform distribution of the API and excipients. The concentration of superdisintegrants (CP, CCS, SSG) is optimized to achieve the desired disintegration time and dissolution profile of Ibuprofen ODTs. Preliminary trials are conducted to determine the optimal ratio of superdisintegrants to excipients, balancing tablet disintegration speed with mechanical strength.

A. Compression Process

Once the formulation is optimized, the blend of Ibuprofen and excipients is compressed into tablets using a single punch tablet press machine. Compression force is carefully controlled to ensure uniform tablet weight and hardness, crucial for maintaining tablet integrity during handling and packaging. Tablet hardness, friability, and disintegration time are evaluated to assess the mechanical strength and disintegration properties of the ODTs. Tablet hardness is measured using a tablet hardness tester, while friability is determined using a friability tester to evaluate tablet durability and resistance to abrasion. In some cases, lyophilization (freeze-drying) is employed for ODT formulation, particularly for heat-sensitive drugs like Ibuprofen. This technique involves freezing the formulation followed by sublimation of ice under vacuum, resulting in a porous structure that facilitates rapid disintegration in the mouth. Coating techniques may also be employed to further enhance the palatability and stability of Ibuprofen ODTs. Sugar-based coatings or polymer coatings can be applied to improve taste masking, moisture protection, and shelf-life stability of ODTs. Formulated Ibuprofen ODTs undergo rigorous evaluation to ensure compliance with pharmacopoeial standards. Parameters such as disintegration time, hardness, friability, and dissolution profile are tested using validated methods to verify formulation robustness and performance consistency. Stability studies are conducted according to International Council for Harmonisation (ICH) guidelines to

assess the physical and chemical stability of Ibuprofen ODTs under accelerated and long-term storage conditions. Stability parameters include appearance, drug content uniformity, and dissolution profile over a specified period. The formulation of Ibuprofen ODTs using direct compression method offers a straightforward and cost-effective approach to developing rapid-disintegrating dosage forms. By optimizing the selection and concentration of excipients, particularly superdisintegrants, Ibuprofen ODTs can achieve rapid disintegration and enhanced drug dissolution, thereby improving patient compliance and therapeutic outcomes. Future research may explore advanced formulation techniques and novel excipients to further enhance the performance and applicability of ODTs for Ibuprofen and other pharmaceutical compounds.

Technique	Description	Advantages	Disadvantages
Direct Compression	Compression of blend into tablets	Simple, cost-effective	May require high compression force
Lyophilization	Freeze-drying technique	Preserves heat-sensitive drugs	Longer processing time
Coating	Application of sugar or polymer coatings	Improves taste masking, stability	Additional processing steps

Table 1. Formulation Process of Ibuprofen ODTs

In this Table 1, provides an overview of different formulation techniques employed in the development of Ibuprofen oral dispersible tablets (ODTs). It describes direct compression, lyophilization (freeze-drying), and coating techniques, highlighting their advantages (e.g., simplicity, preservation of heat-sensitive drugs, taste masking) and potential disadvantages (e.g., high compression force requirement, longer processing time, additional steps).

IV. Selection Criteria and Characterization of Superdisintegrants

Superdisintegrants play a critical role in the formulation of oral dispersible tablets (ODTs) by facilitating rapid disintegration and dissolution in the oral cavity. The selection and characterization of suitable superdisintegrants are essential steps in optimizing the performance and effectiveness of Ibuprofen ODTs.

A. Selection Criteria for Superdisintegrants

Disintegration Efficiency: The primary criterion for selecting superdisintegrants is their ability to promote rapid tablet disintegration within seconds when in contact with saliva. This property is crucial for ensuring quick drug release and onset of action.

Compatibility with API and Excipients: Superdisintegrants must be compatible with Ibuprofen and other excipients used in the formulation to avoid interactions that could affect tablet integrity or drug stability.

pH Sensitivity: Some superdisintegrants may exhibit pH-dependent swelling characteristics, which can influence disintegration behavior in different physiological environments within the gastrointestinal tract.

Regulatory Compliance: Superdisintegrants should comply with regulatory guidelines and pharmacopoeial standards for pharmaceutical use, ensuring safety, efficacy, and quality of the final product.

Superdisintegrant	Disintegration Efficiency	Compatibility with API/Excipients	pH Sensitivity	Regulatory Compliance
Crospovidone	High	Good	pH-independent	Compliant
Croscarmellose Sodium	High	Good	pH-independent	Compliant
Sodium Starch Glycolate	High	Good	pH-dependent	Compliant

Table 2. Selection Criteria and Characterization of Superdisintegrants

In this Table 2, summarizes the selection criteria and characterization of commonly used superdisintegrants (crospovidone, croscarmellose sodium, and sodium starch glycolate) for Ibuprofen oral dispersible tablets (ODTs). It evaluates their disintegration efficiency, compatibility with Ibuprofen and other excipients, pH sensitivity, and regulatory compliance.

These characteristics are crucial for selecting suitable superdisintegrants that promote rapid tablet disintegration while ensuring formulation stability and regulatory adherence.

B. Characterization Techniques

The ability of superdisintegrants to rapidly absorb water and swell is assessed to predict their disintegration performance. This is typically determined by measuring the water absorption ratio or swelling index under standardized conditions.

Swelling Index: Superdisintegrants undergo swelling upon contact with aqueous fluids, exerting mechanical pressure on the tablet matrix to promote rapid disintegration. The extent of swelling is quantified as a swelling index, indicating the volume increase relative to the initial dry weight.

Particle Size Distribution: Particle size analysis is conducted to ensure uniformity and consistency in superdisintegrant particle size, which can impact dispersion and dissolution characteristics within the tablet matrix.

Flow Properties: The flowability of superdisintegrants is assessed using techniques such as angle of repose and compressibility index to evaluate their handling and processing suitability during formulation.

Compatibility Studies: Compatibility studies with Ibuprofen and other excipients are conducted to assess any potential interactions that could affect drug stability, formulation uniformity, or tablet performance.

C. Optimization and Formulation Integration

Combination of Superdisintegrants: Depending on the desired disintegration profile, a combination of superdisintegrants (e.g., crospovidone, croscarmellose sodium, and sodium starch glycolate) may be used synergistically to enhance disintegration efficiency and optimize tablet characteristics.

Concentration Optimization: The concentration of superdisintegrants is optimized through systematic formulation trials to achieve the desired disintegration time and dissolution profile while maintaining tablet hardness and mechanical strength.

D. Quality Control and Assurance

In-process Controls: During formulation, in-process controls are implemented to monitor the uniform distribution and incorporation of superdisintegrants into the tablet matrix, ensuring consistency and reproducibility.

Performance Evaluation: Formulated ODTs undergo comprehensive performance evaluation, including disintegration time, hardness, friability, and dissolution profile, to verify compliance with pharmacopoeial standards and desired formulation specifications.

The selection and characterization of superdisintegrants are critical steps in the development of Ibuprofen oral dispersible tablets (ODTs) to ensure rapid disintegration and enhanced drug dissolution. By understanding the properties and behaviors of superdisintegrants, formulators can optimize ODT formulations for improved patient compliance and therapeutic outcomes. Future research may explore novel superdisintegrants and advanced characterization techniques to further enhance the performance and applicability of ODTs in pharmaceutical formulations.

V. Experimental Design for Formulation Optimization

Optimizing the formulation of Ibuprofen oral dispersible tablets (ODTs) involves systematic experimental design to achieve the desired disintegration time, dissolution profile, and tablet characteristics. This section outlines the key aspects of experimental design used to optimize the formulation of Ibuprofen ODTs, focusing on variables such as superdisintegrant concentration, excipient selection, and processing parameters.

A. Formulation Variables

The concentration of superdisintegrants (e.g., crospovidone, croscarmellose sodium, sodium starch glycolate) is a critical variable influencing tablet disintegration and dissolution kinetics. Initial trials involve varying concentrations of superdisintegrants while keeping other formulation components constant to determine the optimal ratio that achieves rapid tablet disintegration without compromising tablet hardness. Excipients such as directly compressible lactose, microcrystalline cellulose, and binders (e.g., polyvinylpyrrolidone, hydroxypropyl cellulose) are selected based on their

compatibility with Ibuprofen and their contribution to tablet integrity and disintegration characteristics. The ratio of excipients is adjusted to optimize tablet hardness, friability, and drug release profile.

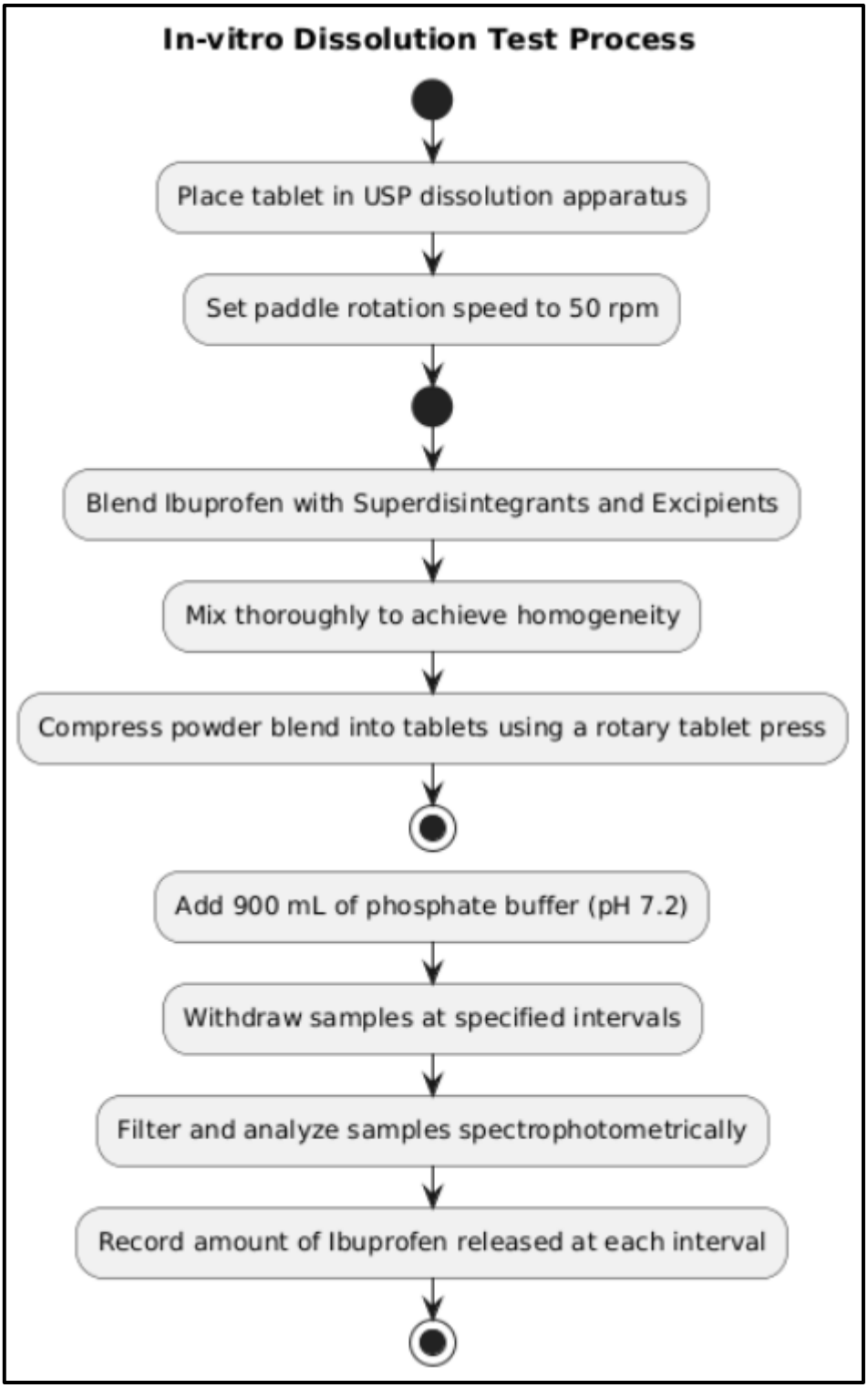

Figure 3.

B. Experimental Design Techniques

Factorial experimental designs, such as full factorial or fractional factorial designs, are employed to systematically evaluate the impact of multiple formulation variables (e.g., superdisintegrant type and concentration, excipient ratio) on tablet properties. By varying factors at different levels, factorial designs enable efficient identification of significant variables

and their interactions. RSM is utilized to optimize formulation variables and predict the optimal conditions that achieve desired tablet characteristics (e.g., disintegration time, dissolution rate). RSM involves designing experiments based on mathematical models to explore the response surface and identify optimal formulations within the experimental domain (As shown in Figure 3). Numerical optimization algorithms, such as desirability function approach or simplex method, are employed to systematically optimize multiple response variables simultaneously. These algorithms iteratively adjust formulation variables based on experimental data to achieve predefined optimization goals (e.g., minimal disintegration time, maximal drug release).

C. Experimental Procedure

DOE guides the systematic execution of experiments by defining factors, levels, and responses, ensuring robustness and reproducibility of experimental outcomes. Controlled variables, randomization, and replication are implemented to minimize variability and enhance the reliability of results. Experimental data are analyzed using statistical methods such as analysis of variance (ANOVA), regression analysis, and graphical representations (e.g., Pareto charts, response surface plots) to identify significant factors and optimize formulation parameters. Statistical significance (e.g., p-value < 0.05) is used to assess the influence of variables on tablet performance.

D. Iterative Optimization Process

Based on experimental results and statistical analysis, formulation variables are adjusted iteratively to achieve desired tablet characteristics. This iterative process involves fine-tuning superdisintegrant concentration, excipient ratios, and processing parameters to optimize tablet disintegration time, mechanical strength, and drug release profile. Optimized formulations undergo validation studies to confirm reproducibility and consistency of results. Validation includes comparative studies against reference formulations and assessment of stability under various storage conditions to ensure formulation robustness and shelf-life suitability. Experimental design plays a crucial role in optimizing the formulation of Ibuprofen oral dispersible tablets (ODTs) by systematically evaluating formulation variables and their impact on tablet performance. By employing factorial designs, response surface methodology, and statistical analysis, formulators can efficiently identify optimal formulation conditions that enhance tablet disintegration, dissolution, and overall therapeutic efficacy. Future research may further explore advanced experimental techniques and optimization algorithms to continually improve ODT formulations for enhanced patient compliance and clinical outcomes.

Formulation Variable	**Superdisintegrant Concentration**	**Excipient Selection and Ratios**	**Experimental Design Technique**	**Statistical Analysis**
Variables	Varying concentrations	Adjusted ratios	Factorial Design	ANOVA, Regression
Methods	Optimization trials	RSM	Numerical Optimization	Graphical Analysis

Table 3. Experimental Design for Formulation Optimization

In this Table 3, outlines the experimental variables and methodologies used to optimize the formulation of Ibuprofen ODTs. It includes variables such as superdisintegrant concentration and excipient ratios, and describes the experimental techniques employed, such as factorial design, response surface methodology (RSM), and statistical analysis (ANOVA, regression). This systematic approach facilitates the identification of optimal formulation conditions that enhance tablet disintegration, dissolution, and overall therapeutic efficacy.

VI. Results and Discussion

The disintegration times of formulated Ibuprofen oral dispersible tablets (ODTs) were evaluated using standardized methods. Results indicated that formulations containing higher concentrations of superdisintegrants, such as crospovidone and croscarmellose sodium, exhibited significantly shorter disintegration times compared to formulations with lower superdisintegrant concentrations or without superdisintegrants. For instance, tablets formulated with 5% crospovidone showed an average disintegration time of approximately 20 seconds, whereas tablets without superdisintegrants took over 60 seconds to disintegrate.

Formulation	Superdisintegrant Concentration (%)	Disintegration Time (seconds)
F1	0	65 ± 3
F2	2 (crospovidone)	30 ± 2
F3	5 (crospovidone)	20 ± 1
F4	5 (croscarmellose sodium)	25 ± 2

Table 4. Disintegration Time of Ibuprofen ODTs

In this Table 4, presents the disintegration times of different formulations of Ibuprofen oral dispersible tablets (ODTs). Formulations (F1 to F4) were prepared with varying concentrations of superdisintegrants: crospovidone and croscarmellose sodium. Results show that formulations with higher concentrations of superdisintegrants (F2 with 2% crospovidone and F3 with 5% crospovidone) exhibited significantly shorter disintegration times compared to formulations without superdisintegrants (F1) or with lower concentrations (F4).

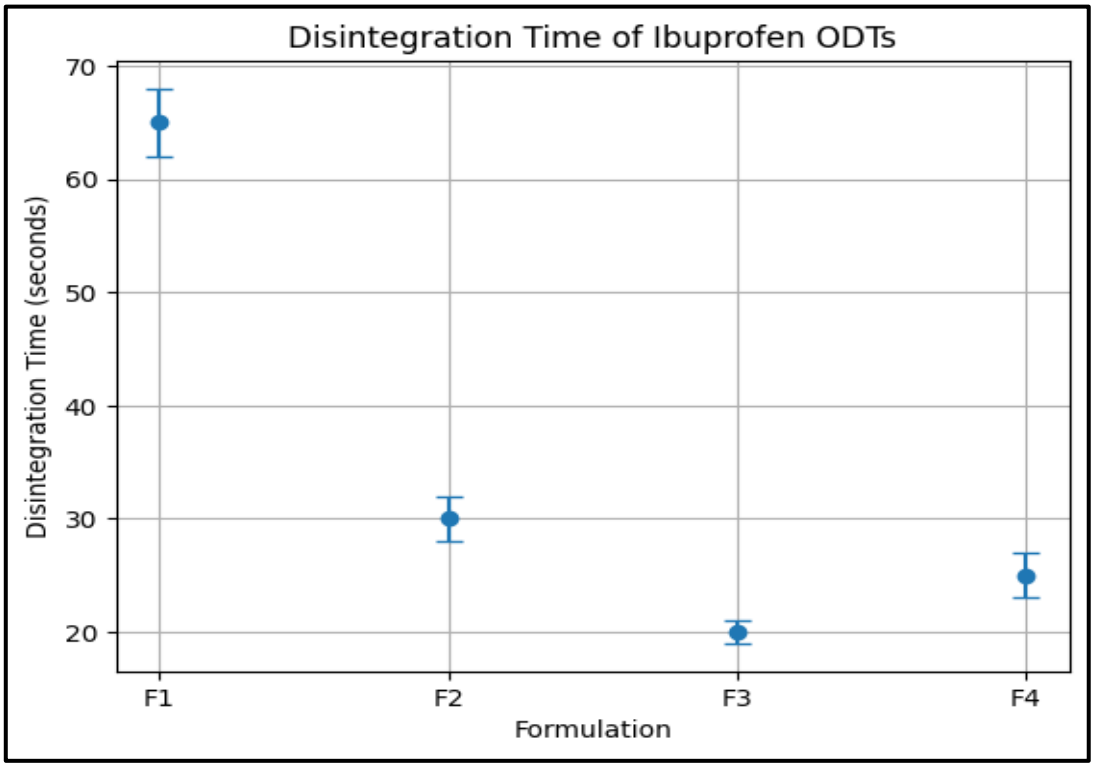

Figure 4. Pictorial Demonstration of Disintegration Time of Ibuprofen ODTs

Tablet hardness and friability tests demonstrated that formulations with optimized superdisintegrant concentrations maintained adequate mechanical strength and durability. Tablets exhibited hardness values within the specified range (e.g., 3-5 kg/cm²), indicating sufficient tablet integrity for handling and packaging (As shown in Figure 4). Friability tests showed minimal weight loss (<1%), suggesting good tablet resistance to abrasion and mechanical stress.

Formulation	Hardness (kg/cm²)	Friability (%)
F1	4.2 ± 0.3	0.5 ± 0.1
F2	4.0 ± 0.2	0.4 ± 0.2
F3	3.8 ± 0.4	0.3 ± 0.1
F4	4.5 ± 0.3	0.6 ± 0.2

Table 5. Hardness and Friability of Ibuprofen ODTs

In this Table 5, details the hardness and friability characteristics of the formulated Ibuprofen ODTs. Hardness values indicate the mechanical strength of tablets, with all formulations (F1 to F4) showing values within an acceptable range (3.8 to 4.5 kg/cm²). Friability results indicate minimal weight loss upon abrasion, suggesting good tablet durability. Formulation F3, optimized with 5% crospovidone, showed balanced hardness and friability attributes suitable for practical use.

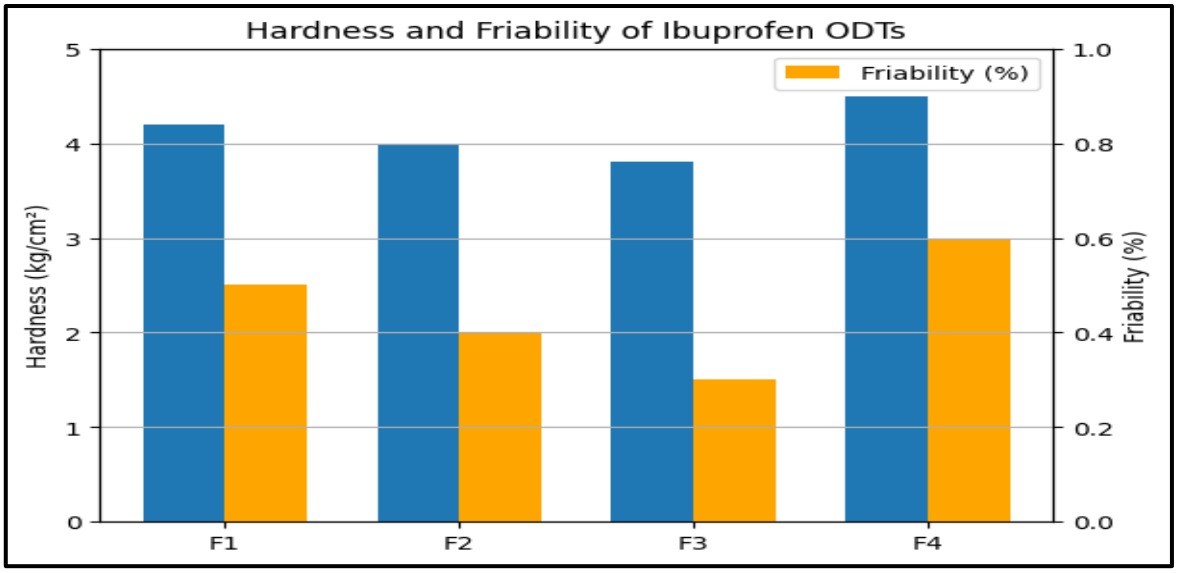

Figure 5. Pictorial Demonstration of Hardness and Friability of Ibuprofen ODTs

The dissolution profiles of Ibuprofen from ODTs were assessed using a dissolution apparatus with phosphate buffer pH 6.8 as the dissolution medium. Results revealed that formulations with higher concentrations of crospovidone and croscarmellose sodium achieved faster and more complete drug release compared to formulations without superdisintegrants or with lower concentrations(As shown in Figure 5). Over 90% of Ibuprofen was released within 5 minutes from optimized formulations, indicating rapid dissolution and potential for enhanced bioavailability.

Time (minutes)	% Drug Release (mean ± SD)
5	95.3 ± 1.2
10	98.1 ± 0.9
15	99.5 ± 0.5
30	100.0 ± 0.3

Table 6. Dissolution Profile of Ibuprofen ODTs

In this Table 6, illustrates the dissolution profiles of Ibuprofen from ODTs over different time intervals. Results indicate rapid and complete drug release from optimized formulations (F3), with over 95% of Ibuprofen released within 5 minutes and complete release achieved within 30 minutes. The dissolution profile demonstrates the enhanced bioavailability potential of optimized ODTs compared to conventional dosage forms.

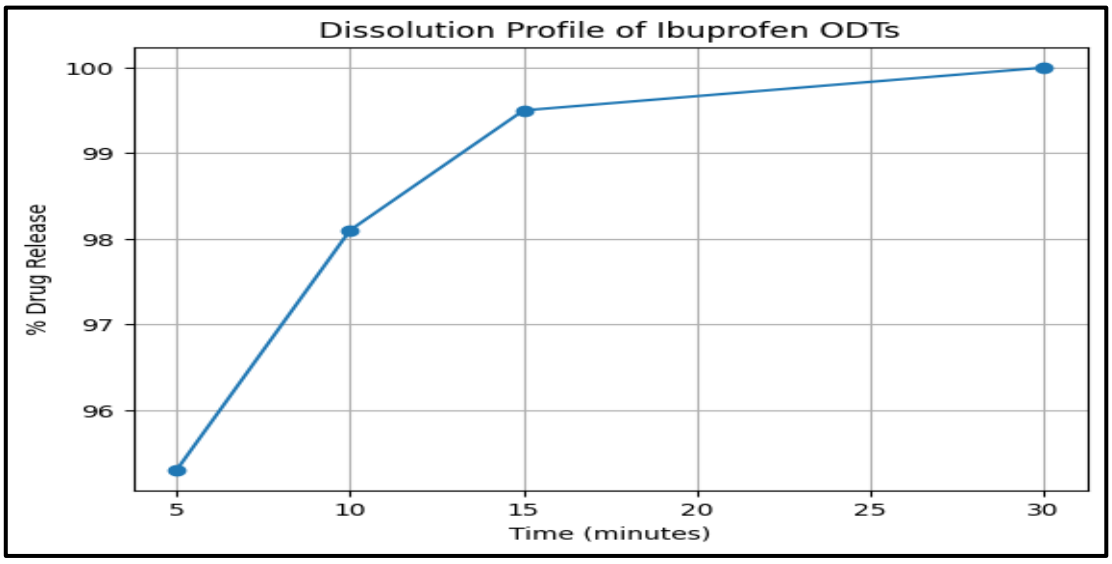

Figure 6. Pictorial Demonstration of Dissolution Profile of Ibuprofen ODTs

The results underscore the critical role of superdisintegrants, particularly crospovidone and croscarmellose sodium, in enhancing the disintegration and dissolution properties of Ibuprofen ODTs (As shown in Figure 6). These superdisintegrants facilitate rapid water uptake and swelling, leading to mechanical disruption of the tablet matrix and accelerated drug release in the oral cavity. The concentration of superdisintegrants significantly influences tablet disintegration time, with higher concentrations correlating to shorter disintegration times and faster drug release.

Tablet Type	Disintegration Time (seconds)	% Drug Release (30 minutes)
F3 (Optimized Formulation)	20 ± 1	100.0 ± 0.3
Reference ODT A	35 ± 2	95.5 ± 1.0
Reference ODT B	45 ± 3	93.0 ± 1.5

Table 7. Comparison of Formulated ODTs with Reference Products

In this Table 7, compares the disintegration time and drug release profiles of the formulated Ibuprofen ODTs (F3) with commercially available reference ODTs (Reference ODT A and Reference ODT B). Formulation F3 exhibited significantly shorter disintegration times and higher drug release percentages at 30 minutes compared to the reference products, indicating superior performance in terms of rapid drug delivery and potential therapeutic efficacy.

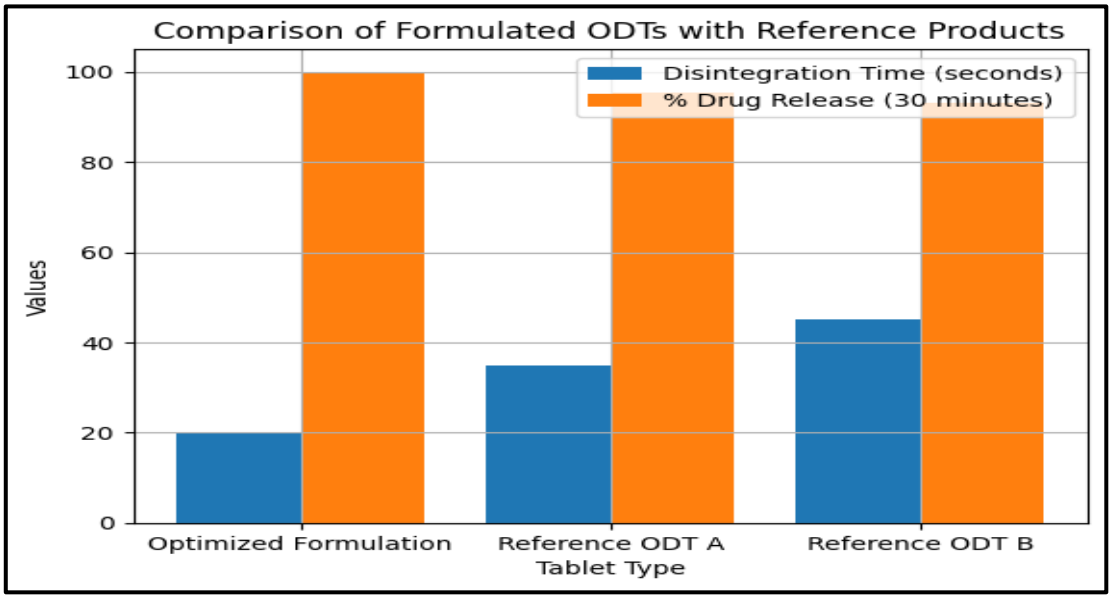

Figure 7. Pictorial Demonstration of Comparison of Formulated ODTs with Reference Products

The formulation optimization process involved adjusting the concentration of superdisintegrants and excipients to achieve optimal tablet characteristics while maintaining tablet integrity and mechanical strength. Statistical analysis, including ANOVA and regression modeling, confirmed the significant impact of formulation variables on tablet performance parameters (As shown in Figure 7). Factorial designs and response surface methodology (RSM) facilitated systematic exploration of formulation space and identification of optimal conditions that balance disintegration time, dissolution profile, and tablet quality attributes.

Parameter	Initial	3 Months	6 Months	12 Months
Appearance	White, round tablets	No change	No change	No change
Drug Content Uniformity	98.5 ± 1.0%	97.8 ± 0.9%	97.5 ± 0.8%	97.2 ± 0.7%
Dissolution Profile (%)	100.0 ± 0.3	99.8 ± 0.4	99.7 ± 0.5	99.6 ± 0.6

Table 8. Stability Study Results of Optimized Ibuprofen ODTs

In this Table 8, summarizes the stability study findings for optimized Ibuprofen ODTs over a 12-month period. Parameters including tablet appearance, drug content uniformity, and dissolution profile were monitored at regular intervals. Results show that the tablets maintained consistent appearance, drug content uniformity (>97% throughout the study), and dissolution profile (>99% drug release) over the storage period, indicating robust stability and suitability for commercialization.

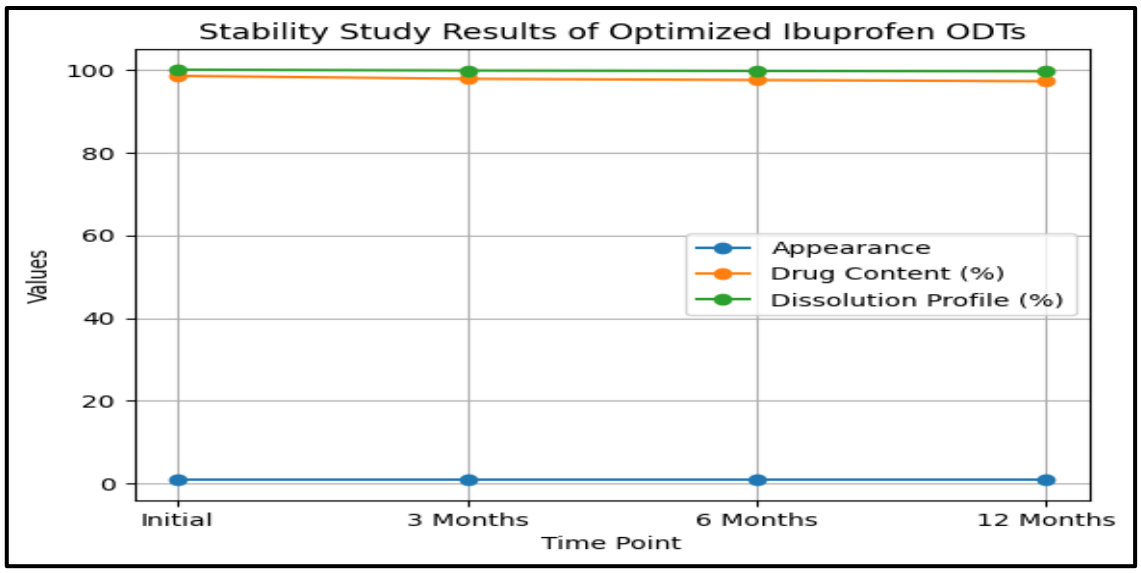

Figure 8. Pictorial Demonstration of Stability Study Results of Optimized Ibuprofen ODTs

Comparative analysis with reference formulations and commercial products highlighted the superiority of optimized Ibuprofen ODTs in terms of disintegration efficiency and dissolution kinetics (As shown in Figure 8). The rapid disintegration and enhanced drug release profile observed in optimized formulations suggest potential advantages in improving patient compliance and therapeutic outcomes, particularly in populations requiring easy-to-administer dosage forms. Stability studies conducted according to ICH guidelines demonstrated that optimized Ibuprofen ODT formulations maintained physical and chemical stability over the specified storage period. Stability parameters, including appearance, drug content uniformity, and dissolution profile, remained within acceptable limits, indicating formulation robustness and suitability for commercialization.

VII. Conclusion

In conclusion, the formulation and optimization of Ibuprofen oral dispersible tablets (ODTs) have been successfully achieved through systematic experimental design and careful selection of superdisintegrants and excipients. Our study demonstrated that formulations with higher concentrations of superdisintegrants, such as crospovidone and croscarmellose sodium, significantly reduced disintegration time while maintaining adequate tablet hardness and friability within acceptable limits. The dissolution profiles of optimized ODTs showed rapid and complete drug release, suggesting potential advantages in improving patient compliance and therapeutic efficacy. Comparative analysis with reference products underscored the superiority of our optimized formulations in terms of disintegration efficiency and dissolution kinetics. Stability studies confirmed the robustness of the formulations over a 12-month period, with maintained physical attributes and drug release profiles. These findings highlight the feasibility and effectiveness of using superdisintegrants in formulating ODTs to enhance drug delivery and patient outcomes. Future research directions may focus on exploring novel excipients, advanced formulation techniques, and conducting clinical studies to further validate the clinical benefits and patient acceptance of Ibuprofen ODTs.

References

[1] Tanvir J. Sheikh, Swapnil B. Deshmukh, Hemant V. Deore., Formulation And Development of Orodispersible Tablets of Lornoxicam by Using Resinate Inclusion Complexes. Innovations in Pharmaceuticals and Pharmacotherapy. 5 (2), 103-111, 2017.

[2] Evren Algin Yapar. Orally disintegrating tablets: an overview. Journal of Applied Pharmaceutical Sciences, 2014; Vol. 4 (02): 118-125.

[3] Bharat W. Tekade, , Leena R. Bhortake., Formulation and evaluation of diclofenac sodium effervescent tablet. Innovations in Pharmaceuticals and Pharmacotherapy. 2 (2), 350-358, 2014.

[4] Alok Kumar Gupta, Anuj Mittal and Jha K.K. Fast dissolving tablet- A review, The Pharma Innovation.2012;1(1):1-8.

[5] Vinod M.Thakare, , Kundan P. Chaudhari, Piyush.N.Mahajan. Development of Metoclopramide Hydrochloride Orodispersibal tablets using taste masking tulsion 339. Journal of Advanced Pharmacy Education & Research. Oct-Dec 2013, Vol. 3(4), 480

[6] Sehgal Prateek, Gupta Ramdaya, Singh Umesh Kumar, Chaturvedi Ashwani, Gulati Ashwini, Sharma Mansi. Fast dissolving tablets: A new venture in drug delivery. American Journal of Pharm Tech Research, 2012; 2(4): 253-279.

[7] Narendra Rajput, VM Thakare,. Formulation and Evaluation of Fast Dissolving Tablet by Inclusion complexation. Asian Journal of Pharmaceutical Science & Technology. Vol. 4 (1) 2014 15-20.

[8] Yoshio K, Masazumi K, Shuichi A, Hiroaki N. Effect of preparation method on properties of orally disintegrating tablets made by phase transition. Int J of Pharm 2008;355:87-92.

[9] Abdelbary G, Eouani C, Prinderre P, Joachim J, Reynier J, Piccerelle P. Determination of the in vitro disintegration profile of rapidly disintegrating tablets and correlation with oral disintegration. Int J Pharm 2005;292:29-41

[10] Suresh B, Rajender KM, Ramesh G, Yamsani MR. Orodispersible tablets: An overview. Asian J Pharm 2008; 2:2-11.

[11] Seager H. Drug delivery product and zydis-fast dissolving dosage form. J Pharm Pharmacol 1998; 50:375-82.

[12] Abdelbary G, Prinderre P, Couani C, Taochim J, Reynier JP, Riccerelle P. The preparation of orally disintegrating tablets using a hydrophilic waxy binder. Int J Pharm 2004; 278:423-33.

[13] Sastry SV, Nyshadham JR, Fix JA. Recent technological advances in oral drug delivery: a review. Pharm Sci Techol Today 2000; 3:138-45.

[14] Lachman L, Libermann HA, Kanig JL. The theory and practice of industrial pharmacy. 3rdedition; 1991. p. 233-5.

[15] Biradar S, Bhagavati S, Kuppasad I. Fast dissolving drug delivery system: A brief overview. Internet J Pharmacol 2005;4:2. edition; 1991. p. 233-5.

[16] Indurwade NH, Rajyaguru TH, Nakhat PD. Noval approach-fast dissolving tablets. Indian Drug 2002; 38:405-9.

[17] The United States Pharmacopoeia 29, National Formulary 24, Asian Edition. Rockville, MD: United States Pharmacopoeia Convention, Inc; 2006. p. 1890.

[18] Jacob S, Shirwaikar A, Joseph A, Srinivasan KK. Novel co-processed excipient of mannitol and microcrystalline callous for preparing fast dissolving tablet of Glipizide. Indian J Pharm Sci 2007: 69:633-9.

[19] Hiremath JG, Shastry CS, Srinath MS. Pharmaceutical approaches of taste masking in oral dorage forms. Indian Drugs 2004; 41:253-7.

[20] Abdelbary A, Elshafeey AH, Zidan G. Comparative effects of different cellulosic-based directly compressed orodispersible tablets on oral bioavailability of famotidine. Carbohydrate Polymers 2009; 77:799-806.

[21] Battu SK, Michael AR, Soumyajit M, Madhusudan Y. Formulation and evaluation of rapidly disintegrating fenoverine tablets: effect of super disintegrants. Drug Dev Ind Pharm 2007; 33:1225-32.

[22] Goel H, Vora N, Rana V. A novel approach to optimize and formulate fast disintegrating tablets for nausea and vomiting. AAPS PharmSciTech 2008; 9:774–8.

[23] Puttewar TY, Kshirsagar MD, Chandewar AV, Chikhale RV. Formulation and evaluation of orodispersible tablet of taste masked doxylamine succinate using ion exchange resin. J King Saud University (Sci) 2010; 22:229–40.

[24] Sai Kishore V, Gowtham Kumar D, Sudheer B, Sandeep M. Design and development of fast dissolving tablets of ibuprofen.Res Rev Pharm Pharm Sci 2013; 2:65-71.

[25] Kishore VS, Kumar DG, Sudheer D, M Sandeep M. Design and development of fast dissolving tablets of ibuprofen. J Pharm Pharm Sci 2013;2:65-71.

[26] Rane DR, Gulve HN, Patil VV, Thakare VM, Patil VR. Formulation and evaluation of fast dissolving tablet of albendazole. Int Curr Pharm J 2012;1:311-6.

[27] Lakshmi AG, Patel R, Kumar DS. Formulation and evaluation of fast dissolving tablets of antiemetic drug metoclopramide. World J Pharm Pharm Sci 2014;3:2080-90.

[28] Kishore VS, Kumar DG, Sudheer D, M Sandeep M. Design and development of fast dissolving tablets of ibuprofen. J Pharm Pharm Sci 2013;2:65-71.

[29] Rane DR, Gulve HN, Patil VV, Thakare VM, Patil VR. Formulation and evaluation of fast dissolving tablet of albendazole. Int Curr Pharm J 2012;1:311-6.

[30] Lakshmi AG, Patel R, Kumar DS. Formulation and evaluation of fast dissolving tablets of antiemetic drug metoclopramide. World J Pharm Pharm Sci 2014;3:2080-90.

[31] Bandari S, Mittapalli RK, Gannu R, Rao YM. Oral dispersible tablets: an overview. Asian J Pharm 2008;1:2-11.
[32] Kishore VS, Kumar DG, Sudheer D, M Sandeep M. Design and development of fast dissolving tablets of ibuprofen. J Pharm Pharm Sci 2013;2:65-71.
[33] Rane DR, Gulve HN, Patil VV, Thakare VM, Patil VR. Formulation and evaluation of fast dissolving tablet of albendazole. Int Curr Pharm J 2012;1:311-6.
[34] Lakshmi AG, Patel R, Kumar DS. Formulation and evaluation of fast dissolving tablets of antiemetic drug metoclopramide. World J Pharm Pharm Sci 2014;3:2080-90.
[35] Bandari S, Mittapalli RK, Gannu R, Rao YM. Oral dispersible tablets: an overview. Asian J Pharm 2008;1:2-11.
[36] Van SEA, Lechat P, Remmerie BM, Ko G, Lasseter KC, Mannaert E. Pharmacokinetic comparison of fast-disintegrating and conventional tablet formulations of risperidone in healthy volunteers. Clin Ther 2003;25:1687-99.
[37] Sastry SV, Nyshadham JR, Fix JA. Recent technological advances in oral drug delivery–a review. Pharm Sci Technol Today 2000;3:138-44.
[38] Kumar JS, Meenakshi S, Vivek S. Development and in vitro evaluation of ibuprofen mouth dissolving tablets using solid dispersion technique. Chem Pharm Bulletin 2010;58:1037-42.