Formulation and Evaluation of Fluconazole 250 mg Immediate-Release Tablet

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Abstract: Fluconazole, a widely prescribed triazole antifungal agent, is commonly used for the management of systemic and superficial fungal infections. Due to its high oral bioavailability and predictable pharmacokinetic profile, the development of an effective immediate release (IR) tablet formulation is essential to ensure rapid therapeutic action, patient compliance, and consistent drug performance. This review summarizes the formulation strategies, critical material attributes (CMAs), and critical process parameters (CPPs) influencing the development of Fluconazole 250 mg IR tablets. Emphasis is placed on the selection of suitable excipients such as diluents, disintegrants, binders, and lubricants, which play a crucial role in optimizing tablet characteristics including hardness, friability, disintegration time, and dissolution rate. The review further highlights the importance of pre-formulation studies, compatibility assessments through FTIR and DSC, and evaluation parameters as per pharmacopeial standards. In vitro dissolution profiling, kinetic modeling, and stability studies are discussed to establish the quality, safety, and efficacy of the final formulation. Several research studies reporting enhanced dissolution behavior through the incorporation of super disintegrants or solubility enhancers are critically examined. The article concludes that a carefully optimized IR formulation of fluconazole can significantly improve onset of action, ensuring effective antifungal therapy while meeting regulatory requirements for quality and performance. This review provides a consolidated understanding of current advancements, challenges, and formulation considerations pivotal for developing a robust Fluconazole 250 mg immediate release tablet.

Keywords: Fluconazole; Immediate Release Tablets; Formulation Development; Dissolution; Pre-formulation Studies; Antifungal Agents; Excipients; Evaluation Parameters.

I. INTRODUCTION

Fluconazole is a widely utilized triazole antifungal agent known for its broad-spectrum activity against Candida, Cryptococcus, and various systemic fungal pathogens. Its mechanism of action involves the inhibition of fungal cytochrome P450-dependent enzyme lanosterol 14-α-demethylase, which interrupts ergosterol synthesis, an essential component of the fungal cell membrane. This disruption leads to increased membrane permeability and eventual cell death. The drug's favorable characteristics, including high oral bioavailability (approximately 90%), long half-life, and minimal first-pass metabolism, make it a preferred antifungal for both acute and chronic infections. The significance of Fluconazole has increased due to the rising prevalence of opportunistic fungal infections, particularly among immunocompromised populations such as individuals undergoing chemotherapy, transplant recipients, and patients with HIV/AIDS. Its inclusion in the World Health Organization (WHO) Model List of Essential Medicines further highlights its global therapeutic relevance. The availability of Fluconazole in various dosage forms—such as capsules, suspensions, and tablets—provides flexibility in clinical use; however, the immediate release (IR) tablet formulation remains most desirable for rapid onset of action, ease of administration, and improved patient adherence.

At a dose strength of 250 mg, the drug is widely prescribed for moderate to severe fungal infections, where quick systemic absorption is essential for achieving therapeutic plasma concentration. To ensure consistent therapeutic outcomes, the formulation must meet stringent quality attributes including rapid disintegration, optimal dissolution, and batch uniformity. Therefore, understanding the physicochemical properties, biopharmaceutical classification, and formulation requirements of Fluconazole is essential for designing an effective IR tablet. This review provides an in-depth discussion on formulation considerations, excipient selection,

evaluation parameters, and reported advancements aimed at improving the overall performance of Fluconazole 250 mg Immediate Release Tablets.

Need for Immediate Release Formulations in Antifungal Therapy

Immediate release (IR) formulations play a crucial role in antifungal therapy due to the need for rapid systemic drug availability and predictable therapeutic response. In infections caused by Candida or Cryptococcus species, delayed treatment onset may contribute to disease progression, systemic spread, and increased morbidity. An IR tablet ensures fast disintegration and dissolution, enabling the drug to reach the bloodstream quickly and exert its antifungal effect at the earliest possible time. This is particularly important for patients requiring prompt intervention, such as those with oropharyngeal candidiasis, vaginal candidiasis, or systemic mycoses.

For Fluconazole—a drug categorized under Biopharmaceutics Classification System (BCS) Class I, characterized by high solubility and high permeability—an IR formulation leverages its inherent biopharmaceutical advantages. The high oral absorption allows formulators to focus on optimizing disintegration and ensuring compliance with pharmacopeial standards. Additionally, IR tablets offer benefits such as ease of manufacturing, dose flexibility, and cost-effectiveness, making them suitable for large-scale production and widespread therapeutic use. The immediate release profile is especially beneficial in cases requiring loading doses, where rapid plasma drug level elevation is necessary. A well-designed IR tablet minimizes variability in dissolution rates, ensuring predictable pharmacokinetics even in diverse patient populations.

Furthermore, excipients such as superdisintegrants (e.g., croscarmellose sodium, sodium starch glycolate) enhance formulation performance by reducing disintegration time and promoting faster drug release. Given the increasing fungal resistance trends and the clinical demand for high-performance formulations, the development of an optimized Fluconazole 250 mg IR tablet remains an essential research area. This review explores current formulation strategies and highlights advancements aimed at delivering faster and more reliable therapeutic outcomes.

Challenges and Considerations in Formulating Fluconazole IR Tablets

Although Fluconazole offers favorable physicochemical properties, formulating an effective immediate release tablet requires addressing several technical challenges. One key consideration is ensuring uniform drug distribution, especially at higher dose strengths like 250 mg, where the API occupies a significant portion of the tablet mass. Achieving uniformity demands careful selection of diluents, binders, and flow enhancers to prevent segregation and ensure content uniformity.

Another challenge is optimizing tablet compressibility. Fluconazole exhibits moderately poor flow properties, which may impact blend homogeneity and tablet consistency. To overcome this, formulators often incorporate excipients such as microcrystalline cellulose, lactose monohydrate, and colloidal silicon dioxide, which improve blend flow, compressibility, and mechanical strength. Selection of an appropriate disintegrant is also critical. While Fluconazole is classified as BCS Class I, rapid disintegration is essential for ensuring fast dissolution rate, which directly influences bioavailability and onset of action.

Compatibility studies—including Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), and Thermogravimetric Analysis (TGA)—are vital to assess interactions between the drug and excipients. Such interactions could alter drug stability, dissolution behavior, or therapeutic activity. Additionally, process parameters such as granulation technique, blending time, and compression force significantly affect final tablet quality attributes, including friability, hardness, wetting time, and disintegration time.

Finally, regulatory expectations require thorough in vitro dissolution profiling, adherence to pharmacopeial limits, and stability testing under ICH guidelines. Ensuring the formulation meets these criteria is essential for developing a robust, high-quality product. This review discusses these challenges in detail and highlights strategies for optimizing Fluconazole 250 mg IR tablet formulations.

II. OBJECTIVES

- To analyze various formulation strategies and approaches used in the development of

Fluconazole IR tablets, with emphasis on the role of diluents, binders, disintegrants, solubility enhancers, and lubricants in optimizing tablet performance.

- To compare different manufacturing techniques such as direct compression, dry granulation, and wet granulation, and evaluate their suitability for producing robust and stable Fluconazole 250 mg IR tablets.
- To summarize reported research findings and advancements in the formulation of Fluconazole IR tablets, focusing on excipient compatibility, enhancement of dissolution rate, and rapid disintegration for improved therapeutic efficacy.
- To assess the critical evaluation parameters such as hardness, friability, weight variation, disintegration time, drug content uniformity, and in vitro dissolution profiles according to pharmacopeial standards for Fluconazole IR tablets.
- To examine the influence of critical material attributes (CMAs) and critical process parameters (CPPs) on tablet quality, performance, and reproducibility, ensuring consistency during formulation development.

III. LITERATURE REVIEW

1. Formulation and Evaluation of Fluconazole Immediate Release Tablets Using Different Superdisintegrants

Patel and colleagues conducted a systematic study to design and optimize Fluconazole Immediate Release tablets using various superdisintegrants such as croscarmellose sodium, sodium starch glycolate, and crospovidone. The research aimed to evaluate the influence of superdisintegrant concentration on tablet properties such as disintegration time, hardness, friability, and dissolution rate. Their study demonstrated that crospovidone at optimal concentration resulted in the fastest disintegration, improved wetting, and enhanced dissolution efficiency, achieving more than 90% drug release within 30 minutes. Precompression parameters like bulk density, tapped density, and angle of repose confirmed good powder flow, supporting direct compression feasibility. The authors emphasized the importance of excipient compatibility and stability testing, concluding that Fluconazole—being a BCS Class II drug—benefits significantly from suitable disintegrant selection to overcome dissolution limitations. This work serves as an important foundation for IR tablet development, highlighting the critical role of formulation design in enhancing bioavailability.

2. Development and Evaluation of Fluconazole Tablets for Improved Dissolution

Singh and colleagues focused on improving the dissolution behavior of Fluconazole tablets through formulation strategies such as particle size reduction, improved wetting, and the inclusion of hydrophilic excipients. Their method involved preparing several batches using both direct compression and wet granulation, assessing which technique provided superior results. The study found that formulations incorporating hydroxypropyl methylcellulose (HPMC) as a binder and sodium starch glycolate as a superdisintegrant showed the most consistent performance, with a dissolution rate exceeding 85% within 20 minutes. The authors also utilized FTIR and DSC studies to confirm drug–excipient compatibility. Post-compression studies indicated acceptable hardness, friability <1%, uniform weight variation, and rapid disintegration. Their findings highlight the need for optimizing both physical and chemical parameters to develop stable IR tablets, demonstrating that excipient selection and granulation technique directly influence dissolution and therapeutic efficiency.

3. Formulation Optimization of Fluconazole IR Tablets by Central Composite Design

Preethi and Rao utilized a Design of Experiments (DoE) approach to systematically optimize Fluconazole IR tablet formulation. Using a central composite design, they studied the combined effects of superdisintegrant concentration and binder levels on tablet hardness, disintegration time, and drug release profile. The optimization model suggested that an ideal formulation required moderate binder concentration along with high superdisintegrant levels to achieve tablets that were strong enough to handle mechanical stress yet disintegrated quickly. The researchers validated their model using checkpoint formulations that closely matched predicted responses, demonstrating the reliability of DoE in pharmaceutical development. Their approach reduced trial-and-error work, improved reproducibility, and ensured regulatory compliance. The study confirmed that Fluconazole tablets can be efficiently formulated using scientific, statistical methods to achieve consistent performance with minimal variation.

4. Formulation Design Strategies for Poorly Soluble Antifungal Drugs

Although based on antifungal drugs in general, this review highlights formulation challenges similar to those encountered with Fluconazole IR tablets. Sharma and Patel discuss techniques such as solid dispersion, particle size reduction, use of wetting agents, and incorporation of hydrophilic polymers to enhance dissolution of BCS Class II drugs. The authors also emphasize the importance of excipient compatibility, pre-compression studies, and stability evaluation. Their analysis provides broader insights and scientific justification for improving Fluconazole dissolution through strategic formulation techniques.

IV. MATERIALS & METHODOLOGY

1. Active Pharmaceutical Ingredient (API)

- Active Pharmaceutical Ingredient (API): Fluconazole (Pharmaceutical grade, purity ≥ 99.0%).

Property	Details	Impact on Formulation
Chemical Name	Fluconazole (2-(2,4-difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl)propan-2-ol)	Determines identity, purity testing, and compliance with pharmacopeial standards
Molecular Weight	306.27 g/mol	Affects dose calculation, molecular dispersion, and processing requirements
Solubility	Freely soluble in water; highly soluble at acidic pH; moderate solubility in neutral/basic pH	Directly influences dissolution behavior, absorption rate, and suitability for immediate release formulation
pKa Values	$pKa_1 \approx 1.76$; $pKa_2 \approx 2.56$ (weakly acidic)	Governs ionization, dissolution at different GI pH levels, and bioavailability
Hygroscopicity	Low to non-hygroscopic	Minimizes moisture-related degradation but still requires controlled humidity during processing
Stability	Stable under normal conditions; susceptible to degradation under strong light and extreme pH	Requires proper storage, inclusion of stabilizing excipients, and protective packaging
Melting Point	138–141°C	Important for thermal stability assessments and selection of processing method (e.g., avoid high-temperature operations)
Biopharmaceutical Classification (BCS)	Class I (High Solubility, High Permeability)	Favors immediate release design; dissolution usually not a limiting factor
Partition Coefficient (log P)	≈ 0.5	Indicates good aqueous solubility and predictable absorption

Table 1: Physicochemical Properties of Fluconazole

2. Excipients

- Diluents:
  - Microcrystalline Cellulose (MCC)
  - Lactose Monohydrate
  - Starch
- Binders:
  - Polyvinylpyrrolidone (PVP K30)
  - Hydroxypropyl Methylcellulose (HPMC)
  - Gelatin
- Disintegrants:
  - Sodium Starch Glycolate (SSG)
  - Croscarmellose Sodium
  - Crospovidone
- Lubricants:
  - Magnesium Stearate
  - Talc
  - Aerosil (Colloidal Silicon Dioxide)
- Stabilizers / Moisture-Control Agents:
  - Anhydrous Lactose
  - Citric Acid (as stabilizer in some studies)
  - Desiccants (for storage)

Equipment:

1. Processing Equipment

- Analytical Balance
- Mortar and Pestle
- Sieve Shaker / Sieves
- Mixer / Blender
- Granulator (dry or wet, depending on method)
- Tablet Compression Machine (Single punch or Rotary press)
- Hot Air Oven / Tray Dryer
- Desiccator

2. Evaluation Equipment

- Hardness Tester (Monsanto / Pfizer / Digital)
- Friabilator (Roche Friabilator)
- Vernier Caliper
- Disintegration Test Apparatus
- Dissolution Test Apparatus (USP Type I/II)
- UV–Visible Spectrophotometer / HPLC System
- Stability Chamber

V. METHODOLOGY

1. Preformulation Studies:

❖ API characterization

- Organoleptic properties: appearance, color, odor.
- Melting point (DSC) and thermogravimetric analysis (TGA) for thermal stability.
- Solubility studies: determine solubility in water, 0.1 N HCl, pH 1.2, pH 4.5 acetate buffer, pH 6.8 phosphate buffer, and selected cosolvents. Record temperature (25 ± 2 °C and 37 °C).
- pKa and partition coefficient (log P) — from literature or experimentally if required.
- Hygroscopicity and bulk/tapped density, angle of repose, Carr's index to assess flow and packing properties.

❖ Compatibility studies (drug–excipient)

- FTIR: check for disappearance/shifts of characteristic peaks after physical mixture (1:1 w/w) and after accelerated stress (e.g., 40°C/75% RH for 2–4 weeks).
- DSC: identify interaction or melting point shifts.
- Stress testing: exposure to light, heat, humidity to detect degradation products (if applicable)

2. Target Product Profile and Batch Size:

- Define target product profile: 250 mg fluconazole per tablet, weight range, dissolution criterion (e.g., ≥ 80% released within 30 minutes), hardness range, disintegration time (< 15 minutes typical for IR), content uniformity limits per pharmacopeia.
- Choose lab batch size (e.g., 5000 tablets or 1–2 kg blend) for process optimization; scale up considerations noted.

3. Formulation Development:

A. Direct Compression Method:

i. Pre-mixing

- Pass API and all powders through appropriate sieve (e.g., 40–60 mesh) to deagglomerate.
- Weigh ingredients for a single batch (or multiple tablets). Use an overage if stability requires.
- Geometrically blend Fluconazole with diluents (MCC + lactose) in a V-blender for 10–15 min (or until homogeneous). Add colloidal silica to improve flow, blend 2–3 min.

ii. Addition of disintegrant & minor excipients: Add croscarmellose sodium (disintegrant) and mix for 3–5 min to ensure even distribution.

iii. Lubrication: Add magnesium stearate (and talc if used) last; blend gently 1–2 min to avoid over-lubrication (which can reduce hardness and affect dissolution).

iv. Compression: Compress with single-punch press or rotary press using selected tooling to obtain target hardness (e.g., 6–10 kp depending on friability results). Optimize compression force to get tablets with acceptable hardness, friability (<1%), and disintegration time.

v. In-process tests: Check weight variation, thickness, hardness, friability, disintegration (USP). If any test fails, adjust formulation (e.g., change MCC grade, disintegrant level) and repeat.

B. Wet Granulation Method:

i. Dry mixing: Sieve and blend API + diluents (MCC, lactose) for 10–15 minutes in a high-shear or V-blender.

ii. Prepare binder solution: Dissolve PVP K30 (or chosen binder) in purified water or ethanol–water mix (solvent selected based on API solubility and drying considerations).

iii. Wet massing/granulation: Transfer powder blend to high-shear granulator. Add binder solution slowly while mixing until a wet mass of appropriate consistency forms (granulation end point determined by hand-ribbon test or torque). Avoid overwetting.

iv. Screening/milling: Pass wet mass through a suitable screen (e.g., 1.0–2.0 mm) to form wet granules.

v. Drying: Dry the wet granules in tray dryer or fluid bed dryer to target moisture content (e.g., <2–3% w/w or as defined from preformulation). Monitor loss on drying (LOD).

vi. Dry milling & sizing: Mill the dried granules to desired size distribution (e.g., pass through 20–30 mesh depending on tablet size). Re-sieve to remove fines/oversize.

vii. Final blending: Blend milled granules with disintegrant (if to be added externally), glidant (colloidal silica), and finally lubricant (magnesium stearate) — add lubricant last and blend gently (1–2 min).

viii. Compression: Compress to target hardness, mass, and thickness. Observe in-process controls.

4. Formulation & Development of Fluconazole 250 mg Immediate-Release Tablet:

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Fluconazole (API)	250	250	250	250	250	250	250	250	250
Micro Crystalline Cellulose (Diluent)	140	120	110	160	160	138	120	127	125
Lactose (Diluent)	60	70	80	50	40	55	65	75	85
PVP-K30 (Binder)	20	25	20	15	20	22	25	18	25
CCS-Crosscarmellose Sodium (Superdisintegrant)	15	20	25	10	15	20	25	15	10
Talc (Glidant)	10	10	10	10	10	10	10	10	10
Magnesium Stearate (Lubricant)	5	5	5	5	5	5	5	5	5
Total Weight (mg)	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg

Table 1: Formulation Table of Fluconazole 250 mg Immediate-Release Tablets

5. Post-Compression Evaluation:

spirin IR tablets must meet pharmacopeial quality standards. Studies typically include:

- Weight variation
- Hardness and friability
- Disintegration time (must be rapid for IR tablets)
- Dissolution profile (ensuring immediate drug release)
- Assay and content uniformity
- Moisture content

These evaluations ensure consistency, safety, and therapeutic effectiveness.

6. Analytical assays:

PLC-UV is preferred for specificity. Set up method validation for specificity, LOD/LOQ, linearity (e.g., 5–150% of expected concentration), precision (RSD ≤2%), accuracy (recovery 98–102% typical), robustness.

- Typical method outline (template to adapt & validate): C18 column (150 × 4.6 mm, 5 µm), mobile phase: buffer (e.g., 20 mM phosphate, pH adjusted): acetonitrile (ratio to be optimised), flow 1.0 mL/min, injection volume 10–20 µL, detection wavelength around ~290 nm (determine λmax experimentally). Use internal standard if required.

7. Dissolution Testing

- Apparatus: USP Type II (paddle) is most common.
- Medium: 900 mL of 0.1 N HCl (pH 1.2) or phosphate buffer pH 6.8 (both acceptable; choose one and justify). For IR, expected release: ≥ 80% in 30 minutes (adjust per in-house specification or pharmacopeia).
- Temperature: 37 ± 0.5 °C.
- Speed: 50–75 rpm (commonly 50 rpm).
- Sampling times: 5, 10, 15, 20, 30, 45 minutes (withdraw 5–10 mL, filter, replace with fresh medium).

VI. RESULTS & DISCUSSION

1. Preformulation Results:

The reviewed studies consistently highlight that Fluconazole possesses favorable physicochemical characteristics for immediate-release (IR) tablet development. Its high aqueous solubility, stability under normal environmental conditions, and BCS Class I classification provide a strong foundation for designing formulations with predictable absorption and rapid dissolution. Pre-formulation investigations—such as FTIR, DSC, and TGA—commonly demonstrate no significant drug–excipient interactions, especially with excipients like MCC, lactose, PVP K30, croscarmellose sodium, and colloidal silicon dioxide. These findings confirm compatibility and support the selection of these excipients in IR formulations.

Flow property analysis from various literature sources indicates that Fluconazole powder exhibits poor to moderate flowability, necessitating the use of glidants and, in some cases, granulation techniques to improve processability. Granules produced via wet granulation often display better compressibility, flow behavior, and uniformity compared with direct compression blends, particularly for high-dose formulations like 250 mg tablets.

2. Formulation Development and Optimization

Multiple studies evaluated different formulation strategies including direct compression, wet granulation, and dry granulation. Among these, direct compression is frequently preferred due to simplicity and lower processing cost. However, its success largely depends on achieving adequate powder flow and uniform blending. Wet granulation methods result in more robust tablets, with enhanced hardness and reduced friability, making them a suitable option when the API or excipient blend exhibits poor mechanical properties.

The incorporation of superdisintegrants—particularly croscarmellose sodium (CCS) and sodium starch glycolate (SSG)—was shown to significantly improve disintegration time and overall dissolution performance. Formulations containing 2–5% w/w superdisintegrant achieved rapid water uptake and faster tablet break-up. The overall trend suggests that CCS often provides slightly faster disintegration compared with SSG, owing to its swelling and wicking mechanism.

3. Evaluation Parameters and Their Impact on Immediate Release Performance

Most reviewed studies assessed tablet quality through standard evaluation parameters including hardness, friability, weight variation, disintegration, dissolution, and assay. Results consistently demonstrated that achieving a balance between tablet hardness and disintegration is critical. Excessive compression forces increased tensile strength but delayed disintegration, while lower forces enhanced disintegration but compromised mechanical integrity.

Dissolution results from various studies indicated that optimized formulations reached more than 80% drug release within 30 minutes, aligning with pharmacopeial expectations for IR tablets. The presence of superdisintegrants and the use of highly soluble excipients influenced dissolution positively. Compatibility studies using FTIR, DSC, and stability analysis further confirmed that avoiding alkaline excipients was essential to prevent degradation.

Parameter	Purpose	Expected Outcome	Parameter
Weight Variation	Ensures dose uniformity	Within pharmacopoeial limits	Weight Variation
Hardness	Measures mechanical strength	Sufficient to withstand handling	Hardness
Friability	Assesses tablet durability	Less than 1% weight loss (typically)	Friability
Disintegration Time	Confirms rapid tablet breakdown	Ideally < 15 minutes for IR tablets	Disintegration Time
Dissolution Profile	Determines rate of drug release	≥80% drug release within 30 minutes	Dissolution Profile
Assay / Content Uniformity	Confirms accurate drug content	95–105% (pharmacopeial range)	Assay / Content Uniformity
Stability Testing	Checks chemical and physical stability	Minimal hydrolysis; stable appearance	Stability Testing

Table 2: Key Evaluation Parameters

4. Dissolution Studies and Release Kinetics

Dissolution profiling revealed that Fluconazole IR tablets generally achieved more than 80% drug release within 20–30 minutes, surpassing typical pharmacopeial benchmarks. In some optimized formulations, release reached 90–100% within 15 minutes, confirming the suitability of Fluconazole for IR applications due to its intrinsic solubility.

Kinetic modeling of dissolution data often fitted best with first-order or Higuchi models, reflecting a release mechanism dependent on concentration gradient and matrix diffusion. However, formulations with high levels of superdisintegrants showed near immediate dissolution, suggesting minimal diffusional control and rapid drug liberation.

The dissolution improvement observed across studies highlights the synergistic effect of high drug solubility, optimized disintegrant concentration, and effective particle size distribution achieved through granulation processes.

5. Stability Findings

Stability studies conducted under accelerated conditions (40°C/75% RH) demonstrated that optimized formulations retained physical integrity, drug content, and dissolution characteristics over 3–6 months. Minor variations in hardness and disintegration time were reported but remained within acceptable limits. These findings support the overall stability of Fluconazole IR tablets when formulated using appropriate excipients and stored in moisture-resistant packaging.

The collective evidence from reviewed literature confirms that Fluconazole 250 mg Immediate Release Tablets can be efficiently developed using standard excipients and conventional manufacturing techniques. The critical factors influencing the final formulation include flow properties, choice of superdisintegrant, granulation method, and blend uniformity. When these parameters are optimized, the resulting tablets exhibit excellent mechanical strength, rapid disintegration, fast dissolution, and consistent bioavailability.

VII. CONCLUSION

The development of Fluconazole 250 mg Immediate Release Tablets represents a scientifically robust and clinically valuable approach for achieving rapid antifungal action, improved patient compliance, and consistent therapeutic outcomes. Based on the compiled research findings and formulation strategies discussed in this review, Fluconazole's intrinsic advantages—such as high aqueous solubility, good permeability, and chemical stability—make it an ideal candidate for immediate-release dosage forms. Pre-formulation studies confirm that the drug exhibits favorable compatibility with commonly used excipients, enabling flexibility in selecting suitable diluents, binders, and superdisintegrants.

Among the various formulation approaches, both direct compression and wet granulation techniques have demonstrated reliable performance, with the choice largely depending on the flowability and compressibility of the blend. Incorporation of effective superdisintegrants such as croscarmellose sodium or sodium starch glycolate significantly enhances disintegration efficiency and dissolution rate, enabling the formulation to meet pharmacopeial requirements for immediate release. The post-compression evaluation of optimized formulations consistently shows acceptable hardness, minimal friability, rapid disintegration, and high dissolution efficiency, confirming the reproducibility and robustness of the developed tablets. Furthermore, accelerated stability studies reveal that Fluconazole IR tablets maintain their physical integrity, assay values, and dissolution characteristics under recommended storage conditions, underscoring their long-term stability and reliability. Overall, this review concludes that a carefully optimized Fluconazole 250 mg immediate-release formulation can provide rapid therapeutic action, meet regulatory quality standards, and serve as a safe and effective treatment option for a wide range of fungal infections. Continued research and refinement in formulation parameters may further enhance product performance, patient experience, and commercial viability.

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