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A COMPREHENSIVE REVIEW ON THE FORMULATION AND EVALUATION OF FLUCONAZOLE DISPERSIBLE TABLETS

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ABSTRACT

Fluconazole is a broad-spectrum antifungal drug commonly used to treat fungal infections. Fluconazole belongs to the triazole family which offers widespread therapeutic utility. This medication addresses a spectrum of fungal infections including Vaginal Candidiasis, Oropharyngeal and Oesophageal Candidiasis, Urinary tract infection, Peritonitis and Systemic candida infections infections.[1] The present study aimed to formulate and evaluate fluconazole dispersible tablets as a patient friendly dosage form for paediatric antifungal therapy. Conventional tablets may be difficult for paediatric patients to swallow, resulting in poor compliance, hence present study aimed to improve ease of administration and patient acceptance. The tablets were prepared by the direct compression method using suitable super disintegrants and other excipients. The formulations were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. Post compression evaluation includes physical appearance analysis, group weight, average weight, weight variation, hardness, friability, thickness, drug content, disintegration and dissolution tests. The optimised formulation showed satisfactory physical properties, uniform drug content, rapid dispersion and faster drug release within pharmacopeial limits. The study concludes that fluconazole dispersible tablets are promising dosage form for paediatric patients, offering improved convenience, better patient compliance and effective antifungal therapy.

KEYWORDS: Fluconazole, Dispersible Tablet, Direct Compression, Pharmaceutical Excipients, Patient Compliance.

INTRODUCTION

Fluconazole was discovered by Richardson et al.[2,3] working at Pfizer in Sandwich, UK in a programme initiated in 1978. The original patent covering its structure had been filed by Riley and colleagues at ICI Pharmaceuticals who discontinued antifungal research prior to fluconazole's launch. Fluconazole was identified because of its in vivo activity, and only many years later were in vitro systems found to measure in vitro activity. Phase 2 studies commenced in 1988 and were focused on Candida, cryptococcal and coccid odal infections, initially using doses of 50 mg daily.[4,5]

Prophylaxis studies in neutropenia followed. The increasing need for orally active azole because of the AIDS epidemic, and respectable efficacy despite low doses of the drug, led to rapid Foods and Drugs Administration and European licensures in 1990. Fears of severe idiosyncratic liver failure akin to ketoconazole effects did not materialize, and larger doses of fluconazole were explored for more seriously ill patients, especially for those with cryptococcal and coccidioidal meningitis and invasive candidiasis. The last is the focus of this review.

The aim of this article is to review the current prophylactic or curative use of fluconazole in the management of invasive candidiasis 15 years after its introduction in the anti-infective armamentarium. Probably in excess of 100 million patients have received fluconazole worldwide between 1990 and 2005.

Fungal infections

Fungal infections are a significant health concern affecting people of all groups, especially children, elderly individuals and immune compromised patients. These infections may involve the skin, oral cavity, gastrointestinal tract or systemic organs, and if left untreated, can lead to serious complications. Effective antifungal therapy is therefore essential for successful treatment and prevention of disease progression.

Oral solid dosage forms remain one of the most preferred methods of drug administration due to their convenience, stability and patient compliance. Fluconazole is a synthetic triazole

antifungal agent with broad spectrum activity against a wide range of fungal pathogens, including Candida species and Cryptococcus neoformans.

Fluconazole is widely used in the treatment of oral candidiasis, oesophageal candidiasis, vaginal candidiasis, cryptococcal meningitis and other systemic fungal infections.

Paediatric patients often experience difficulty in swallowing conventional tablets and capsules which can reduce treatment adherence and therapeutic effectiveness. Dispersible tablets provide a convenient alternative because they rapidly disperse in small amount of water before administration, making them easier to swallow and more acceptable for children. This dosage form also offers accurate dosing, improved stability, ease of transportation and better patient compliance than liquid formulations.

CAUSES OF FUNGAL INFECTIONS

Fungal infections are caused by the overgrowth or invasion of fungi that normally live in the environment or on the human body. Common causes and risk factors include:

- Warm and moist environments: Sweating, wearing tight clothing, and damp skin encourage fungal growth.
- Poor hygiene: Infrequent bathing or not drying the skin properly after bathing can promote infection.
- Weakened immune system: Conditions such as HIV/AIDS, cancer treatment, or immunosuppressive medications increase the risk.
- Diabetes: High blood sugar levels can encourage fungal growth and reduce the body's ability to fight infection.
- Antibiotic use: Broad-spectrum antibiotics can kill beneficial bacteria, allowing fungi such as Candida to multiply.
- Close contact: Sharing towels, clothing, shoes, or having direct skin contact with someone who has a fungal infection.
- Walking barefoot in public places: Public showers, locker rooms, and swimming pools can expose you to fungi that cause athlete's foot.
- Poor circulation or obesity: Skin folds and reduced blood flow can increase the risk of fungal infections.

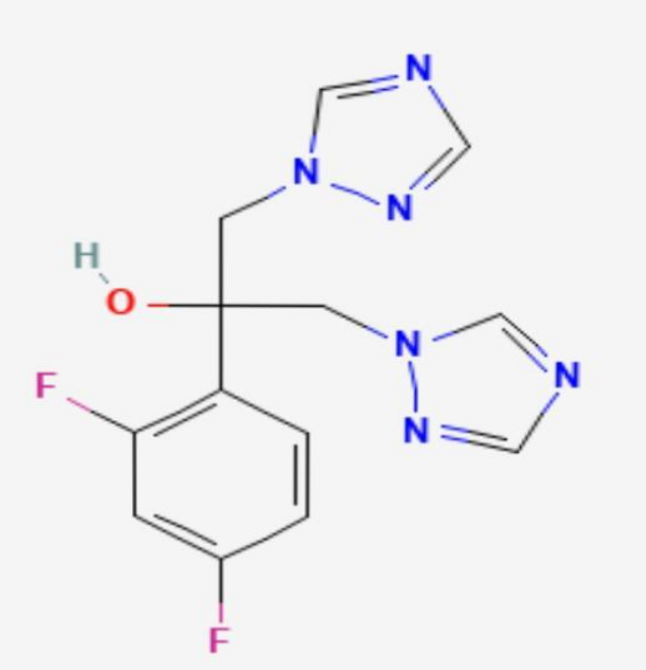
OBJECTIVES

- To identify the spectrum of activity of Fluconazole against different fungal pathogens.

- To assess the appropriateness of Fluconazole as a treatment option in fungal infected patients.
- To apply knowledge of drug interactions involving fluconazole to prevent potential adverse outcomes.
- To improve coordination with laboratory professionals to ensure accurate susceptibility testing.[1]
- To monitor the anti fungal therapy.
- To reduce the risks of prophylaxis and bone marrow transplantation who receive radiation therapy or cytotoxic chemotherapy.[1]

DRUG PROFILE[18]

1. **Drug name:** Fluconazole.
2. **Chemical structure**



3. **Chemical formula:** $C_{13}H_{12}F_2N_6O$.
4. **Molecular weight:** 306.3
5. **Chemical name:** 2-(2,4-Difluorophenyl)-1,3-bis (1H-1,2,4-triazole-1-yl) propan-2-ol.
6. **Category:** Anti fungal, Anti bacterial.
7. **Indication:** For the treatment of fungal infections like Oropharyngeal candidiasis, Oesophageal Candidiasis, Vaginal candidiasis, Systemic candidiasis, Cryptococcal meningitis, Fungal infections in immune comprised patients.
8. **Half life:** ~30 hours.

9. **Character:** Appearance-white almost white crystalline powder.
10. **Solubility:** Partially insoluble in water, freely soluble in acetone, soluble in alcohol.
11. **Storage:** In air tight container protected from light.
12. **Melting point:** 138-142°C.
13. **Wavelength:** 260-261 nm
14. **Beer's Range:** 2-12 mcg/ml.
15. **BCS Classification:** Class I – High soluble and High permeable.
16. **Brand name:** Diflucan, Azocan, Fluka, Forcan, Canseten etc.

17. **Microbiology:** Fluconazole is active against many yeasts such as Candida albicans, Candida tropicalis, Candida parasitosis, Candida Lusitania, Cryptococcal neoformans has reduced susceptibility against Candida glabrata and Candida krusei. It has little or no activity against Aspergillus species, Mucor and other mucormycosis forming fungi and most filamentous fungi called Moulds.

18. **Absorption:** Fluconazole is better absorbed in Oral route and Intravenous (IV) route.
19. **Protein binding:** Approximately 11-12%, it has low protein binding. Sometimes it binds to albumin, a large amount of drug remains free (unbound) in bloodstream.

20. **Biotransformation:** It is metabolised in Liver. Only a small amount of Fluconazole is metabolised, most of the drug remains unchanged. It produces only some minor metabolites. Fluconazole inhibits the CYP enzymes called CYP2C9, CYP2C19 and CYP3A4, so it can increase the blood levels of certain other drugs, leading to drug interaction.

21. **Excretion:** About 80% of drug is removed unchanged in the urine.

22. **Toxicity:** Overdose **of** the drug leads to Nausea, Omitting, Dizziness and Hallucinations and paranoid behaviour. It may cause some serious effects such as Hepatotoxicity, Cardiotoxicity, severe skin reactions such as Stevens – Johnson's syndrome and Toxic epidermal necrolysis, hypersensitivity reactions such as Anaphylaxis and Angioedema.

23. Pharmacokinetics

Fluconazole is well absorbed with a bioavailability of over 80%. Peak levels are reached in a1-2 hr. in healthy fasting adults and gastrointestinal absorption is not influenced by the gastric pH. Its volume of distribution is reported to be 0.7-1.0 L/kg, and 11%is protein bound.[7] The majority is excreted via the kidneys (60-75%) with a further 8-10% being recoverable from the faeces, it is

also removed by hemodialysis. The half-life is 27-34 hr. in adult population, allowing for once-a-day administration.

The pharmacokinetics of fluconazole vary with age. Neonates have a 2-to-3-fold higher volume of distribution than adults (2L/kg) that falls to 1L/kg by 3 months of age.[8] The mean volume of distribution is greater and more variable in premature neonates. It is therefore necessary to double the fluconazole dose for neonates in order to achieve comparable plasma levels. Because of reduced glomerular filtration and reduced activity of hepatic enzymes, the half-life is increased in neonates compared with adults (55-90h). It is thus recommended to administer the drug every 72h in neonates during the first 2 weeks of life, and then every 48 h in weeks 2-4 of life. Following this period, daily dosing would be appropriate.[9,10]

The diffusion in tissues and body fluids is excellent, with CSF concentrations reaching at least 70% of blood levels even in the absence of inflamed meninges (see table).[7]

Table: Diffusion of fluconazole in body tissues and fluids.

Tissues	Ratio of tissue fluconazole concentration to plasma fluconazole concentration
CSF	0.5-0.9
Saliva	1
Sputum	1
Blister Fluid	1
Urine	10
Normal skin	10
Nails	1
Blister skin	2
Vaginal tissue	1
Vaginal fluid	0.4-0.7
Eye	0.8

A case report of acute cholecystitis due to Candida Abbi cans found higher biliary concentration of fluconazole with oral dosing compared with intravenous dosing.[11] Fluconazole penetrates well into joint fluids for the treatment of septic arthritis. Fluconazole can also be administered intraperitoneally for candidal peritonitis in patients on continuous ambulatory peritoneal dialysis with good bioavailability (87%) and plasma levels.[12] The ocular penetration is also good.[13] Indeed, of the serum concentration within the day following administration of a single oral dose of 200mg fluconazole.[14]

MECHANISM OF ACTION

Fluconazole is the highly selective inhibitor of fungal Cytochrome P450 dependent enzyme Lanosterol 1,4-alpha- demethylase.

→ When the drug is administered through oral route.

↓

It inhibits the enzyme Lanosterol 1,4-alpha -demethylase.

↓

Then it prevents the synthesis of Ergosterol which is the essential fungal component.

↓

Inhibition of Ergosterol synthesis results in increased cell permeability.

↓

Damage of fungal cell membrane.

↓

Fungal cell death.[6]

Applications or uses[13]

It is used in the treatment of fungal infections like,

- Oropharyngeal candidiasis.
- Oesophageal candidiasis.
- Vaginal candidiasis.
- Systemic candidiasis.
- Cryptococcal meningitis.
- Fungal infections in immune comprised patients.

Adverse Effects

Fluconazole is generally well tolerated.

1. The most common adverse effects include headache, nausea, vomiting, diarrhoea, abdominal pain and skin rashes.
2. Less common but severe adverse effects include Hepatotoxicity, QT prolongation, severe hypersensitivity reactions.
3. Rare severe cutaneous reactions such as Stevens – Johnson syndrome and toxic epidermal necrolysis.
4. Liver function should be monitored during prolonged therapy, especially in patients with pre-existing liver disease.

Contra Indications[13]

Fluconazole is not suitable for some people like,

1. The people who have allergic reaction to Fluconazole or other medicine.
2. A patient with arrhythmic heart condition, including heart rhythm problems.
3. A patient with kidney or Liver problems.
4. A patient with rare, inherited blood disorder called as acute porphyria.
5. A patient with abnormal levels of potassium, calcium or magnesium in blood.
6. A pregnant woman or a breast-feeding woman.[15]

Drug interactions

❖ Fluconazole + Calcium channel blockers [like Amlodipine, Verapamil, Nifedipine]

↓

Can increase the risk of side effects of calcium channel blockers.

❖ Fluconazole + Statins [like Fluvastatin, Atorvastatin]

↓

May cause Myopathy and muscle damage.

❖ Fluconazole + Diabetes drugs [like Glipizide, Glimepiride]

↓

May cause low blood sugar or Hypoglycaemia.

❖ Fluconazole + Immunosuppressants [like cyclosporine]

↓

May increase the risk of side effects of Immunosuppressants.

❖ Fluconazole + Heart rhythm drugs [like Quinidine, Amiodarone]

↓

Can increase the risk of heart rhythm condition called QT prolongation.

❖ Fluconazole + Warfarin → Can increase the risk of bleeding.

❖ Fluconazole + Phenytoin → Can increase the risk of side effects of Phenytoin.

❖ Fluconazole + Terfenadine → Can increase the risk of cardiac dysrhythmias.

❖ Fluconazole + Rifampicin → Enhances the metabolism of Fluconazole.

MATERIALS AND METHODS

Materials required

- Fluconazole – Active ingredient.
- Micro crystalline cellulose (Avicel pH^{101}) – Diluent / filler, dry binder.

- Di-calcium phosphate – Diluent / filler, improves tablet hardness and flow properties.
- Croscarmellose sodium – Super disintegrant.
- Aerosil – Glidant.
- Beta cyclodextrin – Solubility enhancer.
- Maize starch – Diluent and binder, also acts as disintegrant to facilitate tablet breakup.
- Methyl paraben sodium -Preservative.
- Propyl paraben sodium – Preservative.
- Purified Water – Granulating fluid / solvent.
- Talc – Anti-adherent and Glidant.
- Magnesium stearate – Lubricant, reduces friction between tablet and punches.
- Sodium Starch Glycolate – Super disintegrant.
- Aspartame – Sweetening agent.
- Flavour (Pine apple) – Flavouring agent, improves palatability and patient acceptability.

Formulation Chart

Ingredients	Quantity in mg.
1. Fluconazole	50 mg
2. Avicel pH^{10}^{1}(MCC)	20 mg
3. Di calcium phosphate (DCP)	35 mg
4. Cross Carmel loses sodium (CCS)	2mg
5. Aerosil (Colloidal silicon diamide)	1mg
6. Beta cyclodextrin (K leptose)	2 mg
7. Maize starch	40 mg
8. Methyl paraben sodium	0.3 mg
9. Propyl paraben sodium	0.006 mg
10. Purified water	62 mg (QS)
11. Talc	2 mg
12. Magnesium stearate	1 mg
13. Sodium Starch Glycolate	8 mg
14. Aerosil	1 mg
15. Cross carmellose sodium	6 mg
16. Aspartame	10 mg
17. Flavour	3 mg

METHODOLOGY

- Weigh the required amount of API (Fluconazole), MCC, DCP, CCS, Aerosil, β-cyclodextrin and maize starch.
- Pass the above ingredients through sieve No. 40.
- Sieve them to obtain uniform-sized particles.
- Mix them properly to obtain a homogeneous mixture.

- Take a beaker, add the required amount of distilled water (D.W.) and a pinch of methyl and propyl paraben. Boil to dissolve the parabens in water.
- Slowly add the paraben solution to the above powder mixture and mix to form a lump (wet mass).
- Transfer the wet mass and make it into small particles in a Petri dish.
- Keep the Petri dish in a hot air oven at 70°C for 10 minutes.
- Cool the particles to room temperature (or in a desiccator) – Mixture I.
- Weigh the required amount of talc, magnesium stearate, sodium starch glycolate, Aerosil, CCS, aspartame and flavour.
- Mix them properly by shaking for 10 minutes to obtain a homogeneous mixture – Mixture II.
- Pass Mixture II through sieve No. 40.
- Mix Mixture I and Mixture II thoroughly to obtain a uniform blend.
- Weigh 180 mg of the powder blend and compress it in the tablet compression machine using the cavity.
- After compression, remove the tablet from the cavity. Tablets are ready.

Simple flow chart

Weighing
↓
Screening
↓
Mixing
↓
Wet mass making
↓
Lumps making
↓
Lumps drying
↓
Granules making
↓
Granules drying
↓
Granules screening
↓
Lubrication

↓

Weighing required amount of powder

↓

Tablet compression

↓

Tablets

Evaluation of Fluconazole tablets

The evaluation of tablets is done to ensure safety, efficacy, appropriateness and meeting the pharmacopeial limits.

The evaluation of tablets comprises three (3) parameters: -

→ Pre-compression parameters.

→ Compression parameters.

→ Post-compression parameters

1. Pre compression parameters[14,15]

- Bulk Density
- Tapped Density
- Bulkiness
- Carr's compressibility index
- Angle of Repose
- Hausner Ratio

➢ **Bulk Density (D_b)**

Bulk density depends on the particle size distribution, shape and cohesiveness of particles. Accurately weight quantity of powder carefully poured into graduated measuring cylinder through large funnel and volume was measured which is called initial bulk volume. The cylinder was tapped 10 times on hard surface from height of 1 inch at 2 second interval. It is expressed in gm/ml and is given by

$D_b = M/V_b$ (1)

Where, M= mass of the powder

V_b=bulk volume of powder

D_b= bulk density

➢ **Tapped Density (D_T)**

It is the ratio of total mass of powder to the tapped volume of powder. The tapped volume

was measured by tapping the powder to constant volume. It is expressed in gm/ ml and is given by

$D_t=M/V_t$ (2)

Where, M=mass of the powder

V_t=tapped volume of the powder

D_t=tapped density

- **Bulkiness (B)**

It is the reciprocal of Bulk density. It gives the measure of how much empty space (voids) between individual particles. Used to measure flow property of granules powder. It is expressed in gm/cc and is given by

$B=1/D_b$ (3)

- **Car's consolidation index (I)**

Carr developed an indirect method of measuring powder flow from bulk densities. The % compressibility of the powder was direct measure of the potential powder arch or bridge strength and stability. It is expressed in % and Carr's index of each formulation was calculated using the given formula.

Carr's index (%) = $[(D_t-D_b) \times 100]/D_t$ (4)

Where, D_t is the tapped density of the powder

D_b is the bulk density of the powder

Table: flow property related to Carr's index.

Carr's index	Type of flow
5-15	Excellent
12-18	Good
18-23	Fair to possible
23-35	Poor
35-38	Very poor
>40	Extremely poor

- **Angle of Repose (Ɵ)**

Good flow properties are critical for the development of any pharmaceutical tablets, capsule or powder formulations. Angle of repose is defined as the maximum angle possible between the surface of the pile of powder and horizontal plane. It is performed to determine the flow property of powder done by the funnel method. The powder mass was allowed to flow through the funnel orifice, kept vertically to a plane paper kept on horizontal surface, giving a

heap angle of powder on a paper. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$\Theta = \tan^{-1}(h/r)$ (5)

Where, Θ= angle of repose

h=height

r=radius

Table: Comparison between angle of repose and flow property.

Angle of Repose	Flow
<25	Excellent
25-30	Good
30-40	Moderate
>40	Poor

- **Hausner ratio**

It is the ratio of tapped density and Bulk density. It is used to determine the flowability and friction of a powder or granular material. It has no unit, and it is always greater than or equal to 1 and the formula is given by

$H = D_t/D_b$ (6)

Where, D_t=tapped density

D_b=Bulk density

POST COMPRESSION PARAMETERS[14,16]

- **Appearance**

The tablets are checked for presence of cracks, depressions, pinholes etc. if any, uniformity of the color and the polish of the tablets.

- **Thickness**

The thickness of all the tablets was measured by digital vernier callipers. It is expressed in mm.

- **Hardness**

The strength of the tablet is expressed as tensile strength (kg/cm^2). The tablet crushing load, which is the force required to break a tablet into pieces by compression. It was measured using a tablet hardness tester (Monsanto hardness tester).

➢ **Weight variation**

Ten tablets were randomly selected and average weight was determined. Then individual tablets were weighed and percent deviation from the average was calculated.

➢ **Friability**

Friability of the tablets was determined using Roche friabilator. This device consists of a plastic chamber that was set to revolve around 25 rpm for 4min dropping the tablets at a distance of 6 inches with each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability is given by the formula

$F= W_{initial}\text{-}W_{final}/W_{initial} \times 100$

➢ **In vitro disintegration time**

Disintegration time was measured using a modified disintegration method. For this purpose, a petridish was filled with 10ml of water at 37±0.5◦C. The tablet was carefully put in the centre of the petridish and the time for the tablet to completely disintegrate into fine particles was noted.

➢ **In vitro dissolution study**

The in vitro drug release of fluconazole tablets was determined by using Dissolution apparatus USP XXIII by rotating paddle method. The dissolution test was performed using 900 ml of buffer at 37±0.5◦C. The speed of rotation of paddle was set at 50 rpm. 5ml samples were withdrawn at proper time and same volume was replaced with fresh media. Absorbance of solution was checked by UV spectrophotometer at a wavelength of 260nm.

➢ **Drug content**

2 tablets were powdered in a glass mortar. Powder equivalent to 10mg of fluconazole was weighed and dissolved in 100 ml of buffer. The solution was made up to volume and filtered. Appropriate dilutions were made and absorbance measured by UV spectrometer using appropriate blank solution at 260nm.

➢ **Stability study**[17,18]

Stability of a dosage form has been defined as the ability of a particular formulation, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specification. Accelerated stability study was carried out as per the ICH guidelines.

➢ **Procedure**

In the present study, the stability was carried out for a specific time up to 90 days for selected formulation. The selected formulation was analysed for the

➢ Physical appearance

➢ Drug content

➢ Dissolution profile.

RESULTS AND DISCUSSION

1. Pre-compression parameters

❖ **Appearance**

White amorphous powder and Bitter in taste belongs to BCS Class 1 (High soluble and High Permeable).

❖ **Melting Point:** 138-142°C

❖ **Solubility**

Solvents	Solubility
Water	Slightly soluble
Methanal	Soluble
Petroleum ether	Soluble
Acetone	Soluble
Chloroform	Sparingly soluble

Therefore, it is easily soluble in organic solvent than aqueous solvents.

❖ **Moisture content**: Not more than 3%

❖ **Bulk Density**: 0.4gm/cc

❖ **Tapped Density**: 0.45gm/cc

❖ **Bulkiness:** 2.5 gm/cc

❖ **Carr's index**: 11.11% (Excellent Flow)

❖ **Angle of Repose**: Excellent flow

❖ **Hausner Ratio**: 1.12

2. Post Compression Parameters

❖ **Physical Appearance**

→ Colour: White

→Shape: Round Shape with break line on upper side and plain on lower side.

→Diameter: 6mm

→Thickness: 3.3mm

- **Group Weight:** 1.71 gm.
- **Average Weight:** 0.171 gm
- **Weight Variation:** 180±0.5mg
- **Hardness Test:** 2-3 gm
- **Friability Test:** 0.58%
- **Disintegration Test:** 21 sec
- **Dissolution Test**: 70%

CONCLUSION

The present study concludes that the formulated Fluconazole dispersible tablet was successfully prepared and evaluated. The tablets exhibited satisfactory pre-compression and post-compression characteristics, including acceptable hardness, friability, weight variation, drug content, disintegration time, and dissolution profile. The optimized formulation showed rapid dispersion, uniform drug release, and complied with pharmacopeial quality standards. These findings indicate that the developed Fluconazole dispersible tablet is a promising dosage form for improving patient compliance, especially in paediatric and geriatric patients who have difficulty swallowing conventional tablets.

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CONFLICT OF INTEREST

The author declared that there is no conflict of interest.

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