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IMPROVEMENT OF SOLUBILITY OF TERBINAFINE HYDROCHLORIDE BY USING SOLID DISPERSION

***Mr. Akash Shete, Dr. Sudke S. G.**

GES's Satara College of Pharmacy, Satara, Maharashtra, India.

***Corresponding Author: Mr. Akash Shete**
GES's Satara College of Pharmacy, Satara, Maharashtra, India.

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ABSTRACT
Terbinafine hydrochloride is a widely used antifungal drug; however, its therapeutic effectiveness is limited due to its poor aqueous solubility and low oral bioavailability. The present study aims to enhance the solubility and dissolution rate of terbinafine hydrochloride using solid dispersion techniques. Solid dispersions were prepared using different hydrophilic carriers such as hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), urea, and citric acid in varying drug-to-polymer ratios by the solvent evaporation method. Preformulation studies, including UV spectroscopy, confirmed the λmax of the drug at 283 nm, and calibration curves demonstrated good linearity (R^2 = 0.9977). Fourier Transform Infrared (FTIR) spectroscopy studies revealed no significant interaction between the drug and carriers, indicating compatibility. In vitro dissolution studies showed a significant improvement in the dissolution rate of terbinafine hydrochloride in solid dispersion formulations compared to the pure drug.Among all carriers, HPMC exhibited the highest enhancement in solubility and dissolution, followed by PVP, citric acid, and urea. The increase in dissolution rate is attributed to improved wettability, reduced particle size, and conversion of the drug into an amorphous form. In conclusion, solid dispersion is an effective technique for enhancing the solubility and dissolution rate of poorly water-soluble drugs like terbinafine hydrochloride, thereby potentially improving its bioavailability and therapeutic efficacy.

KEYWORDS: Terbinafine hydrochloride, Solid dispersion, Solubility enhancement, HPMC, Dissolution rate, FTIR.

INTRODUCTION
Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, a major challenge associated with oral delivery is the poor aqueous solubility of many drugs, which leads to low bioavailability. It is estimated that a significant proportion of newly developed drugs fall under the category of poorly water-soluble compounds, making solubility enhancement an important area of pharmaceutical research.Terbinafine hydrochloride is an antifungal agent widely used in the treatment of dermatological infections such as onychomycosis and ringworm. Despite its potent antifungal activity, its clinical effectiveness is limited by its poor solubility and dissolution rate, which in turn affects its oral bioavailability. Therefore, improving the solubility of terbinafine hydrochloride is essential to enhance its therapeutic performance.Various techniques have been employed to improve the solubility of poorly soluble drugs, including micronization, salt formation, use of surfactants, complexation, and solid dispersion. Among these, solid dispersion has emerged as one of the most effective and widely used approaches. In this technique, the drug is dispersed in an inert hydrophilic carrier at the solid state, which enhances wettability, reduces particle size, and may convert the drug from a crystalline to an amorphous form, thereby improving dissolution characteristics.Hydrophilic carriers such as hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), urea, and citric acid are commonly used in solid dispersion systems. These carriers improve drug solubility by enhancing wettability and preventing drug aggregation. The choice of carrier and drug-to-polymer ratio plays a crucial role in determining the efficiency of the formulation.

The present study focuses on the preparation and evaluation of solid dispersions of terbinafine hydrochloride using different hydrophilic carriers. The objective is to enhance the solubility and dissolution rate of the drug and to compare the effectiveness of various carriers in improving its pharmaceutical performance.

DRUG PROFILE: TERBINAFINE HYDROCHLORIDE

1. General Information

- **Drug Name:** Terbinafine Hydrochloride
- **Category:** Antifungal agent
- **Chemical Class:** Allylamine derivative
- **Molecular Formula:** $C_{21}H_{26}ClN$
- **Molecular Weight:** ~327.9 g/mol

2. Mechanism of Action

Terbinafine hydrochloride acts by inhibiting the enzyme **squalene epoxidase**, which plays a key role in the biosynthesis of ergosterol, an essential component of fungal cell membranes. Inhibition of this enzyme leads to accumulation of squalene and deficiency of ergosterol, resulting in fungal cell death.

3. Pharmacological Uses

- Treatment of onychomycosis (fungal nail infections)
- Ringworm (tinea corporis)
- Athlete's foot (tinea pedis)
- Jock itch (tinea cruris)

4. Physicochemical Properties

- **Appearance:** White to off-white crystalline powder
- **Solubility:** Poorly soluble in water
- **Melting Point:** Approximately 204–208°C
- **Log P:** High (lipophilic nature)

5. Biopharmaceutical Classification

Terbinafine hydrochloride is categorized under **BCS Class II drugs**, which are characterized by:

- Low solubility
- High permeability

This makes solubility enhancement a critical factor for improving its bioavailability.

6. Limitations

- Poor aqueous solubility
- Low dissolution rate
- Variable oral bioavailability

7. Need for Solubility Enhancement

Due to its hydrophobic nature, terbinafine hydrochloride shows limited dissolution in gastrointestinal fluids, which reduces its absorption. Enhancing its solubility can significantly improve its therapeutic effectiveness. Solid dispersion is considered a promising approach to overcome these limitations.

MATERIALS AND METHODS

1. MATERIALS

Terbinafine hydrochloride was used as the model drug for the study. Hydrophilic carriers such as **Hydroxypropyl Methylcellulose (HPMC K4M), Polyvinylpyrrolidone (PVP K30), urea, and citric acid** were used for the preparation of solid dispersions. Ethanol (96%) was used as a solvent for the preparation process. All reagents and chemicals used were of analytical grade.

2. Method of Preparation of Solid Dispersion

Solid dispersions of terbinafine hydrochloride were prepared using the **solvent evaporation method**.

Procedure

A required quantity of terbinafine hydrochloride (1 g) was taken and dissolved in ethanol. The selected polymer (HPMC, PVP, urea, or citric acid) was added to the drug solution in different ratios (1:1, 1:2, 1:3, and 1:4 drug-to-polymer ratio).

The resulting solution was stirred thoroughly to ensure uniform mixing and then allowed to stand for solvent evaporation at room temperature. After complete evaporation of the solvent, the solid mass obtained was dried, pulverized, and passed through a suitable sieve to obtain uniform solid dispersion.

3. Drug–Polymer Ratios The solid dispersions were prepared using the following ratios

- 1:1 (Drug : Polymer)
- 1:2
- 1:3
- 1:4

These ratios were selected to study the effect of polymer concentration on drug solubility and dissolution rate.

4. Preformulation Studies

4.1 UV Spectroscopy

The absorption maximum (λmax) of terbinafine hydrochloride was determined using a UV spectrophotometer in ethanol:water (40:60). The λmax was found to be **283 nm**.

A calibration curve was prepared using standard solutions in the concentration range of **5–40 µg/mL**, and absorbance was measured at 283 nm.

4.2 Fourier Transform Infrared (FTIR) Spectroscopy

FTIR studies were carried out to evaluate the compatibility between the drug and excipients. Spectra of pure drug and physical mixtures with polymers were recorded and analyzed for any chemical interaction.

5. Drug–Excipient Compatibility Study

Compatibility studies were performed using FTIR analysis. The spectra of the drug were compared with those of mixtures containing polymers such as HPMC, PVP, urea, and citric acid. The absence of additional

peaks or significant shifts confirmed compatibility between the drug and excipients.

6. In Vitro Dissolution Study

In vitro dissolution studies were carried out to evaluate the release profile of terbinafine hydrochloride from solid dispersions.

The dissolution test was performed using a suitable dissolution apparatus under controlled conditions. Samples were withdrawn at predetermined time intervals and analyzed using a UV spectrophotometer at 283 nm.

The percentage cumulative drug release was calculated and compared with that of the pure drug.

7. Preparation of Dosage Form

The optimized solid dispersion was filled into **hard gelatin capsules (size "000")**, equivalent to 250 mg of terbinafine hydrochloride, to obtain a unit dosage form.

RESULTS AND DISCUSSION

1.UV Spectroscopy and Calibration Curve

Calibration curve of terbina fine hydrochloride.

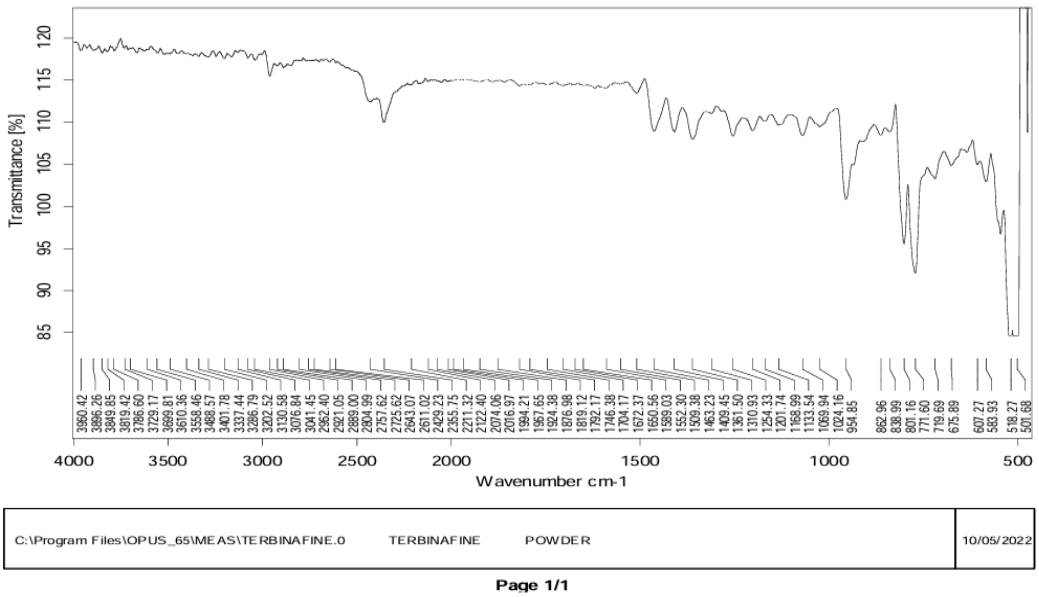
Sr. No.	Concentration(µg/ml)	Absorbance
1	5	0.133
2	10	0.294
3	15	0.401
4	20	0.525
5	25	0.641
6	30	0.754
7	35	0.877
8	40	0.975

The UV spectrophotometric analysis of terbinafine hydrochloride showed a maximum absorbance (λmax) at **283 nm**. A calibration curve was plotted in the concentration range of **5–40 µg/mL**, which exhibited good linearity with a regression coefficient (R^2 = **0.9977**). This indicates that the drug follows Beer-Lambert's law within the selected range and confirms the reliability of the analytical method.

2. FTIR Spectroscopy

FTIR studies confirmed the identity of terbinafine hydrochloride by showing characteristic peaks corresponding to functional groups such as:

- C–H stretching and bending
- C=C bending
- Aromatic ring structures



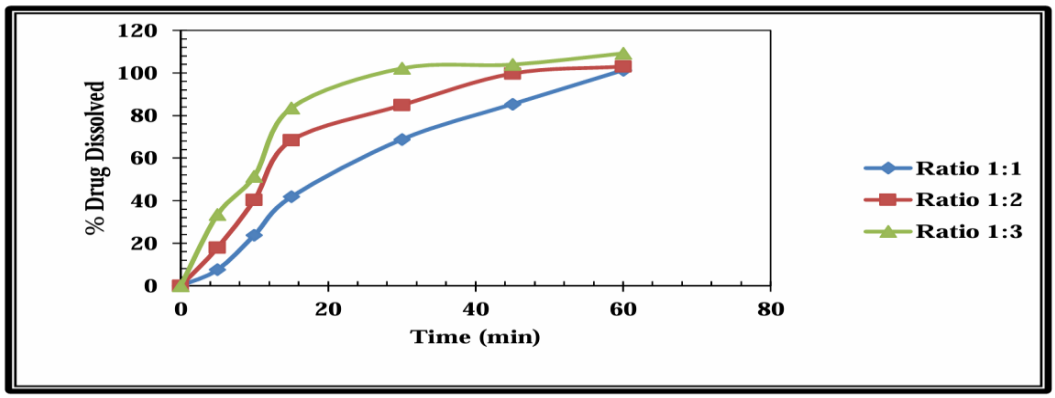
FITR Sepctrum of Terbinafine

The spectra of drug–polymer mixtures (HPMC, PVP, urea, and citric acid) showed no significant shift or disappearance of peaks, indicating **no chemical interaction** between the drug and excipients. This confirms that all selected carriers are compatible and suitable for solid dispersion formulaton.

3. In Vitro Dissolution Studies

The dissolution studies demonstrated a **significant enhancement in drug release** from solid dispersions compared to the pure drug.

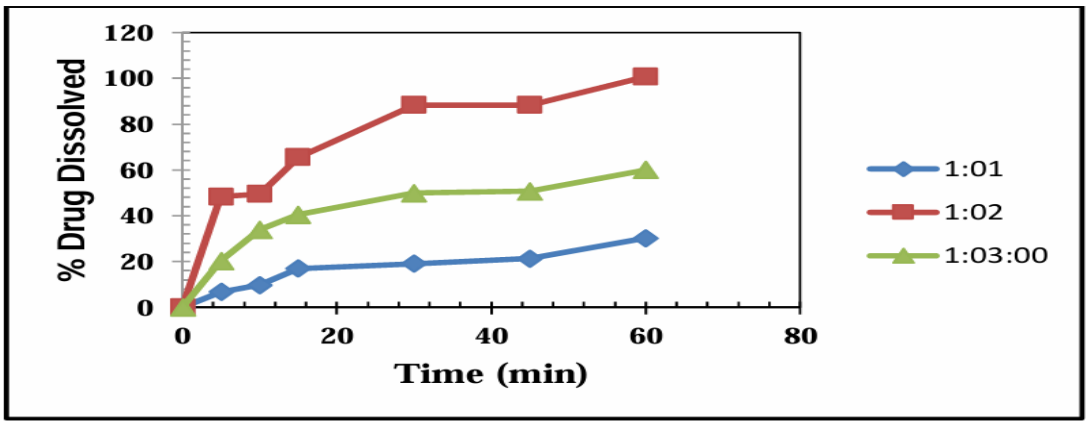
In-vitro dissolution of drug solid dispersion with HPMC K4M

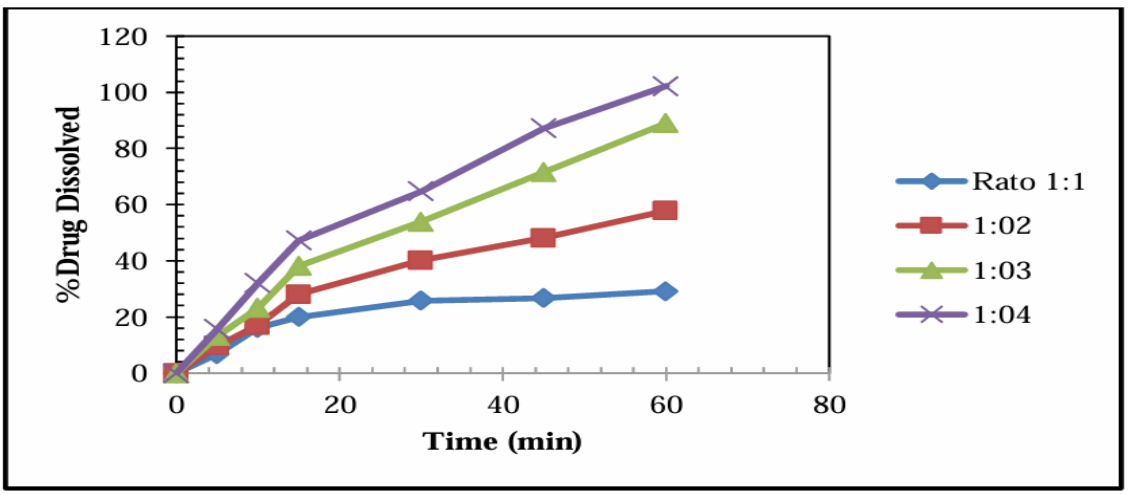


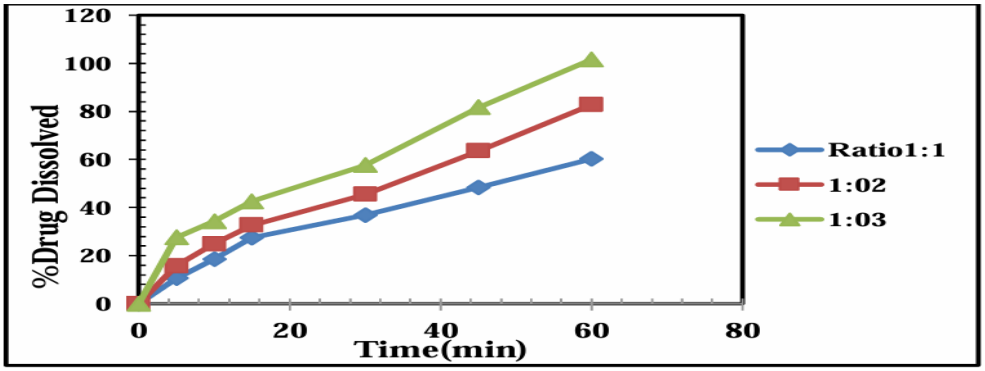
Effect of Polymer Type

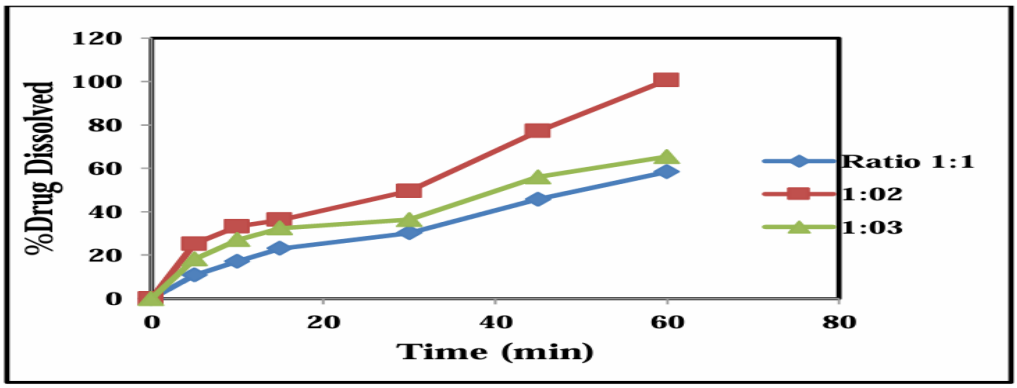
Different carriers showed varying efficiency in improving drug dissolution:

- **HPMC:** Showed the highest enhancement in drug release
- **PVP:** Moderate improvement
- **Citric Acid:** Good improvement due to high water solubility
- **Urea:** Least improvement among all carriers









Effect of Drug–Polymer Ratio

An increase in polymer concentration (from 1:1 to 1:4) resulted in:

- Increased dissolution rate
- Higher cumulative drug release
- Improved wettability and dispersion

For example, in HPMC formulations, cumulative drug release reached above **100% within 60 minutes** at higher ratios, indicating rapid dissolution.

Similarly, urea and PVP formulations also showed progressive improvement with increasing polymer ratio, though less effective than HPMC.

4. Mechanism of Dissolution Enhancement

The improved dissolution of terbinafine hydrochloride from solid dispersions can be attributed to:

- **Reduction in particle size**
- **Improved wettability** due to hydrophilic carriers
- **Decreased crystallinity (amorphous conversion)**
- **Prevention of drug aggregation**
- **Increased surface area for dissolution**

Hydrophilic polymers facilitate faster drug release by forming a molecular dispersion of the drug in aqueous media.

5. Comparative Analysis

Among all formulations studied, **HPMC-based solid dispersions (especially higher ratios)** showed the best performance in enhancing solubility and dissolution rate.
Overall effectiveness of carriers:

HPMC > PVP > Citric Acid > Urea

This trend clearly indicates that polymer selection plays a crucial role in formulation development.

6. DISCUSSION SUMMARY

The results confirm that the **solid dispersion technique is highly effective** for improving the dissolution profile of poorly water-soluble drugs like terbinafine hydrochloride. The enhancement is dependent on both the type of carrier and the drug-to-polymer ratio.

CONCLUSION

The present study successfully demonstrated that the **solid dispersion technique** is an effective approach for enhancing the solubility and dissolution rate of **terbinafine hydrochloride**, a poorly water-soluble drug.Solid dispersions were prepared using different hydrophilic carriers such as **HPMC, PVP, urea, and citric acid** in varying drug-to-polymer ratios. Among all the carriers used, **HPMC showed the most significant improvement** in drug release, especially at higher ratios.

The increase in dissolution rate can be attributed to factors such as:

- Improved wettability
- Reduction in particle size
- Conversion of the drug into an amorphous form
- Increased surface area
- Enhanced drug dispersion in hydrophilic matrices

FTIR studies confirmed the **absence of drug–excipient interaction**, indicating compatibility and stability of the formulation.

Overall, the study concludes that

- Solid dispersion is a **simple and effective method** for improving bioavailability
- Polymer type and concentration play a **crucial role** in formulation performance
- HPMC is the **most suitable carrier** among those studied

This approach can be further explored for the development of **efficient oral dosage forms** of terbinafine hydrochloride and other poorly soluble drugs.

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