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PHARMACEUTICAL DEVELOPMENT AND REGULATORY DOCUMENTATION OF TERBINAFINE: A REVIEW FROM PREFORMULATION TO PRODUCT EVALUATION

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1.ABSTRACT

This study focuses on the formulation and evaluation of Terbinafine tablets, an antifungal drug used to treat fungal infections. The tablets were prepared using the wet granulation method with suitable excipients to ensure proper binding, disintegration, and stability. Various equipment such as a blender, dryer, and compression machine was used during manufacturing. The prepared tablets were evaluated through physical, chemical, and pharmaceutical tests including weight variation, hardness, friability, disintegration, and dissolution. Stability studies and proper packaging were also carried out to ensure product quality and safety. The results showed that the formulated tablets met standard requirements, indicating they are effective, stable, and suitable for therapeutic use.

2.KEYWORDS: Anti-fungal agents, Terbinafine, pre-formulation of Terbinafine tablets, FTIR, DSC, stability studies, wet granulation, evaluation of tablets, package, regulatory documentation.

3.INTRODUCTION

Antifungal agents are drugs designed to combat fungal infections while sparing the human host from harm. Unlike antibiotics, the development of antifungal medications has progressed more slowlyand for good reason. Bacteria are prokaryotic organisms with cellular structures and metabolic pathways that are very different from those of humans, making them easier targets for selective drug therapy. Fungi, however, are eukaryotes, sharing many cellular

features with human cells. This close biological similarity makes it challenging to develop drugs that are deadly to fungi but safe for patients, as many antifungal compounds risk harming both. As a result, the search for effective and selective antifungal therapies has been a far more complex scientific challenge [5].

TERBINAFINE

INTRODUCTION

Terbinafine hydrochloride is a synthetic allylamine antifungal agent and it is highly lipophilic in nature and tends to accumulate in skin, nails, fatty tissues, bacteria of the duodenum and viral infections of the stomach. Like other allylamines, terbinafine inhibits ergosterol synthesis by inhibiting squalene epoxidase, an enzyme that is part of the fungal cell membrane synthesis pathway.So terbinafine prevents conversion of squalene to lanosterol, ergosterol cannot be synthesized. This is thought to change cell membrane permeability, causing fungal cell lysis. It is an anti-fungal which diffuses rapidly into the skin from topical applications and effectively treats athlete's foot i.e.tinea pedis. Terbinafine hydrochloride interferes with the integrity and growth of the fungal cell wall by weakening the cell wall and eventually leading to fungal cell death. It is effective at low levels and diffuses rapidly into the skin to effectively cure tinea [10].

Molecular formula: $C_{21}H_{25}N$

Molecular weight:291.4 g/mol

Chemical structure

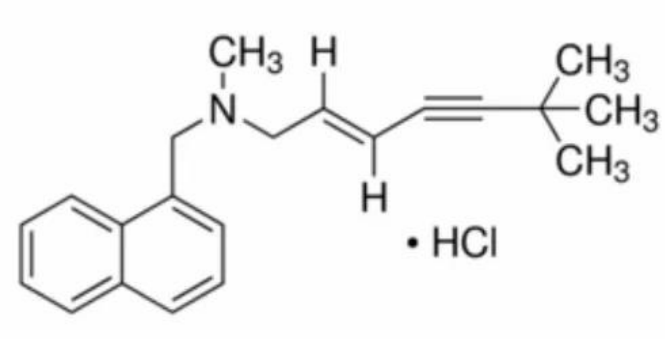

Fig.1: Chemical structure of Terbinafine hydrochloride.

MECHANISM OF ACTION

It inhibits ergosterol synthesis by inhibiting squalene epoxidase, an enzyme that is a part of fungal cell membrane synthesis pathway. Because terbinafine prevent conversion of squalene to lanosterol, ergosterol cannot be synthesized, and caused fungal cell lysis[13].

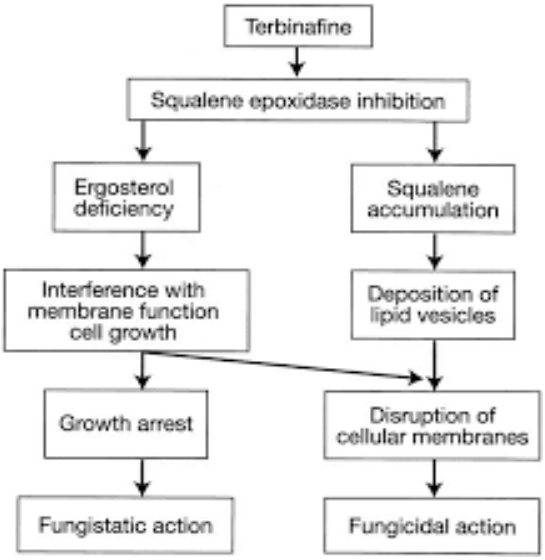

Fig.2: Pathway on mechanism of action of Terbinafine.

ADVERSE EFFECTS[12]

- Epigastralgia
- Nausea
- Tachycardia
- Hepatobiliary dysfunction
- Bloating
- Abdominal pain
- Erythema
- Redness
- Alopecia
- Nausea
- Rashes

CONTRAINDICATIONS[12]

- Pregnancy
- Breastfeeding
- Renal dysfunction
- Hepatic dysfunction
- Tumor patients
- Glucose-galactose malabsorption

USES[12]

Used in treatment of:

- Tinea capitis
- Tinea corporis
- Tinea pedis
- Fingernail onychomycosis
- Toe nail onychomycosis
- Trichophytosis
- Microsporiasis

MARKETED FORMULATIONS

1. Oral tablets

Terbinafine tablets are widely available in the market, primarily as a 250 mg immediate-release tablets.

Doses available:250mg, 500mg

Brand names: TERIGOOD-250, FERBIGET-500

Fig.3: Marketed Terbinafine oral tablet.

2. Creams

Terbinafine cream is a widely used topical antifungal treatment for skin infections.

Dose available-1%

Brand names: TERBINEX, TERBAZ

3. Topical Spray

A **1% solution** intended for quick application and drying on larger skin areas.

Dose available: 1%

Brand names: LAMISIL, TERBICIP

4.METHODS AND MATERIALS:

PREFORMULATION STUDIES OF TERBINAFINE TABLET

1. PHYSICOCHEMICAL PROPERTIES

a) Organoleptic properties[6]

Organoleptic properties are the sensory characteristics specifically color, odor, taste etc. that are perceived by human senses (sight, smell, taste, touch, and sometimes hearing).

Tableno. 1: Organoleptic properties and observation of Terbinafine.

Sl.No.	Test	Observation
1.	Color	White
2.	Odor	Odorless
3.	Taste	Bitter

b) Solubility

Solubility is the maximum amount of a solute (solid, liquid, or gas) that can dissolve in a specific amount of solvent to form a stable, homogeneous solution at a given temperature and pressure.

Procedure[10]

For crude solubility, equivalent amount of the drug was taken in different test tubes containing the different solvents. Test tubes were shaken vigorously after the addition of each portion of solvent and then crude solubility was observed by visual inspection.

Table no. 2: Solubility of Terbinafine in different media.

Sl.No.	Media	Inference
1.	Methanol	Freely soluble
2.	Ethanol	Soluble
3.	Water	Sparingly soluble
4.	0.1N HCl	Sparingly soluble
5.	Chloroform	Insoluble

c) Melting point

The melting point is the specific temperature at which a solid converts into a liquid at a given pressure, where both solid and liquid phases exist in equilibrium.

Procedure[10]

A few of drug were placed in a thin-walled capillary tube 10-15mm long,about 1mm inside diameter, and closed at one end. The capillary,it contains the sample,was suspended to heat the samples slowly and evenly and thermometer placed to check the temperature. The

temperature range over where the sample is observed to melt is taken as the melting point of the drug.

Table no. 3: Melting point of Terbinafine.

Drug	Melting point
Terbinafine	204°C-207°C

d) Partition coefficient

When a material is placed in an environment consisting of organic and aqueous phase, it gets distributed into two phases. The relative quantities that get distributed are expressed in the form of ratio known as partition co-efficient. Partition coefficient of terbinafine was calculated by using the following formula:

Partition coefficient= $Concentration of drug in organic phase$

$Concentration of drug in aqueous phase$

Procedure[8]

It was determined in n-octanol:water system, bytaking 25ml of both n-octanol and water in separating funnel. Shake this mixture for 30 minutes and keep it for 24hours.Then10 mg drug mixed with saturated solution of n-octanol: water in separating funnel. The separating funnel was shaken for 24 hours. The two phases were and the amount of the drug in aqueous phase was analyzed by UV at 282.7 nm after appropriate dilution.

Table no. 4: Partition coefficient and nature of Terbinafine.

partition coefficient	Solvent system	Log P value
Terbinafine	n-octanol:water	3.312±0.005

a) Ionization constant [11]

An ionization constant (also known as a dissociation constant, denoted as K) is a quantitative measure of the extent to which a substance, such as an acid or base, dissociates into ions in a solution.

Procedure

10 mg drug was dissolved in 50 ml of distilled water and then 20ml of drug solution was titrated with 0.1 N NaOH by using phenolphthalein as a indicator and detect the end point till pink color appeared.Note the volume consumed by titrant when the pink color appeared and then remaining 20 ml drug solution was further titrated by using half the quantity of 0.1 N

NaOH consumed for the determination of endpoint during first titration and determine the pH of the drug solution.

The ionization constant (pKa) for Terbinafine is approximately 7.

b) pH[7]:

pH (potential of hydrogen) is a logarithmic scale from 0 to 14 measuring the acidity or alkalinity of an aqueous solution. A pH of 7 is neutral (e.g., pure water), less than 7 is acidic (higher H^+ concentration), and greater than 7 is alkaline/basic.

Terbinafine is found to be a weak base with a pKa of approximately 7.1, a value that significantly influences its solubility and how it is formulated for medical use. In its most common pharmaceutical form, terbinafine hydrochloride, the substance is mildly acidic when dissolved; a 0.5% solution typically maintains a pH of around 4.7.

2. MICROMERITIC PROPERTIES

a) Particle size

Terbinafine hydrochloride was analyzed for particle size distribution by means of sieving method using mechanical sieve shaker Electromagnetic sieve shaker EMS8.

Procedure[1]

50 gm of Terbinafine hydrochloride was taken in sieve no 20 and arrange the sieve in the order of 20,40,60,80,100 and above from top to bottom Then fixed these sieves sets in theelectromagnetic sieve shaker and operated for 5 minutes.

Particle size analysis was carried out by Electromagnetic sieve shaker EMS8 using sieve of different mesh size number which shows that large percentage of particle wasobtained on 40 mesh number sieve whose opening is 425 µm.

Particle size analysis revealed a mean diameter of ~344.3 nm, a unimodal size distribution, and a polydispersity index (PDI) of 0.168, suggesting low aggregation.

b) Flow properties

Flow properties and compressibility properties of powder mixture were evaluated by measurement of angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio.

Angle of repose (θ)[3]

Angle of repose can be defined as the angle that differentiates the transitions between phases of the granular material

The angle of repose was determined by using fixed funnel method. The physical mixtures of drug with different excipients were prepared and the accurately weighed drug powder or its physical mixture was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the drug powder. The powder was allowed to flow through the funnel freely onto surface. The angle of repose was calculated using the following equation.

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

Where, h and r are the height and radius of the powder cone respectively.

Bulk density[11]

It is the ratio of total mass of powder to the bulk volume of powder. It was measured bypouring the weighed powder (passed through standard sieve # 20) into a measuring cylinder and the initial volume was noted. This initial volume is called the bulk volume. From this, the bulk density is calculated according to the formula mentioned below. It is expressed in g/cc and is given by:

Bulk density, $\rho_b = m/Vo$

Where, m= mass of solid particles

Vo= Total volume

Tapped density[11]

It is the ratio of total mass of powder to the tapped volume of powder. The volume was measured by tapping the powder for 500 times. Then the tapping was done for 750 times and the tapped volume was noted (the difference between these two volumes should be less than 2%). If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. It is expressed in g/cc and is given by

Tapped density, $\rho_{tapped} = m/Vt$

Where, m= mass

Vt= Tapped volume

Compressibility (Carr's index)[3]

The flowability of powder can be evaluated by comparing the loose Bulk density (LBD) andTapped density of powder and the rate at which it packed down. Compressibility index of the granules was determined by the

Carr's compressibility: CI (%) = (Tapped density-Bulk density) x 100

Tapped density

Hausner's Ratio[3]:

It is measurement of frictional resistance of the drug. The Ideal range should be 1.2 –1.5, it was determined by the ratio of tapped density and bulk density.

Hausner's ratio, HR= Tapped density/ Bulk density

Table no.7: Angle of repose, Carr's index, Hausner's ratio, bulk density and tapped density of Terbinafine [10].

Parameter	Result
Angle of repose	35°
Carr's index	41.0%
Hausner's ratio	1.695
Bulk density	0.3 g/cm^2
Tapped density	0.508g/cm^2

3. COMPATIBILITY STUDIES

a) FTIR[4]

IR spectroscopy deals with the study of absorption of IR region, which extends from the red end of the visible spectrum to the microwave region. An IR radiation is absorbed by a molecule when the applied IR frequency is equal to the natural frequency of vibration of the molecule. Absorption of IR radiation brings a change in the dipole moment of the molecule.

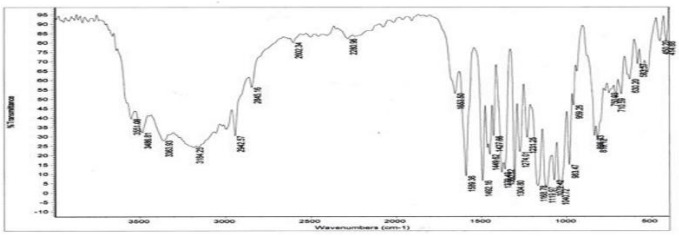

Fig.4: FTIR of Terbinafine.

Table no.8: Peaks and respective wavenumbers of Terbinafine.

Sl. No	Functional Group	Wavenumber(cm^{-1})
1.	OH Stretching	2968
2.	SH Stretching	2443.89
3.	CN Stretching	2222.07
4.	C=O Stretching	1633.76
5.	CH bending	1469.81
6.	COOH Stretching	1361.79
7.	S=O Stretching	1070.53
8.	CH Bending	808.20
9.	C-Cl Stretching	777.34

The drug sample was firstly identified spectroscopically by FTIR (Fourier transform infrared). The result showed that the drug Terbinafine hydrochloride was pure and free from impurities.

b) Differential Scanning Calorimetry (DSC):

Differential scanning calorimetry (DSC) is now generally accepted as the technique of choice to determine the energetics of protein folding/ unfolding transitions and the thermodynamic mechanisms underlying those reactions.

Procedure[2]

1-2 mg of sample were hermetically sealed in a flat-bottomed aluminum pan and heated in the differential scanning calorimetry (DSC) instrument in an atmosphere of nitrogen at a flow rate of 25 ml/min. A temperature range of 40-400°C was used and the heating rate was 10°C/min.

The DSC results of terbinafine are presented in Fig. 2. The first heating run shows an endothermic melting sharp peak with its maximum at 208.9 °C.

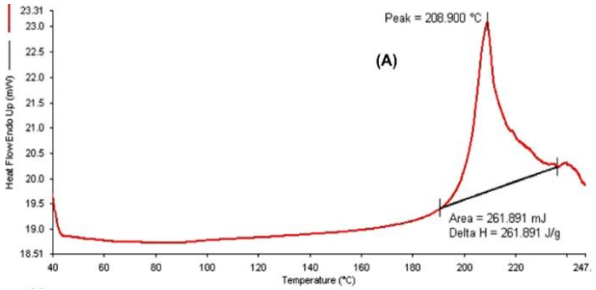

Fig.5: DSC of Terbinafine.

4. STABILITY STUDIES

Stability of a drug can be defined as the time from the date of manufacture and the packaging of the formulation, until its chemical or biological activity is not less than a predetermined level of labelled potency and its physical characteristics have not changed appreciably or deleteriously.

a) Thermal stability

Thermal stability is a characteristic of a material to retain its structure and properties when exposed to higher temperatures.

Accelerated stability studies are designed to increase the rate of chemical degradation and /or physical change of drug substance or drug product by using exaggerated conditions and predicating the shelf life under normal conditions.

Procedure[9]

Samples of terbinafine hydrochloride had been subjected to accelerated stability study according to the following WHO requirements:

- Storage conditions 40±2ºC / 75±5%RH
- Time period 6 months
- Testing frequency 0, 1, 2,3,6 months

The results showed that there was no change in the physical characteristics of the drug and there were small and acceptable changes of pH value.

b) Photostability:

The photostability of a drug substance may be defined as the response of the drug or drug product to the exposure to solar, UV, and visible light in the solid, semisolid, or liquid state that leads to a physical or chemical change.

Procedure[9]

Photostability study had been performed according to ICH requirements where samples should be exposed to light providing an overall illumination of not less than 1.2 million lux hours and an integrated near ultraviolet energy of not less than 200watt hours/square meter and this level can be obtained by exposing drug product outside of its immediate pack to disseminated day light for 50 days.

After subjecting terbinafine hydrochloride cream sample to photostability study according to ICH guide it was noticed that there were two peaks for degraded products and a potency loss of about 14% from the initial assay value.

FORMULATION OF TERBINAFINE TABLETS

Tablets are the most popular oral solid dosage form, comprising active pharmaceutical ingredients (APIs) and excipients compressed into precise, stable, and convenient units. They account for roughly 70% of all dispensed medications, featuring various types like tablets that are coated, uncoated, chewable, or effervescent, designed for specific release rates.

COMPOSITION[14]

Table no. 9: Ingredients used in preparation of Terbinafine tablets and their functions.

SL. No.	INGREDIENTS	FUNCTIONS
1.	Terbinafine hydrochloride	Active pharmaceutical ingredient
2.	Microcrystalline Cellulose	Binder
3.	Sodium starch glycolate	Disintegrant
4.	Hydroxypropyl MethylcelluloseE-LV	Binder
5.	Hydroxypropyl MethylcelluloseE-MV	Binder
6.	Colloidal silicon dioxide	Glidant
7.	Magnesium Stearate	Lubricant

PROCEDURE[14]

1. Sifting and Weighing:

Step: The active ingredient (Terbinafine HCl) and primary excipients (Microcrystalline Cellulose, Sodium Starch Glycolate) are accurately weighed according to the formula.

Action: Each material is passed through a specific mesh sieve (e.g., #40 sieve) to break up lumps and ensure uniform particle size.

2. Pre-blending (Dry Mixing):

Step: The sieved Terbinafine HCl and excipients are loaded into a mixer (such as a High Shear Mixer or a polybag for smaller trials).

Action: They are mixed for a set time (e.g., 10–20 minutes) to create a homogeneous dry powder blend.

3. Wet Granulation:

Step: A binder solution (typically Hypromellose dissolved in purified water) is prepared and slowly added to the dry powder blend.

Action: Continuous mixing transforms the powder into a "wet mass." This mass is then passed through a coarse sieve (e.g., 14 or 20 mesh) to form wet granules.

4. Drying:

Step: The wet granules are transferred to a drying apparatus, such as a Fluid Bed Dryer (FBD) or a tray dryer.

Action: They are dried at controlled temperatures (typically 60°C to 70°C) until the moisture content (Loss on Drying - LOD) reaches a specified range.

5. Milling and Sizing:

Step: The dried granules are passed through a smaller mesh sieve (e.g., 20 or 24 mesh).

Action: This ensures all granules are of a consistent size, which is critical for maintaining uniform tablet weight during compression.

6. Lubrication (Final Blending):

Step: Extra-granular materials like Magnesium Stearate (lubricant) and additional Sodium Starch Glycolate (disintegrant) are added to the dried granules.

Action: A final short mixing cycle (e.g., 2–5 minutes) ensures the granules are evenly coated with lubricant to prevent sticking during the next phase.

7. Compression:

Step: The final lubricated blend is fed into a tablet press.

Action: High-speed punches compress the granules into solid tablets of the required shape and thickness.

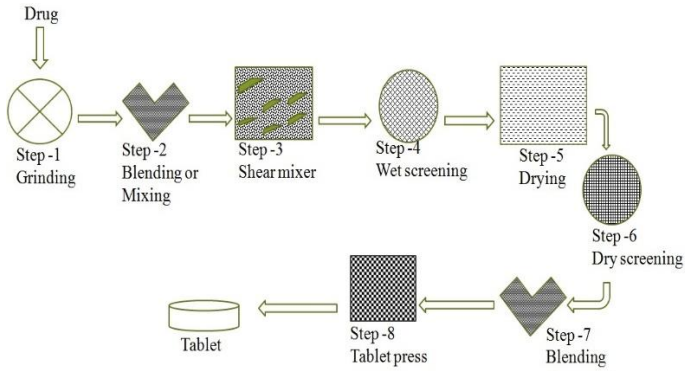

Fig.6: Preparation of Terbinafine tablets by wet granulation method.

EVALUATION OF TERBINAFINE TABLETS

1. PHYSICAL EVALUATION

a) Organoleptic evaluation

Tablets were visually examined for physical characteristics such as color, shape, surface texture, and coating uniformity.

Film-coated tablets should exhibit a smooth, intact coating free from defects such as chipping, cracking or mottling

Terbinafine tablets were found to be white colored oblong shaped tablets.

b) Weight variation test:

This is an important in-process quality control test to be checkedfrequently (every half an hour). Corrections were made during the compression of tablets. Any variation in the weight of tablet (for any reason) leads to either under medication or overdose. So, every tablet in each batch should have a uniform weight.

Procedure

20 tablets were weighed individually. Average weight was calculated from the total weight of all tablets. Individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits (± 3%). The percent deviation was calculated using the following formula.

% Deviation: = Individual weight – Average weight x 100

Average weight

Result: 330 ± 5% from average weight

Fig.12: **Monsanto hardness tester.**

c) Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling.

Procedure:

The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm2. Five tablets were randomly picked and hardness of the tablets was determined.

Result: 3-10 kg/cm^2

d) Friability test

The friability of tablets was determined by using Roche friabilator. It is expressed in percentage (%).

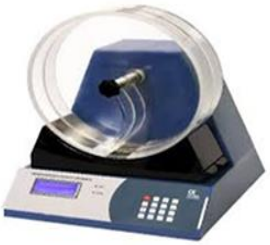

Fig. 13: **Roche friabilator**

Procedure:

Twenty tablets were initially weighed (Wt) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (WF). The % friability was then calculated:

% friability= Initial weight – Final weight x 100

Initial weight

Friability test parameters:

Number of tablets = 6 RPM revolution per minute) = 25

Result: Not more than 1% w/w

e) Thickness

Thickness of a tablet is the distance between its two surfaces. It is measured to ensure uniform size and proper packaging of tablets.

Procedure

The thickness of the tablets was determined by Vernier calipers. 3 tablets from each batch were used and the average values were calculated.

Result: 4.30mm±0.2%

2. CHEMICAL EVALUATION

a) Content uniformity test

Procedure:

Content uniformity was assessed by individually analyzing tablets. Each tablet was powdered, dissolved in a suitable solvent, and the solution was filtered and analyzed using an appropriate analytical method.

Acceptance Criteria: Each tablet must be within 85–115% of the label claim.

3. PHARMACEUTICAL EVALUATION

Fig. 14: **Dissolution test apparatus**

a) Dissolution test

Determines release rate of drug into systemic circulation.

Procedure

In vitro dissolution studies were carried out using dissolution apparatus containing 900 mL of dissolution medium maintained at 37℃ at specified rotational speed and samples were withdrawn at predetermined intervals, filtered and analyzed using UV spectrophotometer or HPLC. The drug release profile should comply with the specified limits mostly not less than 80% within the stated time.

Fig. 15: **Disintegration test apparatus**

b) Disintegration test

Determines the time required for a tablet to break into small particles.6 tablets in each tube of disintegration tester at 37℃ and operate at 28 − 32 cycles per minute and observed.

➢ Film coated tablet-disintegrate within 30 min

➢ Uncoated tablets-within 15 min

➢ Sugar coated-within 60 min

4. STABILITY STUDIES

In any rational drug design or evaluation of dosage forms for drugs, the stability of the active component must be a major criterion in determining their acceptance or rejection. Stability of a drug can be defined as the time from the date of manufacture and the packaging of the formulation, until its chemical or biological activity is not less than a predetermined level of labelled potency and its physical characteristics have not changed appreciably or deleteriously.

PACKAGING OF TERBINAFINE TABLETS

Table no.10*:* Types of packaging of Terbinafine tablet.

Type of packaging	Description
Primary	• Blister pack • HDPE bottles with desiccant
Secondary	• Printed cartoon box
Tertiary	• Corrugated shipper cartons • Palletized transport boxes

STORAGE OF TERBINAFINE TABLETS:

- Store at **20–25°C (room temperature)**.
- Protect from **moisture, heat, and light**.
- Keep in a **dry place** in original container.
- Avoid high humidity to maintain tablet stability.

Fig. 16: **Label of Terbinafine Hydrochloride tablets**

LABELLING REQUIREMENTS OF TERBINAFINE TABLET

- Drug name & strength (e.g., Terbinafine 250 mg)
- Dosage instructions & route (oral)
- Indication (fungal infection)
- Warnings (liver toxicity, precautions)
- Batch number, manufacturing & expiry date
- Storage conditions
- Manufacturer details
- Regulatory compliance marks

REGULATORY DOCUMENTATION OF TERBINAFINE TABLETS

INTRODUCTION

Terbinafine is a widely used antifungal drug belonging to the allylamine class and is commonly prescribed for the treatment of fungal infections such as onychomycosis, tinea

pedis, and tinea corporis. Regulatory documentation plays a crucial role in ensuring that Terbinafine tablets meet the required standards of safety, quality, and efficacy before they are approved for marketing and patient use. Regulatory authorities such as the CDSCO, US FDA, and EMA require comprehensive documentation to evaluate the product throughout its development and manufacturing process.

Common Technical Document (CTD)

The Common Technical Document (CTD) is the internationally accepted format used for regulatory submissions. It consists of five modules. Module 1 contains administrative and prescribing information specific to the region of submission. Module 2 includes summaries of quality, non-clinical, and clinical information. Module 3 provides detailed information regarding the quality of the active pharmaceutical ingredient (API) and finished formulation, including manufacturing processes, specifications, and analytical methods. Module 4 contains non-clinical study reports, while Module 5 includes clinical study reports demonstrating the safety and efficacy of the drug product.

Drug Product Information

Terbinafine tablets are usually available as film-coated tablets in strengths such as 125 mg and 250 mg. The drug is mainly indicated for the treatment of fungal nail infections caused by dermatophytes. The usual duration of therapy is approximately 6 weeks for fingernail infections and 12 weeks for toenail infections. Since the drug is administered orally, the formulation must ensure proper dissolution, bioavailability, and stability throughout its shelf life.

Safety and Labeling Requirements

Safety documentation is an essential component of regulatory submission. Terbinafine is contraindicated in patients with severe liver impairment or active liver disease due to its potential hepatotoxicity. Therefore, liver function monitoring is recommended during treatment. Common adverse reactions associated with the drug include headache, nausea, abdominal pain, skin rash, and taste disturbances. Labeling requirements must clearly mention dosage instructions, contraindications, precautions, storage conditions, adverse effects, and patient counseling information to ensure safe and effective use of the medication.

Quality Control and Specifications

Quality control testing ensures the consistency, purity, and performance of Terbinafine tablets. Important quality tests include identification, assay, impurity profiling, dissolution testing, disintegration testing, and uniformity of weight and content. Impurity profiling is conducted according to ICH guidelines to ensure the absence of harmful impurities. Stability

studies are also performed under different environmental conditions to determine the shelf life and appropriate storage conditions of the product. All specifications must comply with pharmacopeial standards such as USP and NF.

Manufacturing and Regulatory Approval

Manufacturing documentation forms an important part of regulatory submission. Regulatory authorities require detailed information regarding the manufacturing process, equipment used, process validation, and quality assurance measures followed during production. Applications for approval are submitted in the form of an NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) in eCTD format. Compliance with Good Manufacturing Practices (GMP) is mandatory to ensure product quality and batch-to-batch consistency.

Supporting Regulatory Documents

Several additional documents support the regulatory submission process. These include the Master Formula Record (MFR), Batch Manufacturing Record (BMR), Certificates of Analysis (CoA), analytical method validation reports, stability study reports, and records related to storage and transportation conditions. These documents provide evidence that the product has been manufactured and tested according to approved standards.

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