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PHARMACEUTICAL DEVELOPMENT AND REGULATORY DOCUMENTATION OF TOLNAFTATE: A REVIEW FROM PRE-FORMULATION TO PRODUCT EVALUATION

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1. ABSTRACT

This study describes the formulation and evaluation of Tolnaftate cream, a topical antifungal used to treat skin infections. The cream was prepared as an oil-in-water emulsion using suitable ingredients to ensure stability and effectiveness. It was evaluated for physical, chemical, and biological properties such as texture, spreadability, pH, and drug content. The results showed that the cream had good consistency, proper pH for skin, and effective drug release without causing irritation. Proper packaging, storage, and regulatory guidelines were also followed. Overall, the formulation was found to be safe, stable, and suitable for treating fungal skin infections.

2. KEYWORDS: Anti-fungal agents, Tolnaftate, cream formulation, pre-formulation studies, FTIR, DSC, stability, spreadability, skin infections, regulatory aspects, package and label

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 slowly—and 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].

TOLNAFTATE

INTRODUCTION

Tolnaftate (TNF) is a synthetic antifungal medication classified under the BCS class IV category. Research has shown that TNF is effective when used topically, but it does not demonstrate the same level of efficacy when administered orally or via the intraperitoneal route. It is available in various topical forms, including creams, powders, sprays, and liquid aerosols. Tolnaftate is effective against several fungal species, such as Epidermophyton, Trichophyton, Malassezia furfur, and Candida albicans[1].

Molecular formula

$C_{19}H_{17}NOS$

Molecular weight

307.41

Chemical structure

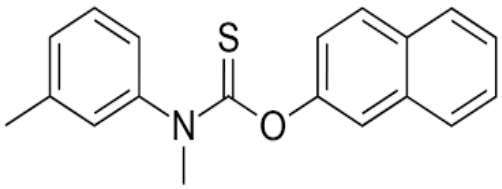

Fig.1: Chemical structure of Tolnaftate.

MECHANISM OF ACTION

Tolnaftate is a synthetic thiocarbamate antifungal that primarily acts as a reversible and non-competitive inhibitor of the enzyme squalene epoxidase. By blocking this enzyme, it disrupts the biosynthetic pathway that converts squalene to ergosterol—a critical structural component of fungal cell membranes. This inhibition leads to a lethal depletion of ergosterol and a toxic accumulation of squalene within the cell, which increases membrane permeability, disrupts cellular organization and ultimately causes cell death[12].

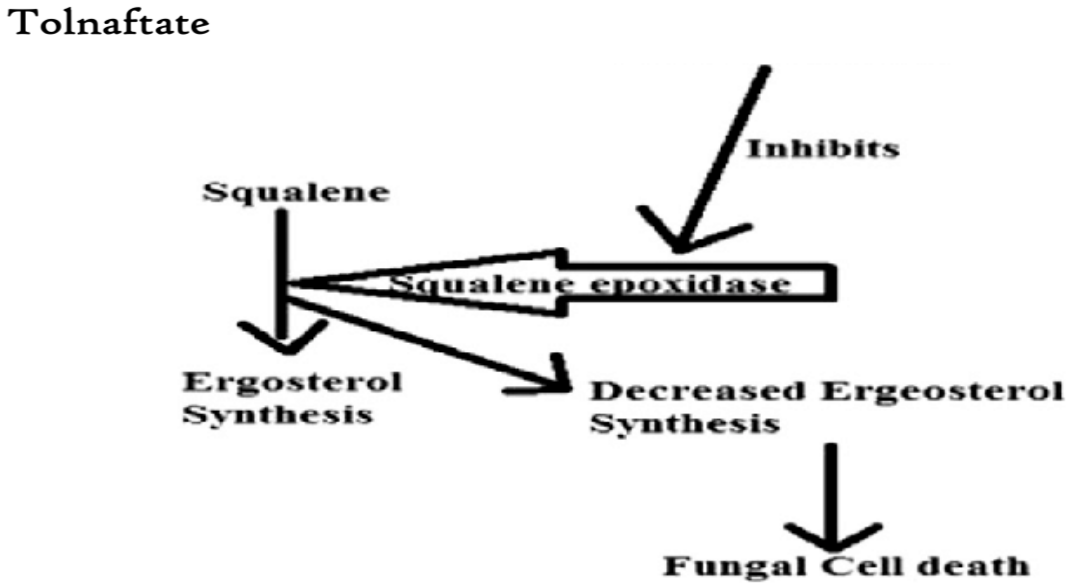

Fig.2: Pathway on mechanism of action of Tolnaftate.

ADVERSE EFFECTS[12]

- Pruritus
- Skin irritation
- Redness
- Skin peeling
- Skin discoloration

CONTRAINDICATIONS[12]

- Children under 2 years of age
- Hypersensitivity
- Nail and scalp infections

USES[9]

Used in the treatment of:

- Tinea pedis (Athlete's foot)
- Tinea cruris (Jock itch)
- Tinea corporis (body ringworm)
- Tinea versicolor
- Otitis externa

MARKETED FORMULATIONS:

1. Cream

Tolnaftate 1% cream is a commonly available, over-the-counter (OTC) antifungal formulation.

Doses available: 1%w/w

Brand names: TINACTIN, TINEACREAM

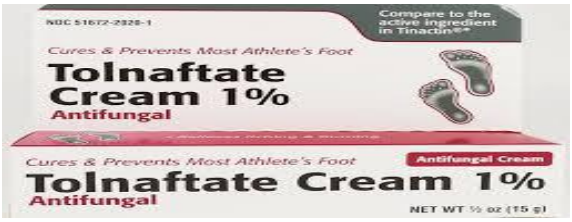

Fig.3: A marketed Tolnaftate cream 1%.

2. Topical solution

Tolnaftate 1% topical solution is widely available over-the-counter (OTC) as an antifungal treatment.

Doses available:1%w/w

Brand names: TOLZEN, TINADERM, TOLZIDE

3. Powder:

Tolnaftate powder is an effective over-the-counter (OTC) antifungal medication used to treat and prevent common fungal skin infections such as athlete's foot, jock itch, and ringworm.

Dose available: 1%w/w

Brand names: AFTATE, LOTRIMIN

4. Spray:

Tolnaftate spray is used to relieve associated symptoms like itching, burning, cracking, and scaling.

Dose available: 1%

Brand names: TING, TINACTIN

4.METHODS AND MATERIALS

PREFORMULATION STUDIES OF TOLNAFTATECREAM

1. PHYSICOCHEMICAL PROPERTIES

a) Organoleptic properties

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

Table no. 1: Organoleptic properties and observation of Tolnaftate.[3]

Sl.No.	Test	Observation
1.	Color	Slightly yellow
2.	Odor	Slightly pungent
3.	Taste	Slightly sweet

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[14]

Solubility of tolnaftate was determined in different media i.e. water, carbon tetrachloride, acetone, ethanol and ether at room temperature.An excess amount of the solute was added to a specific volume of the solvent in a sealed glass vial. The mixture was subjected to continuous mechanical agitation using a magnetic stirrer for a minimum of 24 to 48 hours to ensure saturation. After reaching equilibrium, the suspension was allowed to settle, and the supernatant was filtered through a 0.22µm or 0.45µm membrane filter to remove undissolved particles. The concentration of the solute in the filtrate was subsequently quantified using UV-Visible spectrophotometry or HPLC by comparing the absorbance or peak area against a pre-established standard calibration curve.

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

S.No.	Media	Inference
1.	Water	Insoluble
2.	Carbon tetrachloride	Freely soluble
3.	Acetone	Freely soluble
4.	Ethanol	Very slightly soluble
5.	Ether	Sparingly soluble

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[11]

The melting point of the drug was determined using digital melting point apparatus.
The melting point of Tolnaftate was found to be between 110.5-111.5°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 tolnaftate was calculated by using the following formula:

Partition coefficient $= Concentration of drug in organic phase$ $Concentration\ of\ drug\ in\ aqueous phase$

Procedure [11]

The partition coefficient of Tolnaftate between n-octanol & water was determined by slight modification of "Shake Flask Method", at room temperature. Excess amount of drug was added in 10ml mixture of n-Octanol and water (1:1). The system was prepared in triplicate and was shaken gently in the separating funnel for 24 hours for achieving equilibrium. Then the two phases were separated and the concentration of drug in both phases were determined by UV spectroscopy and partition coefficient was calculated using the equation.

Log P =4.5

e) pH

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.

Procedure[11]

A 1 gm sample of Tolnaftate was dissolved in 100 mL of distilled water and left to stand for two hours. The pH of the resulting solution was then measured using a pH meter to determine the pH of drug.

The pH value of Tolnaftate was found to be 5.7 to 6.3, which is good because it helps prevent skin irritation.

f) Ionization constant

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.

Tolnaftate is a non-ionic compound, meaning it does not have a standard ionization constant within the physiologically relevant pH range (1–14).

As a synthetic thiocarbamate, its chemical structure lacks easily ionizable acidic or basic functional groups. Consequently, it remains in a non-ionized (neutral) state regardless of pH changes in biological environments[11].

2. MICROMERITIC PROPERTIES

a) Particle size[3]

The particle size of tolnaftate is important to distinguish between the conventional raw powder and modern nano-formulations. In its standard pharmaceutical grade, Tolnaftate is typically processed into a micronized powder, with a particle size distribution generally ranging from 10 μm to 50 μm. This reduction to the micrometer scale is essential for achieving a uniform distribution within topical creams and powders, as the drug itself is practically insoluble in water.

The average particle size of drug was determined by using a microscope fitted with ocular micrometer and stage micrometer.

The particle size of un-milled Tolnaftate powder was 41μm.

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[4]**

This is the maximum angle possible between the surface of a pile of powder and the horizontal plane. Angle of repose of granules was determined by funnel method. The funnel was fixed at a particular height (2.5 cm) on a burette stand. The blends were passed through the funnel until it forms a heap. Further adding of granules was stopped as soon as the heap

touches the tip of the funnel. A circle was drawn across it without disturbing the pile. The radius and height of the heap was noted down. The same procedure was repeated for three times and the average value was taken. The angle of repose was calculated by using equation.

$\tan \theta = h/r$

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

- **Bulk density[8]**

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring 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:

$\rho_b = M/V_0$

Where, ρ_b= Bulk density

M= Mass (or weight) of the sample

V= Total volume of the sample

- **Tapped density[8]**

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:

$\rho_{tap} = M/V_f$

Where, ρ_{tap}= Tapped density

M= Mass (or weight) of the sample

V= Final tapped volume of the sample

- **Compressibility (Carr's index)[4]:**

The flowability of powder can be evaluated by comparing the bulk density and tapped density of powder and the rate at which it packed down. Compressibility index of the granules was determined by the equation:

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

Tapped densityx 100

- **Hausner's Ratio[4]:**

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.

HR= Tapped density/Bulk density

Table no. 5: Angle of repose, Carr's index, Hausner's ratio' tapped density and bulk densityof Tolnaftate.[3]

Parameter	Result
Angle of repose	18.9±0.093
Carr's index	9.06±0.016
Hausner's ratio	1.03±0.007
Bulk density	0.312 g/cm^3
Tapped density	0.326 g/cm^3

3. COMPATIBILITY STUDIES

a) Fourier Transform Infrared(FTIR) Spectroscopy[6]

Fourier transform infrared spectrometer (FTIR) consisting of a DLGNS detector with a Germanium internal reflection element (IRE) crystal was utilized at range 3500-500 cm-1 to identify spectrum of the drug tolnaftate. A total of 1% (w/w) of sample, with respect to the potassium bromide (KBr) disc, was mixed with dry KBr. The mixture was grounded into fine powder before compressing into KBr disc under a hydraulic press at 10,000 psi. The characteristic peaks interoperating presence of functional groups identifying compounds were recorded as in Fig.4.

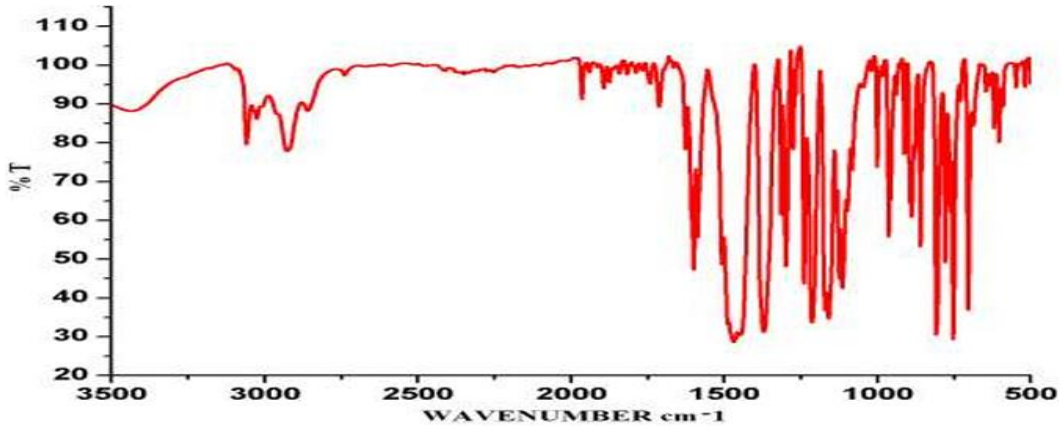

Fig.4: FTIR of Tolnaftate.

Table no. 6: Wavenumbers with respect to different functional groups in Tolnaftate.

Sl. No	Functional Group	Wavenumber(cm^{-1})
1.	Asymmetric CH Stretching	3084
2.	Symmetric CH Stretching	2890
3.	C-N-C Stretching	1501.38
4.	Aromatic C=C Stretching	1627–1680
5.	OH Stretching	1282.37
6.	C=S Stretching	1205
7.	Aromatic C-O-H Stretching	1056.21
8.	N-H Stretching	3339

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[6]

5 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 50 ml/min. A temperature range of 0-600°C was used and the heating rate was 10°C/min.

The DSC results of tolnaftate are presented in Fig.5. The first heating run shows an endothermic melting sharp peak with its maximum at 111°C.

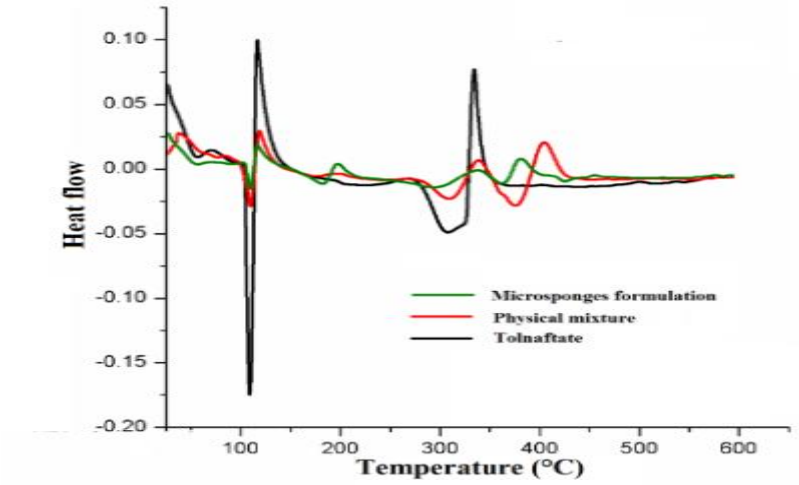

Fig.5: DSC of Tolnaftate.

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.

Procedure[2]

The Tolnaftate sample is kept away from light, at temperatures: 25±2°C, 40±2°C, and 4±2°C for three months. After this period, the samples were tested for their physical appearance, pH etc.

The Tolnaftate sample is found to be stable after 3 months at room temperature. No change was recorded in parameters like Physical appearance, Color, pH, etc.

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[2]

100 mg of tolnaftate sample was exposed to UV light in a UV chamber for 24, 48, 72, 96 and 120 hours. At regular intervals, accurately weighed 10 mg of drug was taken and dissolved in 10 ml of mobile phase in separate volumetric flasks to obtain concentration of 1000 µg/ml. The resulting solutions were injected in HPLC to check the degradation behavior.

It was observed that the drug showed no photolytic degradation till 120 hours. Hence the drug was reflected to be photolytically stable.

FORMULATION OF TOLNAFTATE CREAM

A **cream** isa preparation usually for application toskin.They are semi-solid emulsions of oil and water.Tolnaftate topical is used to treat skin infections such as athlete's foot, jock itch, and ringworm infections.

COMPOSITION

Table no. 7: Ingredients used and their functions in preparation of Tolnaftate cream.

SL. No.	INGREDIENTS	FUNCTIONS
1.	Tolnaftate	Active pharmaceutical ingredient
2.	White petrolatum	Emollient
3.	Liquid paraffin	Emollient
4.	Cetostearyl alcohol	Stabilizer
5.	White beeswax	Stiffing agent
6.	Purified water	Vehicle
7.	glycerin	Humectant
8.	Sodium lauryl sulfate	Surfactant

PREPARATION OF TOLNAFTATE CREAM[15]:

1. Preparation of the Oil Phase:

- Ingredients: Accurately weigh the lipophilic components such as white petrolatum, liquid paraffin,Cetostearyl alcohol, and white beeswax.
- Heating: Place these ingredients in a beaker and heat them to approximately 75°C until they are completely melted and form a uniform mixture.
- Preservatives: Add oil-soluble preservatives like propylparaben to this phase while it is hot.

2. Preparation of the Aqueous Phase:

- Ingredients: In a separate beaker, combine purified water, glycerin, and a stabilizer/emulsifier such as borax or sodium lauryl sulfate.
- Heating: Heat this mixture to the same temperature as the oil phase (75°C) to prevent the oil phase from solidifying prematurely during mixing.

3. Emulsification (Mixing the Phases):

- Combination: Gradually add the heated oil phase to the heated aqueous phase while stirring constantly.
- Cooling: Continue stirring the mixture as it cools down to room temperature. This mechanical action ensures the formation of a smooth, stable cream base.

4. Drug Incorporation (Active Ingredient):

- Active Agent: Tolnaftate (1% w/w) must be integrated into the cooled base.
- Method: For laboratory-scale preparations, use geometric dilution (mixing the drug with a small amount of base first, then gradually adding the rest) on a tile or in a mortar to ensure even distribution.

- Advanced Delivery: In research settings, tolnaftate may first be encapsulated in liposomes or niosomes before being mixed into the cream base to enhance skin penetration.

5. Final Packaging and Storage:

- pH Adjustment: If necessary, adjust the pH to be skin-compatible (typically between 6.8 and 7.0) using agents like sodium hydroxide.
- Storage: Store the finished cream at controlled room temperature, 20°C to 25°C (68°F to 77°F), in a tightly closed container.

EVALUATION OF TOLNAFTATE CREAM

Evaluating a pharmaceutical cream ensures its safety, stability and therapeutic efficacy before patient use.

Tolnaftate cream is evaluated by the following methods:

PHYSICAL INVESTIGATION [15]

(a) Organoleptic Properties

The prepared cream was tested for color, odor, texture and phase separation as well as feels upon application to observe stiffness, truthiness, freshness and tackiness of formulation.

Texture: Smooth and consistent application.

Homogeneity: Absence of coarse particles or lumps.

Phase separation: Stable under ambient storage.

(b)Light microscopic studies

In order to study the texture of the anisotropic phases of liquid crystalline systems, the samples were investigated under polarized light microscope. A small quantity of the sample was placed on a clean glass slide and observed by microscope at 100x magnification.

Procedure

Freshly prepared and stored samples of the cream containing 1% drug was investigated under polarized light microscopy. Fig. shows a typical polarized light micrograph of liquid crystals.The birefringence that is characteristic of concentric lamellar liquid crystal was observed around the oil globules. The oil is uniformly dispersed with a definitive cross similar to those described as Mathesian crosses, indicating a lamellar Structure.

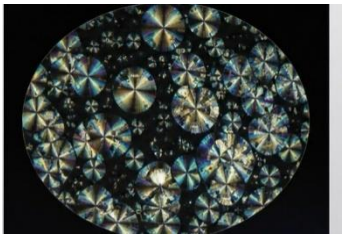

Fig. 7: Polarised light microscopic view of Tolnaftate cream.

(c)Spreadability

Spreadability was determined by modified wooden block and glass slide apparatus. The apparatus made up of a wooden block with glass slide and pulley.

Procedure

For determination of spreadability measured amount of cream was places on fixed glass slide, the movable glass slide with a pan attached to it, was placed over the fixed glass slide, such that cream were sandwiched between the two slides for 5 min. The weight was continuously removed. The time taken for the slides to separate was noted. Spreadability was found out using the following formula.

$$S = \frac{W \times L}{T}$$

Where, S=Spreadability,

L=length of the glass plate (14.5 cm),

W=Weight tied to upper plate (50gm),

T=Time taken to separate the slide completely from each other.

Spreadability The efficacy of topical therapy depends on the spreading ability of the formulation in an even layer to deliver a standard dose. The optimum consistency of such formulation helps to ensure that a suitable dose is applied or delivered to the target site. The delivery of the correct dose of the drug depends highly on the spreadability of the formulation so spreadability is directly proportional to efficacy.

(d)Viscosity measurement

Liquid crystalline systems were thought to have an intermediate behavior between liquid and solids. The performance of dermatological products depends to a great extent on their rheological behavior.

***Fig. 9*: Brookfield viscometer.**

Procedure

Viscosity of liquid crystalline cream formulation was measured by using Brookfield viscometer using spindle no. 62 at different rpm. The viscosity of the cream can also be determined to estimate the gel strength.

2.CHEMICAL INVESTIGATION [15]

(a)DRUG CONTENT

Procedure

Accurately 1gm of cream was measured and transfer to 100 ml of volumetric flask. To this 20-30 ml of Phosphate buffer solution (pH 7.4) was added to dissolve drug. The resultant solution Filtered through 0.45-micron membrane filter and suitably diluted with methanol. Absorbance was measured at 257nm using UV-spectrophotometer. The content was determined from calibration curve of tolnaftate in Phosphate buffer solution (pH 7.4).

It ranges in between 83.4% - 88.9%.

(b)pH

The pH of cream was determined to find out the irritant effect of formulations on skin and to study the compatibility of preparations with the skin.

***Fig. 10:* pH meter.**

Procedure

The electrode was dipped in cream for 10 seconds, and subjected to pH measurement by using a Calibrated digital pH meter. A solution containing 1 gm of cream in 30 ml of

Phosphate buffer solution (pH 7.4) was prepared and subjected to pH measurement by using a Calibrated digital pH meter.

The pH was measured in each of the liquid crystalline cream of Tolnaftate, using a calibrated digital pH meter. All the formulations are within required pH range suitable for absorption and no irritation and compatibility with the skin was observed.

3. BIOLOGICAL INVESTIGATION [15]

(a) Sensitivity test

Procedure

A drop of diluted suspension of the tested cream (1:1) and another drop of saline (control) were put on two corresponding spots of the arms of three human volunteers. After ten minutes the patch was investigated for any erythema, wheel or any allergic reaction.

b) In-vitro drug release of tolnaftate cream

It measures how the drug (Tolnaftate) is released from the cream over time. Usually done using a diffusion method (like Franz diffusion cell).

Procedure

A small amount of cream is placed on a membrane. The membrane separates it from a receptor fluid (buffer solution). Samples are taken at different time intervals. Drug amount is measured using instruments (e.g., UV spectrophotometer).

PACKAGING OF TOLNAFTATE CREAM

Table no. 8: Types of packaging of Tolnaftate cream. [15]

TYPE OF PACKAGING	DESCRIPTION
Primary packaging	• Aluminum tubes • Plastic tubes/ jar
Secondary packaging	• Printed cartoon box • Leaflet
Tertiary packaging	• Corrugated shipping boxes • Bulk transport packaging

STORAGE OF TOLNAFTATE CREAM

- Store at 25°C (room temperature)
- Permitted range: 15–30°C
- Protect from heat & direct sunlight
- Do not freeze

- Keep container tightly closed
- Store in a cool, dry place
- Keep out of reach of children [15]

LABELLING REQUIREMENTS OF TOLNAFTATE CREAM

- Product name & strength (Tolnaftate 1% w/w)
- Composition details
- Directions for use
- Storage conditions
- Batch number, Manufacturing & Expiry date
- Manufacturer details
- WARNING: For external use only[15]

***Fig. 11*: Label for Tolnaftate cream.**

REGULATORY DOCUMENTATION OF TOLNAFTATE CREAM

- Tolnaftate cream is a topical antifungal preparation used for the treatment of fungal skin infections such as athlete's foot and ringworm. The product identification includes the name of the product, strength (1% w/w), dosage form, category, and therapeutic use.
- The regulatory authority for tolnaftate cream in India is the Central Drugs Standard Control Organization (CDSCO), while in the USA it is regulated by the U.S. Food and Drug Administration under OTC antifungal monograph guidelines. The formulation must comply with national and international regulatory standards.
- The documentation requirements include application forms, manufacturing license, excipient formula, batch formula, details of the active pharmaceutical ingredient (API), manufacturing process, and in-process quality control records. These documents ensure the quality, safety, and consistency of the product.

- Good Manufacturing Practices (GMP) must be followed during production. The manufacturing site should comply with GMP guidelines, use validated equipment and processes, employ trained personnel, and maintain a clean and controlled environment.
- Post-marketing surveillance is also important for tolnaftate cream. It involves monitoring adverse effects, pharmacovigilance reporting, and preparation of Periodic Safety Update Reports (PSUR) when required.
- The major compliance goals of regulatory documentation are to ensure patient safety and efficacy, maintain product quality and consistency, fulfill regulatory requirements, and ensure proper storage and labeling of the cream.

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