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Terbinafine: A Review on Properties, Application and Analytical Methods

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ABSTRACT

Qualitative and quantitative estimation plays a key role in ensuring the safety and efficacy of drugs in different matrices. A detailed literature survey is one of the most essential requirements for all focused research activities.Terbinafine is an allylamine derivative and it is approved by USFDA in 1999. Terbinafine inhibits the growth of fungal and bacterial cell wall, leading to the death of the cell, as the contents of the cell are unprotected. Therefore, it is applied to the skin in the occurrence of dermatophytoses, pityriasis versicolor and cutaneous candidiasis, and superficial fungal infection like seborrheic dermatitis, tineacapatis, and onchomycosis especially for its short-duration therapy. It is also used in treatment of jock itch (tineacrusis), athlete's foot (tineapedis) and ringworm. The objective is to survey and discuss the characteristics, properties and existing analytical methods. For the literature survey, data searches were conducted by scientific papers in the literature as well as in official compendium. The characteristics and properties are shown, also, methods using liquid chromatography techniques, titration, absorption spectrophotometry in the ultraviolet and the infrared region. It is necessary the knowledge of researcher involved in the optimization of the methods applied consider all parameter of Terbinafine.

Key words: *Terbinafine; Analytical Methods; Estimation; Matrices.*

ABBREVIATIONS

USP: *United State Pharmacopoeia*
ICH: *International Conference on Harmonization*
FDA: *Food and Drug Administration*
RP-HPLC: *Reverse Phase High Performance Liquid Chromatography*
LC-MS-MS: *Liquid chromatography - Mass spectrometry – Mass spectroscopy*
UPLC-MS/MS: *Ultra Performance Liquid Chromatography Tandem Mass Spectrophotometry*
IR: *Infrared spectroscopy*
UV: *Ultra violet spectroscopy*

INTRODUCTION

Terbinafine Hydrochloride is an allylamine derivative. Chemically, it is [(2E)-6,6-dimethylhept-2-en-4-yn-1-yl] (methyl) (naphthalen-1-ylmethyl)amine hydrochloride. The molecular weight of TFH is 327.89 and melting point is 195-198 °C corresponding to the molecular formula of $C_{21}H_{26}NCl$. It is freely soluble in methanol and methylene chloride; soluble in ethanol; and slightly soluble in water [1]. Like all other allylamine, it inhibits ergosterol synthesis by inhibiting squalence epoxidase an enzyme that plays a role in fungal cell wall synthesis pathway [2]. TFH inhibits the growth of fungal and bacterial cell wall, leading to the death of the cell, as the contents of the cell are unprotected. Therefore, it is applied to the skin in the occurrence of dermatophytoses, pityriasis versicolor and cutaneous candidiasis, superficial fungal infection like seborrheic dermatitis, tineacapatis, and onchomycosis especially for its short-duration therapy [3-4]. TFH is comes as a tablet for oral administration, and is usually taken once a day for 6 weeks for fingernail fungus

treatment and once a day for 12 weeks for toenail fungus treatment. The cream and powder formulations of the drug are used for superficial skin infections such as jock itch (tineacrusis), athlete's foot (tineapedis) and ringworm. Terbinafine is highly lipophilic in nature and tends to accumulate in skin, nails and fatty tissues. Excessive terbinafine may cause some side effects such as allergic reactions (difficulty in breathing, throat closing, and swelling of hips, tongue, face and liver), rash, and changes in vision and blood problems. Because of its therapeutical importance, quantitative determination of terbinafine in pharmaceuticals and human physiological fluids is of considerable significance in both quality control of preparations and chemical diagnosis. In the last approximately 25 years, several methods have been reported for the determination of terbinafine in pharmaceuticals and biological materials including body fluids. The current review surveys the properties, application and methods developed to determine terbinafine in drug, drug products, body fluids and other biological materials.

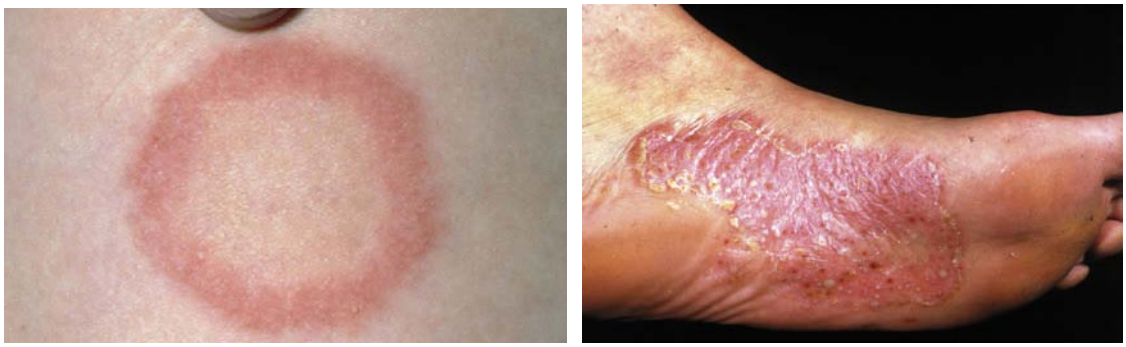

Fig 1 Tineacrusis and Tineapedis

Table 1. Physical Properties of Terbinafine Hydrochloride

Appearance	White to off white Solid
Solubility	Soluble in ethanol (45 mg/ml), DMSO (30 mg/ml) or water (3 mg/ml).
Pka	8.86
Log p	5.53
Melting point	195-198 °C

Table 2. Taxonomy of Terbinafine Hydrochloride

Kingdom	Organic compound
Super class	Benzenoids
Class	Naphthalenes
Direct parent	Naphthalenes
Alternative parent	Aralkylamines/Trialkylamines/Organopnictogen compounds/Hydrocarbon derivatives
Substituent's	Amine / Aralkylamine / Aromatic homopolycyclic compound / Hydrocarbon derivative / Naphthalene / Organic nitrogen compound / Organonitrogen compound / Organopnictogen compound / Tertiary aliphatic amine / Tertiary amine
Molecular framework	Aromatic heteropolycyclic compounds.
External descriptors	Piperidines, tertiary amino compound, aldehyde, Imidazobenzapine.

Mechanism of Action of Terbinafine [6]

Terbinafine is speculated to act by inhibiting squalene monooxygenase, thus blocking the biosynthesis of ergo sterol which is an essential component of fungal cell membranes. This inhibition also results in an accumulation of squalene, which is a substrate catalysed to 2,3-oxydo squalene by squalene monooxygenase. The resultant high concentration of squalene and decreased amount of ergo sterol are both thought to contribute to Terbinafine antifungal activity.

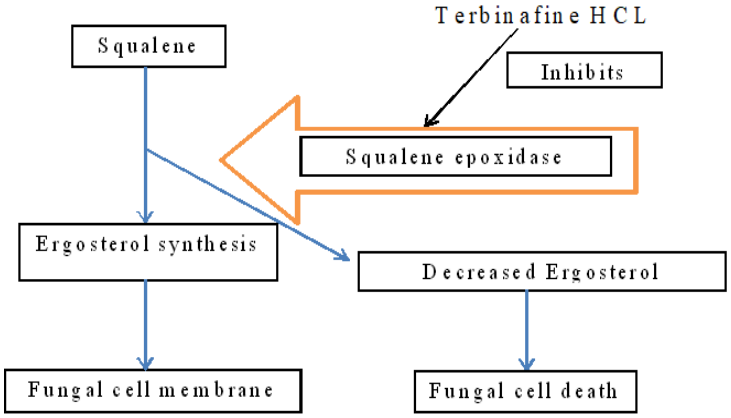

Fig 2 Mechanism of action of Terbinafine

Pharmacokinetic of Terbinafine

The 80% TFH is eliminated in urine, while the remaining is eliminated in feces. The other pharmacokinetic parameter is mentioned in table 3.

Table 3. Pharmacokinetic Parameter of Terbinafine Hydrochloride

Bioavaibility	70–90%
Protein binding	>99%
Metabolism	Liver
Half life	36 hr

Table 4. Official Analytical Methods for Estimation of Terbinafine hydrochloride.

S. No.	Pharmacopoeia	Method	Description	Ref No
1	United states Pharmacopoeia (USP 2018)	Liquid chromatography	Stationary phase: Silica gel Mobile phase: Methanol and acetonitrile Flow rate: 0.8ml/min Wavelength: 280 nm	9
2	British Pharmacopoeia (BP 2018)	Liquid chromatography	Stationary phase: Octa-decylsilyl silica gel Mobile phase: Acetonitrile, Methanol and Buffer pH 3.5 (15:35:50 v/v/v) Flow rate: 1.5 ml/min Wavelength: 239 nm	10
3	European Pharmacopoeia (EU 2014)	Potentiometric titration	Solvent: Ethanol and hydrochloric acid Titrant: 0.1M sodium hydroxide	11

4	Japanese pharmacopoeia (JP 2016)	Potentiometric titration	Solvent: Acetic acid and acetic anhydride Titrant: 0.1 mol/L perchloric acid	12

Table 5. Reported Analytical Methods for Estimation of Terbinafine hydrochloride in Bulk, Pharmaceutical Formulation and Biological Fluids.

Sr No	Author	Title	Method	Description	Ref No
1	Rode D, et al. (2019)	Terbinafine Hydrochloride and Itraconazole In tablet dosage forms.	RP-HPLC	Wavelength: 225nm Stationary phase: C18 GIST column (5µ, 238mm x 50mm). Mobile phase: Acetonitrile and 0.1% triethylamine (90:10; v/v) Flow rate: 1.2 mL/min Retention time: 3.464min and 8.705min Detector: UV	13
2	Patel k, et al. (2019)	Terbinafine Hydrochloride In tablet dosage form.	HPTLC	Wavelength: 282 nm Stationary phase: 60F254 silica gel on aluminium sheet Mobile phase: Acetonitrile:1,4 dioxan :hexane: acetic acid (1:1:8:0.1; v/v/v/v) Linearity: 500-4500 µg/mL Rf value: 0.45 Detector: UV	14
3	Sireesha, et al. (2018)	Terbinafine Hydrochloride In bulk & pharmaceutical dosage form	RP-HPLC	Wavelength: 220 nm Mobile phase: Potassium dihydrogen phosphate and Acetonitrile (65:35 v/v) Linearity: 50-150 µg/ml Flow rate: 1.5 mL/min Detector: PDA	15
4	Manohar M, et al (2017)	Terbinafine Hydrochloride & Mometasone Furoate in combined dosage form	RP-HPLC Method	Wavelength: 242 nm Stationary phase: C18 Enable (150 × 4.6 mm) 5 µm column Mobile phase: Acetonitrile and 0.1% Orthophosphoric acid (67:33 %v/v) Flow rate: 1.0 mL/min Linearity: THF : 0.5-1.6	16

				µg/mL MF: 1-32 µg/mL Retention time: THF :2.2 min MF: 3.5 min Detector: UV	
5	Nagib A, et al. (2015)	Terbinafine Hydrochloride with Alizarin Red dye	Extractive spectrophotometric	METHOD A Wavelength: 450 nm Solvent: HCl Linearity: 2.5-60 µg/mL Method B Wavelength: 570 nm Solvent: Alcoholic KOH Linearity: 4-24 µg/mL	17
6	Patel M, et al. (2014)	Terbinafine Hydrochloride and Mometasone furoate in combined dosage form	RP-HPLC	Stationary phase: C18Enable (238 × 4.6 mm) 5 µm column. Mobile phase: Methanol: water (95:5 v/v) Flow rate: 1.2 mL/min Retention time: 6.9 min and 3.2 min Linearity: 20-200 µg/mL and 2-20 µg/mL Wavelength: 248 nm Detector: UV	18
7	Bommadevara P, et al. (2014)	Terbinafine Hydrochloride and other drugs in bulk and pharmaceutical dosage form	RP-HPLC	Stationary phase: C18 Enable (238 × 4.6 mm) 5 µm column Mobile phase: Ortho phosphoric acid buffer pH 2.5 and acetonitrile (82:18; v/v) Flow rate: 1 mL/min Retention time: Terbinafine hydrochloride: 7.3 min Ofloxacin: 0.7min Ornidazole: 1.9 min clobetasol propionate: 9.2 min Wavelength: 255 nm Detector: UV	19
8	Kaseem H, et al. (2014)	Terbinafine Hydrochloride in bulk drug substance	HPLC	Stationary phase: C18 Enable (238 × 4.6 mm) 5 µm column. Mobile phase: Methanol and acetonitrile (60:40, v/v) with (0.15% triethylamine	20

				and 0.15% phosphoric acid) Flow rate: 0.4 mL/min Retention time : 8.5 min Wavelength: 224 nm Detector: UV	
9	Goswami P, et al. (2013)	Terbinafine HCL In Tablet Dosage Form	UV	Solvent: 0.1N HCL Linearity Range: 1-3.5 µg/mL Wavelength: 223 nm	21
10	Patel H, et al. (2013)	Terbinafine hydrochloride and Mometasone furoate in combined dosage form	UV	Solvent: Methanol Linearity : 10-70 µg/mL and 1-7 µg/mL Wavelength: 282 nm and 248 nm	22
11	Goswami p, et al. (2013)	Terbinafine hydrochloride In bulk and tablet dosage form	Stability indicating HPLC method	Stationary phase: Neosphere C18 (238 x 4.6 mm) 5 µm column Mobile phase: Methanol: 0.5% Triethanolamine Flow rate: 1.2 mL/min Retention time: 11.7 min Wavelength: 238 nm Linearity: 2-12 µg/mL Retention time: 4.13 min	23
12	Vamsi KP, et al. (2013)	Terbinafine Hydrochloride in bulk drug and tablets	Two UV methods	METHOD A Wavelength: 222 nm Solvent: 0.1 M HCl Linearity: 0.2-4.0 µg/mL METHOD B Wavelength: 282 nm Solvent: 0.1 M Acetic acid Linearity: 2.0-50.0 µg/mL	24
13	Domadiya V, et al. (2012)	Terbinafine Hydrochloride In cream	RP-HPLC	Stationary phase: Phenomenex C18 (238mm x 4.6mm, 5µ) Mobile phase: Acetonitrile: Methanol: Water (40:10:50 %v/v/v) Detector: UV Wavelength: 282 nm	25
14	Jain PS, et al. (2012)	Terbinafine hydrochloride in bulk and in formulary	UV	Solvent: Water Linearity: 15-30 µg/mL Wavelength: 283 nm	26

15	Raju R, et al. (2011)	Terbinafine and bezafibrate drugs	RP-HPLC	Stationary phase: Phenomenex C18 (238mm x 4.6mm, 5µ) Column Mobile phase: Methanol, water, Ammonium dihydrogen Phosphate (60:15:25; v/v/v) for Terbinafine hydrochloride and Methanol, Acetonitrile, Orthophosphoric acid (35:55:10; v/v/v) for benzafibrate Linearity: 2-12 µg/mL For Terbinafine Hydrochloride Flow rate: 1.0 mL/min Wavelength: 225 nm Retention time: 5.1 min For Bezafibrate Flow rate: 1.0 mL/min Wavelength: 232 nm Retention time: 6 min	27
16	Pasumarthy G, et al. (2008)	Terbinafine in Pharmaceutical Dosage Forms	RP-HPLC	Stationary phase: RP-C18 column (Bondapak, 5 µm particle size) Mobile phase: Buffer: Acetonitrile (65:35; v/v). Flow rate: 1.8 mL/min Wavelength: 220 nm Linearity: 20-1000 µg/mL Retention time: 14.95 min	28
17	Cordeoso SG, et al. (1999)	Terbinafine Hydrochloride in dosage from	UV	Solvent: Methanol Linearity: 0.8-2.8 µg/mL Wavelength: 224 nm	29

ANALYTICAL DECISION

1) Rode D, et al. specifies that stability-indicating method development and validation of itraconazole and Terbinafine HCL in bulk and pharmaceutical tablet dosage form using Shim-pack C18 GIST (250 mm×50 mm, 5µm) column. The separation was carried out by using mixture of mobile phase consisted of acetonitrile and 0.1% triethylamine in the ratio of 90:10. The analysis was performed with a flow rate of 1.2 mL/min and run time of 12 min. The detection was measured at 225 nm. The retention time was found to be 3.464 min and 8.705 min for itraconazole and Terbinafine HCL, respectively. [13]
2) Patel K, et al. specifies that HPTLC method for estimation of Terbinafine hydrochloride in its tablet formulation. The TLC plates employed were aluminium backed silica gel 60 F254 (100×50 mm, thickness of layer 0.2 mm) pre-washed with methanol and dried at room temperature and mobile phase comprising of Acetonitrile: 1, 4 dioxan: Hexane:

Acetic acid (1:1:8:0.1) (v/v/v/v). The developing solvent was run upto 70 mm in Camag chamber. Densitometic scanning was then performed with Camag TLC scanner-3 at λmax 282 nm. The linearity and range for Terbinafine Hydrochloride was found to be 500-4500 ng/spot. [14]

3) Sireesha R, et al. specifies that RP-HPLC method for the estimation of antifungal drug Terbinafine HCL in bulk and pharmaceutical dosage form using Reverse Phase C-18 Column (50 mm x 4.6 mm) particle size 5 µm. The separation was carried out by using mixture of Potassium dihydrogen phosphate and Acetonitrile (65:35 v/v) as a mobile phase. The analysis was performed with the flow rate of 1.5 mL/min. The detection was measured at 220 nm. The linearity was observed in a concentration range of 50-150 µg/mL. The retention time was found to be 6.2 mins for Terbinafine hydrochloride. [15]
4) Manohar M, et al. specifies that RP-HPLC Method for Simultaneous Estimation of Terbinafine hydrochloride and Mometasone Furoate in Combined Dosage form by using C18 Enable (150 × 4.6 mm)µ5m column. The separation was carried out by using acetonitrile and 0.1% orthophosphoric acid (67:33 v/v) as a mobile phase. The analysis was performed with the flow rate of 1.0 mL/min. The detection was measured at 242 nm. The linearity wasobserved in a concentration range of 0.5 to 1.6 µg/mL and 1-32 µg/mL for Terbinafine Hydrochloride and Mometasone Furoate, respectively. The retention time was found to be 2.2 min for Terbinafine hydrochloride and 3.5 min for Mometasone Furoate. [16]
5) Nagib A, et al. specifies that two spectrophotometric methods based on ionpair complexation reaction described for the determination of Terbinafine hydrochloride. The first method was based on the formation of ion-pair complex between TBH and alizarin red S (ARS) dye in HCL medium followed by its extraction into methylene chloride and was measured at 450 nm (method A).The other method entails breaking of drug-dye complex in alcoholic KOH medium and measuring the absorbance of the blue dye at 570 nm (method B). Beer's law was obeyed over the concentration ranges 2.5-60 µg/mL for method A and 4-24 µg/mL for method B. [17]
6) Patel M, et al. specifies that RP-HPLC method for simultaneous estimation of Terbinafine Hydrochloride and Mometasone Furoate in combined dosage form by using C18 Enable (250 × 4.6 mm) 5µm column. The separation was carried out by using Methanol: Water (95:5 v/v) as a mobile phase. The analysis was performed with the flow rate of 1.2 mL/min. The detection was measured at 248 nm. The linearity was observed in a concentration range of 20-200 µg/mL and 2-20 µg/mL for Terbinafine Hydrochloride and Mometasone Furoate, respectively. The retention time was found to be 6.9 min for Terbinafine hydrochloride and 3.2 min for Mometasone Furoate. [18]
7) Bommadevara P, et al. specifies that RP-HPLC method has been developed and validated for simultaneous estimation of Ofloxacin, Ornidazole, Terbinafine hydrochloride, Clobetasol propionate, Methyl paraben, Propyl paraben, in bulk and pharmaceutical dosage formsby using Zodiac C18 Enable (250 × 4.6 mm) 5µm column. The separation was carried out by using Ortho phosphoric acid buffer, pH 2.5 and Acetonitrile in the ratio (82:18 v/v) as a mobile phase. The analysis was performed with the flow rate of 1 mL/min. The detection was measured at 255 nm. The linearity was observed in a concentration range of 1-960 µm/mL. The retention time was found to be Ofloxacin 0.712 min, Ornidazole 1.933 min, Terbinafine hydrochloride 7.302 min, Clobetasol propionate 9.224 min, Methyl paraben 4.074 min, Propyl paraben 7.926min. [19]
8) Kaseem H, et al. specifies that a stability indicating high performance liquid chromatographic assay (HPLC) for the determination of Terbinafine hydrochloride in bulk drug substance by using C18 column. The separation was carried out by using

isocratic mobile phase consisting of methanol and acetonitrile (60:40, v/v) with (0.15% triethylamine and 0.15% phosphoric acid) the analysis was performed with the flow rate of 0.4 mL/ min. The detection was measured at 224nm. The peak of Terbinafine hydrochloride appeared at a retention time of 8.5 minute. [20]

9) Goswami P, et al. specifies that, UV-spectrophotometric method has been developed for the determination of Terbinafine hydrochloride in bulk and in tablet dosage form by using 0.1N hydrochloric acid (HCL) as a solvent system and wavelength of detection was 223 nm, The linearity and range was found to be 1-3.5 µm/mL with coefficient of correlation (R2) value 0.995. [21]
10) Patel H, et al. specifies that UV spectrophotometric method for simultaneous estimation of Terbinafine hydrochloride and Mometasone furoate in combined dosage form by using methanol as a solvent system and wavelength of detection for Terbinafine hydrochloride was 282 nm and for Mometasone Furoate was 248 nm, The linearity and range was found to be 10-70µg/mL and 1-7µg/mL for Terbinafine hydrochloride and Mometasone Furoate respectively. [22]
11) Goswami p, et al. specifies that stability-indicating RP-HPLC method for analysis of Terbinafine hydrochloride in bulk and in tablet dosage form by using Neosphere C18 (250 x 4.6 mm) 5 µm column. The separation was carried out by using methanol: 0.5% Triethanolamine as a mobile phase 0.5% Triethanolamine was added to pure methanol to reduce tailing problem. The analysis was performed with the flow rate of 1.2 mL/min. The detection was measured at 250 nm. The linearity was observed in a concentration range of 2- 12 µg/mL. The retention time was found to be 4.13 min. [23]
12) Vamsi KP, et al. specifies that two sensitive, precise and cost-effective UVspectrophotometric methods are described for the determination of Terbinafine hydrochloride (TFH) in bulk drug and tablets. Methods A and method B are based on the measurement of absorbance of THF in 0.1M HCL at 222 nm and in 0.1M acetic acid at 282 nm respectively. Beer's law is obeyed over the concentration ranges of 0.2- 4.0 and 2.0-50.0 µg/mL TFH in method A and method B, respectively. [24]
13) Domadiya V, et al. specifies that method development and validation for assay of Terbinafine HCL in cream by RP-HPLC method by using Phenomenex C18 (250mm x 4.6mm, 5Âµ) The separation was carried out by using was filtered and degassed mixture of Acetonitrile: Methanol: Water (40:10:50), 0.1 mL O-Phosphoric Acid and 0.1 mL of Triethalamine. The detection was measured at 282 nm. [25]
14) Jain PS, et al. specifies that development and validation of the UVspectrophotometric method for determination of Terbinafine hydrochloride in bulk and in formulation by using water as a solvent system and wavelength of detection for Terbinafine hydrochloride was 283 nm, the linearity and range was found to be 15-30 µg/mL for Terbinafine hydrochloride. [26]
15) Raju R, et al. specifies that, reversed phase high performance liquid chromatographic method for Terbinafine and bezafibrate drugs by using C18 (250mm x 4.6mm). The separation was carried out by using different mobile phases of methanol, water, ammonium dihydrogen phosphate and methanol, acetonitrile, orthophosphoric acid respectively. The analysis was performed with the flow rate of 1.0 mL/min for Terbinafine and 1.0 mL/min for bezafibrate. The detection of wave length is 225 nm for Terbinafine and 232 nm for bezafibrate. The linearity was observed in a concentration range of 2- 12 µm/mL. The retention time was found to be 5.1 min for Terbinafine and 6 min for bezafibrate. [27]
16) Pasumarthy G, et al. specifies that, Reverse Phase HPLC Method for the Analysis of Terbinafine in Pharmaceutical Dosage Forms by using RP-C18 column (Bondapak, 5 µm

particle size). The separation was carried out by the mobile phase containing buffer: acetonitrile in the ratio 65:35 v/v. The flow rate of the mobile phase pumped was 1.8 mL/min. The detection of wavelength was 220 nm. The linearity was observed in a concentration range of 20-1000 µg/mL. The retention time was found to be 14.95 min. [28].

17) Cordeoso SG, et al. specifies that UV-Spectrophotometry and non-aqueous determination of Terbinafine HCL in dosage form by using methanol as a solvent system and wavelength of detection for Terbinafine hydrochloride was 224 nm, the linearity and range was found to be 0.8-2.8 µg/mL for Terbinafine hydrochloride. [29]

CONCLUSION

This review represents the reported spectrophotometric and chromatographic methods developed and validated for determination of Terbinafine. According to the literature review it can be concluded that for Terbinafine in single component and its combination with other drug spectroscopy and chromatography methods available. This all methods are found to be simple, accurate, economic, precise, and reproducible in nature. Comparing various validation parameters of already reported methods, it can be concluded that different analytical methods like spectrophotometric, HPTLC and HPLC can be developed for terbinafine showing its simplicity, sensitivity (low LOD and LOQ values) linearity and accuracy. As per Review most of work have used the reversed-phase HPLC and UV absorbance detection because this provided with best available reliability, repeatability, analysis time and sensitivity. There is a great scope for researcher to develop newer analytical methods for drugs such as Terbinafine.

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REFERENCES

1. Mushrif H. Common diseases of dermatophytic infection and sensitivity determining of diagnostic procedures. American Journal of Medical Sciences and Medicine, 2016; 4(4): 87-91.
2. Fungal infections signs and symptoms www.medicalnewstoday.com/articles/317970 (last review on Oct 2020)
3. Diagnostic tests for fungal infections medlineplus.gov/lab-tests/fungal-culture-test/ (last review on Oct 2020)
4. Tripathi KD. Essentials of medical pharmacology; 6th edn; Jaypee Brothers Medical Publishers Limited, New Delhi, 200; 757.
5. Terbinafine Hydrochloride. https://www.drugbank.ca/drugs/DB00857.(last review on august 2019)
6. Skoog DA, West DM, and Hollar FJ. Fundamentals of Analytical Chemistry; 8th Edn; Saunders College Publishing, Philadelphia, 2004; 973-992.
7. Willard HH, Merritt LL, Dean JA, and Settle FA. Instrumental Method of Analysis; 7th Edn, CBS publication and distributors, New Delhi, 1986; 2-5.
8. Sethi PD, High Performance Liquid Chromatography: Quantitative Analysis of Pharmaceutical Formulations. 1st Edn; CBS Publication and Distributors, New Delhi, 2001; 3-7
9. United State Pharmacopoeia 31 National Formulary 26, The United State Pharmacopoeial Convection, Rockville, 2018; Vol.-II: 3984-3987.

10. British Pharmacopoeia. Her Majesty's Stationary Office, London, 2018; Vol. I: 1050-1051.
11. European Pharmacopoeia, Council of Europe, Starsbourg Cedex; France, 2010; Vol. Ⅱ 3375-3377.
12. Japanese Pharmacopoeia, Ministry Of Health, Labour And Welfare, 2016; 17: 910-911
13. Rode D and Roa N. Stability-indicating Method Development And Validation of Itraconazole and Terbinafine Hcl in Bulk and Pharmaceutical Tablet Dosage Form. Asian journal of pharmaceutical and clinical research. 2019; 12(9): 51-55.
14. Patel K and Karkhanis V. A Validated HPTLC Method for Determination of Terbinafine Hydrochloride in Pharmaceutical Solid Dosage Form. Int J Pharm Sci Res. 2019; 3(11): 4492-4495.
15. Sireesha R, et al. RP-HPLC Method Development and Validation for the Estimation of Antifungal Drug Terbinafine Hcl in Bulk and Pharmaceutical Dosage Form. Int. J. Res. Pharm. Chem & Analy. 2018; 1(1): 8-12.
16. Manohar M, Akkamma H, Chandanam S, Rao S and Thakur K. Development and Validation of RP-HPLC Method for Simultaneous Estimation of Terbinafine Hydrochloride and Mometasone Furoate in Combined Dosage Form. Journal of Pharmacy Research. 2017; 11(4): 286-291.
17. Nagib A and Kanakapura B. Assay of Terbinafine Hydrochloride by Extractive-Spectrophotometry with Alizarin Red S-A Modified Approach. Eurasian J Anal Chem. 2015; 10(1): 34–45.
18. Patel M and Patel H. Development and Validation of RP-HPLC Method for simultaneous estimation of Terbinafine Hydrochloride and Mometasone Furoate in Combined Dosage Form. Int J Pharm Pharm Sci. 2014; 6(1): 106-109.
19. Bommadevara P and Rahaman A. Validated Stability Indicating RP-HPLC Method For Simultaneous Determination Of Oflocacin, Ornidazole, Clobetasol Propionate, Terbinafine Hydrochloride, Methyl Paraben, Propyl Paraben in Bulk Pharmaceutical Dosage Form. Int. j. of pharmacy and analytical research. 2014; 3(4): 301-318.
20. Kaseem H, Almardini MA and Ghazal H. A Stability Indicating High Performance Liquid Chromatographic Assay (HPLC) for the Determination of Terbinafine Hydrochloride in Bulk Drug Substance. Research J. Pharm. and Tech. 2014; 7(1): 23-28
21. Goswami PD. Validated spectrophotometric method for the estimation of Terbinafine HCL in bulk and in tablet dosage form using inorganic solvent. Scholar Research Library. 2013; 5(3): 386-390.
22. Patel HD and Patel MM. Development and validation of UV-Spectrophotometric method for simultaneous estimation of Terbinafine HCL and Mometasone furoate in combined dosage form. Asian Journal of Research Chem. 2013; 6(1): 29-34.
23. Goswami p. Stability-Indicating Rp-Hplc Method For Analysis Of Terbinafine Hydrochloride In Bulk And In Tablet Dosage Form. Int J Pharm Pharm Sci. 2013; 5(3): 536-540.
24. Vamsi K P and Kanakapura B. Stability Indicating UV Spectrophotometric Assay Of Terbinafine Hydrochloride in Dosage Forms. International Journal of ChemTech Research. 2013; 5(5): 2645.
25. Domadiya V, Singh R, Jat R and Chokshi R. Method Development And Validation for Assay of Terbinafine Hcl in Cream by RP-HPLC Method. Inventi Impact - Pharm Analysis & Quality Assurance. 2012; 12: 307.
26. Jain PS, Chaudhari AJ, Patel S, Patel Z and Patel D. Development and Validation of the Uv Spectrophotometric Method for Determination of Terbinafine Hydrochloride in Bulk and in Formulation. Pharma methods. 2011; 2(3).

27. Raju R and Bujjj B. Simultaneous Analysis RP-HPLC Method Development and Validation of Terbinafine and Bezafibrate Drugs in Pharmaceutical Dosage Form. Pharmacophore. 2011; 2(4): 195-201.
28. Pasumarthy NV, Hemakumar AV and Padma SAV. Reverse Phase HPLC Method for the Analysis of Terbinafine in Pharmaceutical Dosage Forms. Asian Journal of Chemistry. 2008; 20(1): 551-555.
29. Cardoso SG and Schapoval ES. UV spectrophotometry and Nonaqueous determination of Terbinafine Hydrochloride in dosage Forms. Journal of AOAC International. 1999; 82(4): 830-833.