CHAPTER III
DRUG PROFILE
CHAPTER-3

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3.1. STRUCTURE

IUPAC NAME[15]
(E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine.Hydrochloride

MOLECULAR FORMULA  \( \text{C}_{21}\text{H}_{26}\text{NCl} \)

MOLECULAR WEIGHT  327.89
3.2. ACTION AND CLINICAL PHARMACOLOGY

Terbinafine hydrochloride is a synthetic allyl amine derivative. It is hypothesized to act by inhibiting the epoxidation of squalene, thus blocking the bio-synthesis of ergosterol. This leads to the deficiency of ergosterol and an intra cellular accumulation of squalene, thus disrupting fungal membrane function and cell wall synthesis, resulting in fungal cell death.

3.3. PHARMACOKINETICS[16]

Terbinafine hydrochloride undergoes first pass metabolism(40%). In plasma, terbinafine is greater than 99% bound to plasma protein and there are no specific binding sites. Peak plasma concentration of 1mcg/ml appear within 2 hour after a single 250 mg dose. Prior to excretion, terbinafine is extensively metabolized. Approximately 70% of the administered dose is eliminated in the urine.

3.4. INDICATIONS AND CLINICAL USES

Terbinafine is mainly effective on the dermatophytes group of fungi. As a 1% cream or powder it is used for superficial skin infections and other types of ring worm. Terbinafine hydrochloride is commonly used in the treatment of microporpsis, its fungicidal action permits short period of treatment.

GENERAL PRECAUTIONS

Terbinafine hydrochloride are not recommended to patients with chronic or active liver disease. In patients with renal impairment, the use of Terbinafine hydrochloride has been adequately studied and is not recommended.
Because of all the advantages and limitations in the use of drug Terbinafine hydrochloride, determination of its moiety becomes necessary to validate. An in-house titrimetric method for the determination of assay of Terbinafine hydrochloride drug substance was developed in Orchid chemicals and pharmaceuticals Limited., R&D Centre. It was validated to show specificity, linearity, precision, ruggedness, solution stability and accuracy. The method has been validated as per the guidelines given by ICH and US FDA requirements. It was planned to collect all validation guidelines available in literature and finalize the validation parameters for validation of assay method and preparing a validation protocol.

The following parameters were planned to validate by both aqueous and non-aqueous methods.

Specificity, Linearity, Precision, Ruggedness, Solution stability, and Accuracy.

After the completion of analytical work all results were compiled, compared and presented in the results and discussion part.