SPECTROPHOTOMETRIC DETERMINATION OF TERBINAFINE HYDROCHLORIDE IN BULK DRUG AND PHARMACEUTICAL FORMULATION

CHAUDHARI V. P.*[1], KULKARNI M. S.[2], KUCHEKAR B. S. [3], ,CHAUDHARIK. P.[4]

1- Maharashtra Institute of Pharmacy, Pune-38, MS, 2- STES's Smt. Kashibai Navale College of Pharmacy, Kondhwa, Pune

4- Govt. College of Pharmacy, Karad, MS 5. University Institute of chemical technology, Mumbai.

INTRODUCTION:

Terbinafine Hydrochloride, chemically it is (E)-N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-naphthalenemethanamine hydrochloride it can be used as antifungus drug. A survey of literature reveals that no spectrophotometric method has been developed for Terbinafine Hydrochloride. The present investigation deals with a simple spectrophotometric estimation of the drug in its dosage form using methanol:glass distilled water (70:30) as a solvent.

EXPERIMENTAL:

INSTRUMENT:

A Systronics 119 U.V visible spectrophotometer, Matched quartz cells, 1cm

REAGENT: Methanol (Analytical Grade)

PROCEDURE:

A solution of Terbinafine Hydrochloride of concentration 1000mg/ml was prepared by dissolving 50mg of pure drug in 50 ml of methanol: glass distilled water (70:30). The solutions were scanned in the U. V. range; the absorbance was measured at 223 nm (λmax) against reagent blank. Fig1

Standard stock solution was suitably diluted with methanol: glass distilled water (70:30) to give a concentration range of 0.6-4.2 mg/ml. The solutions were scanned in the U. V. range; the absorbance was measured at 223 nm against reagent blank. Fig 2

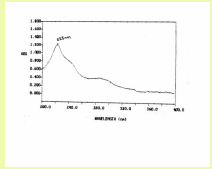

FIG 1: lMAX OF TERBINAFINEHYDROCHLORIDE

Tablet Formulation:

The above method was used to determine Terbinafine Hydrochloride in tablet. Twenty tablets were weighed and powdered. The amount of powdered drug equivalent to 50 mg of Terbinafine Hydrochloride was weighed accurately and transferred into a suitable flask. The tablet powder was dissolved in methanol: glass distilled water (70:30) and filtered through a Whatman filter paper no. 41. This filtrate was diluted to 50 ml with methanol: glass distilled water (70:30). Further dilutions were made to get the concentration of 1.8, 2.2, 2.6, 3.0 and 3.4 mg/ml. The absorbances of these solutions were measured at 223 nm. The drug content of the preparation was calculated using a standard curve.

RECOVERY STUDY:

Recovery studies were conducted by the additions of different amounts of pure drug to the known concentration of preanalyzed tablet solution. The recovery was calculated by using a formula

$$\% \text{ Recovery} = \frac{N(\Sigma xy) - (\Sigma y)(\Sigma x)}{N(\Sigma x^2) - (\Sigma x)^2}$$

Where, x = amount of standard drug added

y = amount of drug found by proposed method

N = no. of observations

RESULT AND DISCUSSION:

The proposed method shows absorption maxima at 223 nm and obeyed Beer's law in the concentration range of 0.6-4.2 mg/ml. Table-1 shows the optical characters

TABLE I: OPTICAL CHARACTERISTICS AND PRECISION

Absorption maxima (nm)	223
Beer's law limit (mg/ml)	0.6-3.8
Correlation coefficient	0.998909
Molar absorptivity (lit/mole/cm)	9.378×10^3
Sandell's sensitivity(mcg/sqcm/0.001	0.034975
Regression equation:	
Slope (m)	0.028592
Intercept	-0.014683
% COV	0.302275
Confidence limit with 0.05 level	0.002221

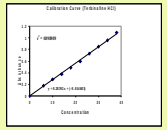

FIG2: CALIBRATION CURVE OF TERBINAFINE HYDROCHLORIDE

The % Recovery value of 98.46 (table – 2) indicates that there is no interference of the excipients in the formulation.

The low value of standard deviation and coefficient of variation indicates that the proposed method is precise. All statistical data proved validity of proposed method, which can be applied in industries for routine analysis of this drug from tablet.

TABLE II:ANALYSIS DATA OF TABLET FORMULATION

Pharmaceutical Formulation	Label claim (mg)	Amount found*		% Recovery *	Standard Deviation	Coefficient of variation
		mg	%			
Daskil	250	247.62	99.05	98.46	1.89	1.91

* Mean of five determinations

STATISTICS:

Sr.No		Mean	S.D. +/-	C.V. (%)	S.E.
1	Daskil	99.05	2.00	2.00	0.92

For correspondence chaudharivp@rediffmail.com