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Quantitative Determination of Finasteride from Tablet Formulation by UV-Spectrophotometry

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Abstract

A simple, accurate and economical UV-Spectrophotometric method has been developed for routine analysis of Finasteride Hydrochloride in tablet. Finasteride showed maximum absorbance at 287.0 nm in saline phosphate buffer (PBS) pH 7.4. In this method, Finasteride obeyed linearity in the concentration range of 2-20 µg/mL with a correlation coefficient of 0.9998. The limit of detection and Limit of Quantification for finasteride was found to be 0.82µg/ml and 2.76µg/ml respectively. The percentage recovery was found to be 99.3% and showed good repeatability with relative standard deviation less than 2. Methods were validated statistically using the principle of least squares by the equation Y = 0.080 X – 0.007.

Keywords: Finasteride, Phosphate buffer, UV-Spectrophotometry

INTRODUCTION

Finasteride is approved generally with the alpha-blocker, doxazosin. Finasteride is 5-alpha reductase inhibitor. 5-alpha reductase used to convert testosterone to dihydrotestosterone. Finasteride is used to treat symptoms of benign prostatic hyperplasia (BPH) such as frequent and difficult urination and may reduce the chance of acute urinary retention. Finasteride treats male pattern hair loss by blocking the body's production of a male hormone in the scalp that stops hair growth [1,2]. No simple, sensitive work has been reported for the estimation of Finasteride in tablets. Hence, the present work was an attempt to develop accurate, simple and sensitive and less expensive method for the estimation of Finasteride in tablets.

MATERIALS AND METHODS

Chemicals: Finasteride hydrochloride was supplied as a gift sample by Torrent Pharmaceuticals Ltd, Ahmadabad. Tablet was procured from local market, containing Finasteride (strength 5mg) manufactured by Zydus Pharms USA Inc. All other chemical were used of analytical grade.

Instrumentation: A UV-Visible spectrophotometer (1700 Shimadzu) with spectral bandwidth 1 nm was employed for all spectroscopic measurements.

Selection of common solvent: Phosphate buffer (PBS) pH 7.4 was selected as common solvent for developing spectral characteristics of FOX. The selection was made after evaluating the solubility of FOX in different solvents [3].

Preparation of Stock standard solution and selection of wavelengths: A stock standard solution of Finasteride was prepared by dissolving 10 mg in 100 mL of phosphate buffer pH 7.4 to obtain concentrations 100 µg/mL. After appropriate dilutions, 20 µg/mL solution of Finasteride was scanned in the UV-region i.e. 400 - 200 nm. Finasteride showed maximum absorbance at 287.0 nm. The statistical evaluation of the calibration plot have been done using the principle of least squares using the

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equation Y = 0.080 X – 0.007 and statistical parameters are given in table no.1 (4, 5).

Assay of Finasteride in dosage forms: 20 tablets (Zydus Pharms USA INC, 5 mg) were accurately weighed and average weight of the tablets was calculated. Weight equivalent to 100mg was transferred to 100ml volumetric flask and made up to volume with phosphate buffer pH 7.4 and sonicated for 15 minutes. The solution was mixed and centrifuged for excipients to settle down. The resultant 1mg/ml of the solution was further diluted to get a concentration of 100µg/ml. Later, 1, 1.5 and 2ml of the above solution were pipetted out into three 10ml standard flasks and the volumes were made up using phosphate buffer pH 7.4. This gave sample solution having concentration 10, 15, and 20µg/ml. The absorbance of each concentration was measured and the results of analysis of tablet formulations were shown in Table No. 2.

Validation: The methods were validated with respect to linearity, accuracy, precision and LOD and LOQ.

Study of linearity curves: To examine the linearity of the assay, the calibration curve for Finasteride at a concentration range of 2-20 µg/mL in Phosphate buffer pH 7.4 was prepared in Figure1. The optical characteristic and statistical data is shown in Table 1 (6).

Accuracy: To study the accuracy of the proposed methods, recovery studies were carried out by adding a known amount of drug to the pre-analysed tablet powder and percentage recoveries were calculated. The result of recovery studies were satisfactory and are presented in Table no 3.

Precision: The reproducibility of the proposed method were determined by performing the tablet assay at different time intervals on the same day (intra-day assay precision) and on three different days (inter-day assay precision).The results of intra-day and inter-day precisions were expressed in % RSD. The % RSD for intra-day assay precision was found to be 0.4 and inter-day assay precision was found to be 0.6 [7, 8].

Limit of Detection and Limit of Quantitation: The LOD and LOQ were determined based on the standard deviation of the y-intercept and the slope of the calibration curves. LOD and LOQ for Finasteride were found to be 0.82 µg/ml and 2.76 µg/ml, respectively.

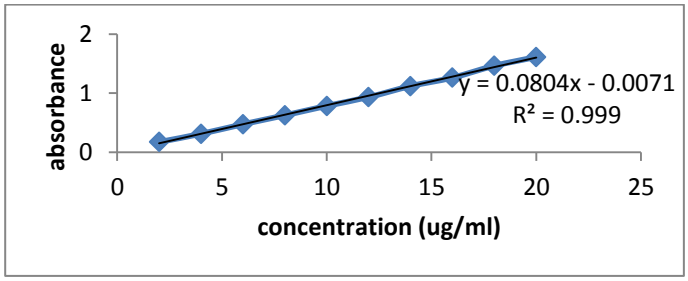

Figure 1: Standard calibration curve of Finasteride in PBS pH 7.4

Table 1: Statistical parameters of the calibration plot

Statistical parameters	Observed value
co-relation coefficient	0.999915
Standard deviation	0.217166
Variance	0.047161
Standard error	0.002961
r2	0.99983

Table 2: Results of tablet analysis

Brand	Label Claim	Amount of Drug Estimated	Percentage Label Claim	Standard Deviation
Zydus	5mg	4.891	97.80	0.02

Table 3: Results of recovery studies

Brand	Label Claim	Amount of Pure Drug added	Percentage recovery	Standard Deviation
Zydus	5mg	50	99.37	0.29

RESULTS AND DISCUSSION

In Phosphate buffer pH 7.4 Finasteride from formulation showed maximum absorbance at 287.0 nm. In this

method, Finasteride followed linearity in the concentration range of 2-20 µg/mL. Accuracy of the proposed method was ascertained by recovery studies and the results were expressed as percentage recovery and were found in the range of 99.25-99.37%. Intra-day and Inter-day precision studies were carried out by analysing the tablet powder at different time interval on the same day and on three different days respectively. Standard deviation and coefficient of variance for Intra-day and Inter-day precision studies was found to be less than 2 indicating precision of the proposed method. Based on the results obtained, it was found that, the proposed methods were accurate, precise, reproducible and economical and can be employed for routine quality control of Finasteride in tablet dosage forms.

CONCLUSION

This developed method is simple, economical, accurate and precise and can be used for routine estimation of Finasteride from its pharmaceutical formulations.

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