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Development and Validation of UV Spectrophotometric Method for the Estimation of Finasteride in Tablets

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ABSTRACT

A simple, accurate, precise, reproducible, highly sensitive, economic spectrophotometric method has been developed for the estimation of Finasteride in tablet dosage form. UV spectrophotometric method is based on measurement of absorption at maximum wavelength 254 nm. The percent recovery of Finasteride ranged from 98.82 – 102.11% in tablet dosage form. The developed method was validated with respect to linearity, accuracy (recovery), Precision (inter and intra day variations). Beer's law was obeyed in the concentration range of 5 – 25 µg/mL with correlation coefficient of 0.9986. Results of the analysis were validated statistically and by recovery study. Hence the developed and validated method can be used for estimation of finasteride in tablets.

Keywords: UV Spectroscopy, Finasteride, Development, Validation

INTRODUCTION

Finasteride ((5α, 17β)-N-(1, 1-dimethylethyl)-3-oxo-4-azaandrost-1-ene-17-carboxamide) is a selective inhibitor of type II- 5 α- reductase [1,2]. Thus, the inhibition of type II -5α-reductase suppresses the metabolism of testosterone to dihydrotestosterone (DHT), resulting in significant decrease in plasma and intra prostatic DHT concentrations. Hence it is used as an antiandrogen agent. At low doses it is used in benign prostatic hyperplasia (BPH) and at higher doses used in prostate cancer. Additionally, it is registered in many countries for male pattern-baldness. At steady state, Finasteride suppress DHT levels by approximately 70% in plasma and by as much as 85-90% in the prostate. Long term therapy with Finasteride can reduce clinical significant end points of BPH, such as acute urinary retention or surgery.

Pharmaceutical analysis plays an important role in the quality assurance and quality control of bulk drug samples as well as pharmaceutical formulations. Spectroscopy is one of the most powerful tools for the analysis of a wide range of pharmaceutical dosage forms. If a suitable method, for specific need, is not available then it becomes essential to develop a simple, sensitive, accurate, precise, rapid and reproducible method for the estimation of drug samples. Finasteride is not official in I.P and B.P. The drug is official in Martindale, The Extra Pharmacopeia and United States Pharmacopoeia and the latter describes HPLC procedure for assay in pure drug and in tablets. Literature review revealed that there are few methods based on HPLC, HPTLC, RP-HPLC, polarography and spectroscopy for its estimation in bulk and dosage form.

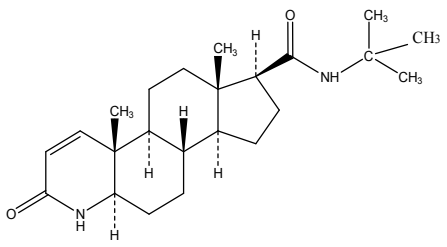

Figure 1. Structure of Finasteride

The present work describes the development and validation of UV spectrophotometric method, which can quantify the Finasteride (Fig 1). An attempt was made to develop a simple, accurate, precise and rapid spectrophotometric method for the estimation of

Finasteride in tablet dosage form in dichloro methane (DCM). The method was validated as per International conference on Harmonization (ICH) guidelines.

MATERIALS AND METHODS

Materials

Finasteride was obtained as gift sample from Hetero Drugs Ltd. (Hyderabad, A.P, INDIA). All chemicals used were of analytical grade. One marketed tablet of Finasteride was procured from local market.

Instruments

An ELICO SL 244 double beam spectrophotometer, wavelength accuracy ±0.5 nm and a pair of 1.0 cm matched quartz cells were used to measure absorbance of resulting solution.

Procedure

Preparation of Finasteride standard solutions

Accurately weighed 10 mg of Finasteride was transferred into 100 ml volumetric flask. It was dissolved and diluted up to mark with DCM to obtain stock solution (100µg/mL). The standard solutions in concentration range of 5-25 µg/mL were prepared by dilutions of the stock solution with DCM. The determination was conducted six times at room temperature.

Preparation of sample solution (Assay of marketed formulation)

Ten tablets were weighed to obtain the average tablet weight, which were then powdered. Powder equivalent to 10 mg of Finasteride was weighed and transferd to 100 ml volumetric flask and allowed to dissolve in 70 ml of DCM. This mixture was sonicated for 15 min to ensure complete solubility of the drug and filtered through Whatman filter paper no. 41. The volume was made up to mark with DCM to get the solution having Finasteride 100 µg/mL and the sample solutions were prepared with in the concentration range. The results were reported in Table 1.

Table 1. Assay of Finasteride marketed formulation (Tablet)

Formulation	Sample no	Label claim	Amount obtained (in mg)	Assay value (in %)	%RSD
FINAX-1	1.	1 mg	1.02	102	1.7± 0.51
	2.	1 mg	0.995	99.5	
	3.	1 mg	1.03	103	

Scanning for λ_{max}

The standard solution of Finasteride was scanned in the wavelength range of 200 nm - 400 nm using UV spectrophotometer. The spectrum was depicted in Figure 2.

Preparation of calibration graph using UV spectrophotometric method

A calibration graph was constructed over a concentration range of 5-25 µg/mL. Absorbance of each solution was measured at the wavelength of 254 nm. Calibration graph was constructed for Finasteride by plotting concentration (µg/mL) *vs.* absorbance at 254 nm. The graph was depicted in Figure 3.

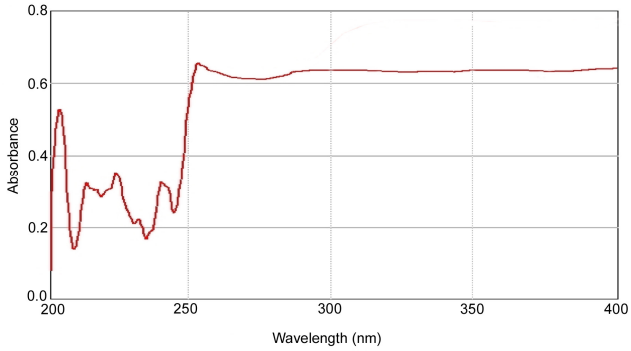

Figure 2. UV Spectrum for standard Finasteride in dichloromethane.

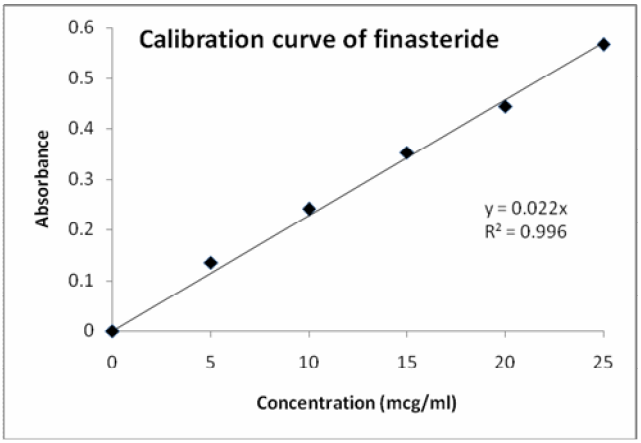

Figure 3. Calibration graph of Finasteride in dichloromethane.

RESULTS AND DISCUSSION

Development and Optimisation

The solubility of Finasteride was tested in water, alcohol and dichloromethane. Based upon the free solubility of Finasteride in DCM, it was selected as solvent for method development Finasteride estimation. The analyte was estimated at 254 nm and respective UV spectrum was depicted in Figure 2.

Validation

The developed UV spectrophotometric method was validated for linearity range, accuracy, precision, limit of detection, limit of quantification and robustness parameters as per ICH guidelines.

Linearity range

The linearity was determined for Finasteride by plotting a calibration graph of concentration against absorbance. Finasteride showed linearity in the range of 5-25 µg/mL. Calibration curve of Finasteride was depicted in Figure 3. The linear regression for the drug was represented in Table 3.

Table 2. Accuracy data (Recovery studies)

S.No	Concentration of drug in formulation (µg/ml)	Concentration of pure drug added (µg/ml)	Total concentration of drug (µg/ml)	Amount found (µg/ml)	Percentage of drug recovery
1	10	8	18	17.91	98.82
2	10	10	20	19.95	99.5
3	10	12	22	22.24	102.1

Table 3. Summary of validated parameters

λ_{max} (nm)	254nm
Beer's Linearity (µg/ml)	5 – 25
Molar absorpitivity	8899.89
Regression equation (Y= mx + c)	Y = 0.022x
a) Slope (m)	0.0213
b) Correlation coefficient (r^2)	0.9986
c) Sandell's sensitivity	0.0436
% RSD	0.411
LOD	1.138µg/ml
LOQ	3.448 µg/ml

Accuracy

Accuracy of developed method was determined by a recovery study at 3 concentration levels by replicate analysis (n=3). Standard drug solutions were added to a pre-analysed sample solution and percentage of total drug content was calculated. The results of accuracy studies were reported in Table 2.

Precision

Precision was determined by studying the repeatability and intermediate precision. The standard deviation and relative standard deviation were calculated for the drug. Repeatability was determined by six estimations of Finasteride 5-25 µg/mL and %RSD was calculated. The results of precision studies were reported in Table 3.

LOD and LOQ

The LOD and LOQ of Finasteride were found to be 1.138 µg/mL and 3.448 µg/mL respectively.

CONCLUSION

The developed UV Spectrophotometric method was found to be simple, economic, easy, accurate, precise, reproducible and highly sensitive and can be used for routine estimation of Finasteride in bulk and other formulations.

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