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METHOD DEVELOPMENT AND VALIDATION OF UV-SPECTROPHOTOMETRIC ESTIMATION OF FINASTERIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM

Y KESAVA*, M.S.RIYAZULLAH, D JOTHIESWARI, ABHISHEK PANDEY, ANSHIKA YADAV, C GEETHA, SHAIK MOHAMMED DAWOOD, SHAMS TABREZ

Department of Pharmaceutical analysis, Sri Venkateswara College of Pharmacy, Chittoor, Andhra Pradesh, India.

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ABSTRACT

A simple, rapid, and cost-effective UV–Visible spectrophotometric method was developed and validated for the quantitative estimation of finasteride in bulk drug and pharmaceutical dosage forms. Finasteride, a selective inhibitor of type II 5α-reductase, is widely used in the management of benign prostatic hyperplasia and androgenic alopecia. The proposed method was based on measurement of absorbance at a wavelength of approximately 210 nm using methanol as solvent. The method exhibited good linearity over the concentration range of 2–10 µg/mL with a high correlation coefficient ($r^2 \approx 0.999$), indicating adherence to Beer–Lambert's law. Validation of the method was carried out in accordance with ICH guidelines, including parameters such as accuracy, precision, linearity, ruggedness, limit of detection (LOD), and limit of quantification (LOQ). The accuracy studies showed satisfactory recovery within 98–102%, while precision studies demonstrated low %RSD values (<2%), confirming reproducibility. The method also showed adequate sensitivity with acceptable LOD and LOQ values. Overall, the developed UV spectrophotometric method is reliable, economical, and suitable for routine quality control analysis of finasteride in pharmaceutical formulations.

Keywords: *Finasteride, Linearity, Accuracy, UV- spectroscopy, Validation.*

***CORRESPONDING AUTHOR**

Y. Kesava
Associate Professor
Department of Pharmaceutical Analysis
Sri Venkateswara College of Pharmacy
Chittoor, Andhra Pradesh, India.

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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 [3].

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. The therapeutic importance of this compound justifies research to establish analytical methodsfor its determination in bulk and pharmaceutical formulations. Only few analytical methods were found for the quantitative estimation of the Finasteride and hence in

the present work, an attempt was made to provide a newer, simple, accurate and low-cost UVVisible spectrophotometric methods for the effective quantitative determination of Finasteride as an active pharmaceutical ingredient as well as in pharmaceutical preparations [4, 5]. 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.The present work describes the development and validationof the UV spectrophotometric method for the estimation of Finasteride bulk and tablet dosage form.

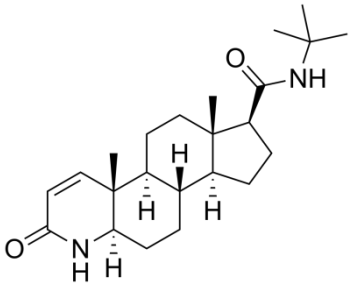

Fig 1. Structure of Finasteride

MATERIALS AND METHODS

Finasteride was obtained as a gift sample from Intas Pharmaceuticals Ltd and marketed formulations of Finasteride, Finpecia (1mg) were procured from Cipla Private Limited. Finarid (5mg) were procured from Sun Pharmaceuticals Industries. Finax (1 mg) were procured from Dr. Reddy's Laboratories. Finasteride tablets IP (5 mg) were procured from Hetero Drugs Ltd. All the chemicals use are AR Grade. UV Visible spectrophotometer (Systronics 2202) was employed with spectral bandwidth of 1 nm attach with computer loaded PC software (UV probe) version 2.31.

Preparation of standard primary drug stock solutions

Standard drug stock solution of Finasteridewas prepared by dissolving equivalent to 10 mg of Finasteride in 100 ml of volumetric flask containing solvent as Methanol with sonication [6]. The volume was madeup to 100ml with methanol to obtain the standard primary stock solution of knownconcentration.

Preparation of standard secondary drug stock solution

From the above standard primary drug solution, 10ml of stock solution was withdrawn and diluted with 100ml of Methanol to produce 10μg/ml concentration.

Preparation of linearty working standard solution

Linearity standard solutions were prepared from secondary standard stock drug solution. Pipette out 20ml, 40ml, 60ml, 80ml, & 100ml, from secondary stock solution and transfer them in to 100 ml volumetric flasks and further dilute it to 100ml with primary diluent to get a final linearity concentration of 2μg/ml to 10μg/ml of Finasteride [7].

Preparation of standard solution

A working standard solution concentration having 10 μg/ml of Finasteride was prepared from the above secondary standard stock solution.

Preparation of sample solution

Ten tablets of Finasteride were weighed and finely powdered. An accurately weighed quantity of the tablet powder equivalent to approximately 10 mg of Finasteride was transferred to a 100 ml standard flask. and extracted with 80 ml of methanol and further 10ml water was added and shake well for 15 minutes then finally it was diluted to 100 ml by using water. Filter this solution using Whatman filter paper- 1 and from this pipette out 10 ml and dilute to 100 ml by using primary diluent. Then from above solution pipette out 10 ml and transfer in 100 ml standard volumetric flask ad dilute to 100 ml with primary diluent to get final concentration of 10ug/ml.

RESULTS AND DISCUSSION

Optimization of the method

A number of trials were made to find the ideal solvent system and increase the solubility of the drug. It was performed by co solvency studies based on the solubility profile of the drug. Finasteride was dissolved in ethanol, methanol, DMSO, Chloroform, miscible solvent mixtures. After careful observation ofspectrum of Finasteride was having λmax absorbance at 210 nm with Methanol: Water [80:20] solvent system used for primary dilution and final dilution made with primary diluent. The working standard stock solution was prepared and scanned the spectrum by UV spectrophotometer range between 200- 400 nm. After careful observation of spectrum, the λ max was obtained as 210nm and spectrum showed at Figure 2.

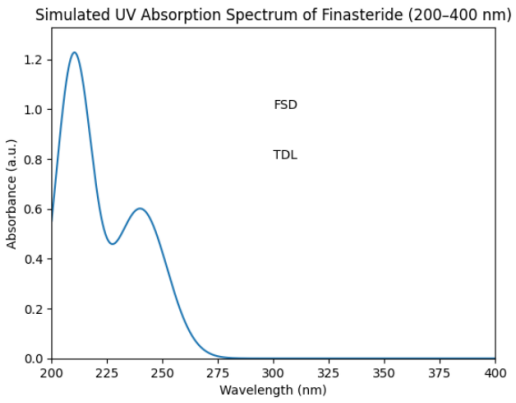

Fig 2. Absorption spectrum of Finasteride from 200nm-400nm

Validation is defined as the establishing evidence which provide high degree of assurance that a specific process will consistently produce a product meeting its determined specification quality characteristics [8]. The following parameters used for validation studies are

Linearity

Linearity of Finasteride was evaluated by preparing standard solutions in the concentration range of 2–10

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µg/ml. The absorbance of each solution was measured at 210nm, and a calibration curve was plotted between concentration and absorbance. The plot showed a straight line with a correlation coefficient ($r^2 \geq 0.999$), confirming that the method obeys Beer–Lambert's law within this range.The linearity data was showed in Figure 3. The correlation coefficients were found to be 0.999.

Table 1. Linearity data for Finasteride

S.No	Concentration (ug/ml)	Absorbance
1	2	0.020
2	4	0.032
3	6	0.038
4	8	0.044
5	10	0.052

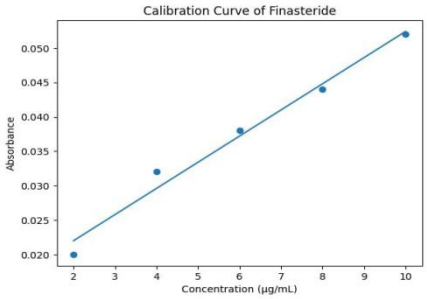

Fig 3. Linearity Curve of Finasteride

Table 2. Statistical analysis of calibration curve

Regression equation (Y*)	Y=0.0038X+ 0.014
Slope (b)	0.0038
Intercept(a)	0.014

Accuracy

The accuracy of the UV method for Finasteride was checked using the standard addition (recovery) method [9]. Known amounts of Finasteride standard were added to the sample solution at three levels: 80%, 100%, and 120%. The absorbance of each solution was measured at λ max (~210–215 nm), and the concentration was calculated using the calibration curve equation (Y = 0.0038 X + 0.014*).

The recoveries were 99.44%, 99.52%, and 99.57% for 80%, 100%, and 120% levels, respectively. These values are within the acceptable range of 98–102%, showing that the method is accurate and results were reported in Table 3.

Table 3.Recovery studies

Tablet sample	Level of recovery (%)	Amount present (mg/tab)	Amount standard (mg)	Total amount recovered (mg)	% Recovery
T1	80	10	8	17.90	99.44
		10	8	18.00	100.00
		10	8	17.80	98.89
	100	10	10	20.90	99.52
		10	10	21.00	100.00
		10	10	20.80	99.05
	120	10	12	22.80	99.23
		10	12	22.70	98.70
		10	12	22.90	99.57

Table 4. Statistical validation of recovery studies

Tablet sample	Level of recovery (%)	%mean*	S.D.*	(C.O.V.) %RSD	S.E.*
T1	80	99.52	0.72	0.72	0.42
	100	99.84	0.65	0.65	0.38
	120	100.12	0.70	0.70	0.40

Mean–Average % Recovery; SD–Standard Deviation; % RSD – Precision as %; COV – same as % RSD (Coefficient of Variation = SD/Mean×100); SE – Standard Error = SD/ √n (n = number of readings)

Precision

Precision of the developed UV spectrophotometric method was evaluated by analyzing the same Finasteride sample solution multiple times to check the reproducibility of the results [10]. Intra-day precision was determined by measuring the absorbance of a fixed concentration of the sample solution three times on the same day, and the % relative standard deviation (%RSD) was calculated. Similarly, inter-day precision was assessed by measuring the same sample solution on three different days. The %RSD values for both intra-day and inter-day precision were found to be within acceptable limits (less than 2%), indicating that the method produces consistent and repeatable results. The low %RSD values confirm that the method is precise and reliable for routine estimation of Finasteride in tablet dosage form. The precision of the proposed method i.e. the intra and inter-day variations in the absorbance of the drug solutions was calculated in terms of % RSD and the results are presented in the below table. (Table 5)

Table 5.Precision studies

Concentration (µg/ml)	Inter-day Absorbance Mean ± SD	%RSD	Intra-day Absorbance Mean ± SD	%RSD
2	0.0198±0.00063	3.18%	0.0203±0.00058	2.86%
4	0.0320±0.00070	2.19%	0.0323±0.00065	2.01%
6	0.0381± 0.00060	1.5%	0.0384±0.00055	1..43%
8	0.0442± 0.00050	1.17%	0.0445±0.00050	1.12%
10	0.0521± 0.00040	0.92%	0.0524± 0.00045	0.85%

Intra-day and inter-day precision values are expressed as Mean± SD and %RSD.

All %RSD values were found to be within acceptable limits (<2%), indicating that the method is precise and reproducible.

Table 6.Statistical validation for precision

Component	Mean*	S.D	C.O.V.	S.E
Intra-day	0.0379	0.00051	1.35%	0.00029
Inter-day	0.0399	0.00067	1.68%	0.00039

Limit of Detection (LOD)

The parameter LOD was determined on the basis of response and slope of the regression equation. The LOD for this method was found to be 0.45µg/ml.This value is based on method validation data where the calibration curve showed good linearity and sensitivity.

Limit of Quantification (LOQ)

The parameter for LOQ which means that concentrations at or above ~1.36 µg/mL can be quantified with acceptable accuracy and precision using the developed UV method.

Ruggedness

Ruggedness is a part of analytical method validation that shows how reproducible test results are when the method is used under normal but varying conditions. These conditions include changes like different analysts, different instruments, different days, or even different laboratories.

Table 7.Ruggedness results for Finasteride at 210nm

Sample	Label claim (mg)	AnalystI		Analyst II	
		Amount found (mg)	Recovery± SD** (%)	Amount found (mg)	Recovery± SD** (%)
Finasteride	5	4.97	99.40 ± 0.18	4.95	99.00 ± 0.20

Determination of Finasteride Tablets

Finasteride was determined by a UV spectrophotometric method at 210 nm using methanol as solvent [11]. Ten tablets were accurately weighed and powdered. A quantity of powder equivalent to 10 mg of finasteride was transferred to a 100 mL volumetric flask. The drug was extracted with methanol by sonication and the volume was made up.The solution was filtered and suitable dilutions were prepared [12]. A standard solution offinasteride was prepared in methanol. The absorbance of standard and sample solutions was measured at 210 nm using methanol as blank. Linearity was observed in the concentration range of 2–10 µg/mL with a correlation coefficient of 0.999. Precision studies showed %RSD less than 2%. The limit of quantification was found to be approximately 1.36 µg/mL, indicating good sensitivity of the method.

Table 8. Assay of Finasteride in tablets

Tablet	Concentration	Amount present (mg/tab)	Amount found (mg/tab)	% of drug found
T1	4	50	49.75	99.5
	6	87.5	87.68	100.2
	8	100	100.60	100.6

*Average of six determinations

Acceptance criteria for %Recovery of Finasteride at 210nm was within 98–102%, with% R.S.D below 2%.The assay parameter meets acceptance criteria and is therefore considered passed.

CONCLUSION

The present study successfully developed and validated a simple, rapid, and cost-effective UV–Visible spectrophotometric method for the quantitative estimation of Finasteride in bulk drug and pharmaceutical dosage forms. The method, based on measurement at the selected wavelength (λmax ≈ 210 nm), demonstrated good linearity over the chosen concentration range, with a high correlation coefficient, confirming adherence to Beer–Lambert's law within the working limits. Validation parameters including accuracy, precision, ruggedness, and recovery studies were found to be within acceptable limits as per ICH guidelines, indicating the reliability and reproducibility of the proposed method. Low values of %RSD and satisfactory recovery results confirmed that the method is precise and accurate. The developed method also showed adequate sensitivity, as reflected by acceptable LOD and LOQ values. Overall, the method can be effectively applied for routine quality control analysis of Finasteride in bulk and tablet formulations. Its simplicity, minimal requirement of reagents, and economical nature make it a suitable alternative to more complex analytical techniques for regular laboratory use.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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