JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

Area Under Curve Spectrophotometric Method for Determination of Finasteride in Pharmaceutical Formulation

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Article history:

Received 14 July 2017
Revised 16 November 2017
Accepted 17 November 2017
Available online 01 Dec 2017

Citation:

Gaikwad S. S., KhanH. N., Zameeruddin M., Bharkad V. B. Area Under Curve Spectrophotometric Method for Determination of Finasteride in Pharmaceutical Formulation **J Pharm Sci Bioscientific Res**. 2017. 7(5):310-313

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(www.jpsbr.org)

ABSTRACT:

A simple, accurate and precise Area Under Curve spectrophotometric method was developed for determination of Finasteride in pharmaceutical dosage form. This method involves the calculation of integrated value of absorbance with respect to the wave-length between two selected wavelengths. The area selected between 210-220 nm for the determination of Finasteride. The drug follows Beer-Lambert's law over the concentration range of 2-10 µg/ml for Finasteride. The % estimation of the drug 99.546% representing the accuracy of the method. The recovery of Finasteride found near to 99.68. The validation of the proposed method was carried out for its accuracy, precision, limit of detection and limit of quantitation according to ICH guidelines. The proposed methods can be successfully applied in routine work for the determination of Finasteride in its pharmaceutical dosage form.

KEY WORDS: Spectroscopy, Area under curve,Methanol, Dimethyl Sulfoxide (DMSO), Finasteride, validation.

INTRODUCTION:

Finasteridechemically is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (Figure. 1).It is white in colour and crystalline powder. The molecular weight of Finasteride is 372.6g/ml and molecular formula is $C_{23}H_{36}N_2O_2$.[1]. It is competitive inhibitor of enzyme 5α-reductase which converts testosterone responsible for androgen action in tissues including prostate gland and hair follicles. Finasteride is antiandrogenicdrug and also found effectively in male baldness. It is effective orally,metabolized in liver and excreted in urine faeces.[2]Literature survey revealed UV ,HPLC and UPLC analytical methods for its estimation.[3-17] The validation of the proposedmethod was carried out by ICH guidelines.[18]

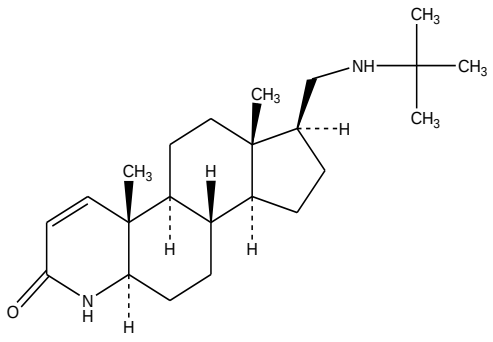

Figure 1: Chemical structure of Finasteride

MATERIAL AND METHODS:

Chemical:

A standard sample ofFinasteride was obtained as gift from Cipla Ltd. Mumbai, Maharashtra. FINAST 5mg tablet was procured from Local pharmacy. Methanol, Dimethyl Sulfoxide (DMSO), Potassium Dihydrogen Phosphate (PH 7.2) was used. All chemical and reagents were of analytical reagent (AR) grade.

Instrumentation:

A shimadzu (Japan) and UV-1800 double beam UV-visible spectrophotometer attached with computer operated software UVprobe2.0 with spectral width and 2nm, wavelength accuracy of 0.5nm and pair of 1cm matched quartz cells was used to measure absorbance and resulting.

Preparation of stock solution:

Preparation of standard stock solution of accurately weighed quantity of standard Finansteride (5mg) powder were weight transferred to 10ml volumetric flask and dissolved in Methanol : DMSO (9:1v/v) solution. The flask shaken and volume made containing 500 µg/ml.

Methodology:

Appropriate volume 4ml of standard stock solution of Finasteride was transferred into100ml volumetric flask, diluted with potassium phosphate buffer (PH7.2) up to give concentration of 20µg/ml .The resulting solution was scanned in UV range (200nm-400nm).In UV-spectrophotometric method two wavelength 210-220 nm were selected for determination of Area Under Curve of Finasteride (Figure 2)

Study of calibration curves:

The calibration curves was plotted over a concentration range of 2-10µg/ml for Finasteride regression equation calculation. Accurately measured standard 0.2, 0.4, 0.6, 0.8 and 1.0 µg/ml were transferred to series of 10 ml of volumetric flasks of diluted to mark with potassium phosphate buffer (PH7.2) separately.The areas of solution was measured at 210nm – 220 nm against phosphate buffer (PH7.2) as blank.

Assay procedures:

Pharmaceutical formulation of FINSAT (Brand name) 5ml marketed pharmaceutical formulation was purchased by local pharmacy sample stock solution was prepared as described earlier. Appropriate dilutions were made with phosphate buffer (PH7.2) from stock solution for area under curve spectrophotometric method.

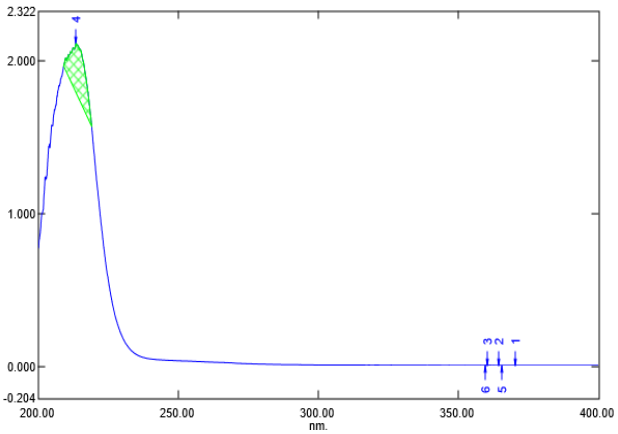

Figure 2: Spectrum of Finasteride (AUC)

RESULTS AND DISCUSSION:

The area under curve spectra for Finasteride was recorded at wavelength of 210 nm – 220nm. Figure.2

Linearity and range:

Regression analysis was made for slope, intercept and correlation coefficient values. The regression equation of calibration curve was y=0.200x +0.0012 (r^2 =0.999) at 210-220nm. For area under area spectrophotometric method figure.3

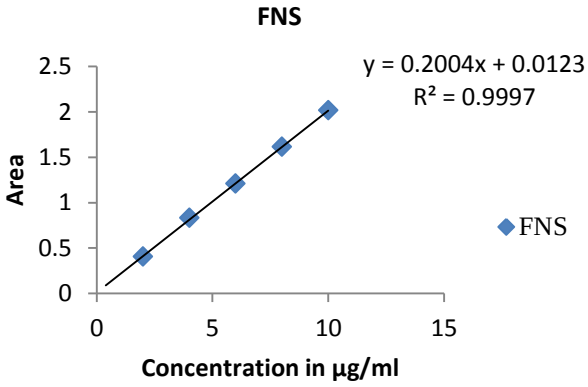

Figure 3: Calibration Curve of Finasteride at 210-220 nm for Area Under Curve

Table 1 : Regression analysis data for Finasteride area under curve method

Parameter	Area Under Curve
Wavelength range (nm)	210-220nm
Concentration rang(µg/ml)	02-Oct

Slope (m)	0.2
Intercept (c)	0.012
Correlation coefficient (r2)	0.0999

Table 2: Results of intra and inter Day Precision*n=6

Parameter	Inter-day Precision		Intra-day Precision	
	SD	%RSD	SD	%RSD
Area Under Curve	0.7023	0.70117	0.7023	0.70117

Table 3: Data of recovery Studies

Amount of sample in µg/ml	Amount of drug added in µg/ml	Amount Recovered in µg/ml	% Recovery
10	80%	70.98	99.88
10	100%	90.97	99.49
10	120%	111.93	99.68
		Mean	99.68
		SD	0.195
		%RSD	0.1956

*n=3

Table 4: Assay results for the determination of Finasteride in pharmaceutical formulation

Parameter	Label Claim (mg/vial)	Amount Found (mg/vial)	%label claim (mg/vial)
Area under Curve	5	4.97	99.54

Precision:

To determine the precision of the method, a Finasteride solution at a concentration 10 µg/ml was analyzed each six times for area under the curve spectrophotometric method. Solutions for the standard curves were prepared fresh everyday (Table 2.)

Sensitivity:

The limit of detection (LOD) and limit of quantification (LOQ) were calculated by using the equations LOD = 3 × σ / s and LOQ = 10 × σ /s, where σ is standard deviation of intercept, S is the slope found to be 0.2 µg/ml and 0.8 µg/ml respectively for area under the curve method.

Recovery:

To study the accuracy of the proposed methods, and to check the interference from excipients used in the dosage forms, recovery experiments were carried out by the addition of known amounts of Finasteride to reanalyzed solution of commercial tablets. (Table 3)

Analysis of the Marketed formulation:

There was no interference from the excipients commonly present in the tablet. The drug content was found to be 99.54% for area under the curve spectrophotometric method. It may therefore be inferred that degradation of Finasteride. The low % R.S.D. value indicated the suitability of this method for routine analysis of Finasteride.

Table 5: Summary of validation parameters

Parameters	Area Under Curve
Wavelength range	210-220nm
Concentration range (µg/ml)	02-Oct
Regression Equation (*Y)	Y=0.200x-0.012
Slop (m)	0.2
Intercept (c)	0.012
Correlation Coefficient (r2)	0.0999
LOD (µg/ml)	0.2
LOQ (µg/ml)	0.8
Accuracy (Recovery)%	99.68 ± 0.1956
Precision %RSD	
Interday (n = 6)	0.7011
Intraday (n = 6)	0.7011

In pharmaceutical dosage form (Table 4). The summary of the validation parameters is depicted in (Table 5)

CONCLUSION:

Simple, fast and reliable are under curve spectrophotometric method was developed for the routine determination of Finasteride. The developed method can be concluded as accurate, sensitive and precise and can be easily applied to the pharmaceutical formulation.

ACKNOWLEDGEMENT:

The authors thank full to Sahayog Sevabhavi Sanstha's Indira College of Pharmacy, Vishnupuri, Nanded, Maharashtra; for providing necessary facilities to carry out research work. A special thank full to Mr. Ravindra B. Bedarkar for his valuable guidance.

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