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Original Article

Validated Uv Spectrophotometric Quantification of Dutasteride In Pharmaceutical Formulations by Using Multivariate Technique

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ABSTRACT

The Present work focuses an accurate, simple and precise UV method with multivariate calibration technique for the estimation of Dutasteride in pharmaceutical dosage form. Multivariate calibration method uses the linear regression equations by correlating the relation between concentration and absorbance at 5 different wavelengths. The λmaxof Dutasteride shows at 269 nm and obeyed Beers law in the range of 1-5µg/ml. The percentage recovery of tablet formulation was found to be in the range of 98.50 to 99.88%. The limit of quantification and limit of detection were found to be 1.272 and 0.0420µg/ml respectively. The low percentage RSD values are indicated the accuracy and precise of the method. The present method can be successfully applied for method development and validation by multivariate analysis of Dutasteride.

Keywords: Dutasteride, λmax, Development, Validation, Multivariate Technique

INTRODUCTION

Dutasteride is an aza-steroid that is inasteride in which the tert-butyl group is replaced by a 2,5- bis (trifluoromethyl)phenyl group. A synthetic 4-azasteroid, dutasteride is a selective inhibitor of both the type 1 and type 2 isoforms of steroid 5alpha-reductase, an intracellular enzyme that converts testosterone to 5alpha-dihydrotestosterone. Dutasteride is used for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate gland. It has a role as an EC 1.3.1.22 [3-oxo-5alpha-steroid 4-dehydrogenase (NADP (+))] inhibitor and an anti-hyperplasia drug. It is an aza-steroid, a member of (trifluoromethyl)benzenes and a delta- lactam. It derives from a hydride of a 5 alpha-androstane. Benign Prostatic Hyperplasia Is Currently Treated with The Drug Dutasteride. Similar to The Finasteride, nearly 50 % Of Serum Prostate Specific Antigen Is Reduced At The Period Of 6 Months and Having a 25 % Of Prostate Volume In 2 Years. Dutasteride Is a Competitive and Specific Inhibitor Of Both Type I and Type II 5α-Reductase Isoenzymes and When Evaluated Under In-Vitro and In-Vivo Conditions, The Dissociation Of The Drug From The Drug-Enzyme Complex Is Reported To Be Extremely Slow. Dutasteride Does Not Bind to The Human Androgen Receptor. Multivariate Calibration Refers to The Process of Constructing a Mathematical Model That Relates a Property Such as Content Or Identity To The Absorbance Of a Set Of Known Reference Samples At More Than One Wavelength. If the Absorbance of An Analyte (z) Is Measured At Five Wavelength Set, Straight Line Equation Can Be Written As; Aλ= Ax (Cz+k) Where A λ Represent The Absorbance Of The Analyte, a Is The Slope and k is The Intercept Of The Linear Regression Function Of The Analyte. Cz Represents the Concentration Of Analyte. At Five Selected Wavelengths, The Equation System Can Also Be Summed As; At= Ax(Cz+b)x(Cz+c)x(Cz+d)x(Cz+e)x(Cz+Kt),
Which Can be Simplified To At=Cz (a+b+c+d+e)+K tWhere a,b,c,d,e are The Slopes, At And KtRepresents The Sum Of Absorbance Obtained And Sum Of Intercepts Of Regression Equation At Five Wavelength Set Respectively .The Concentration Of The z Analyte In a Mixture Can be Calculated By

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Given Equation Cz = At–Kt/(a+b+c+d+e) .The Present Research Work Focuses On The Application Of Uv Spectral Multivariate Calibration Technique Having Simple Mathematical Content For The Quantitative Determination Of Dutasteride In Pharmaceutical Formulation.

- **Drug Profile:**

Drug Name: Dutasteride

Chemical Name: N- [2,5-bis (trifluoromethyl) phenyl] -3-oxo-4-aza- 5α-androst- 1-ene- 17β-carboxamide

Molecular formula: C27H30F6N2O2

Molecular Weight: 528.5 g/mol

Strength: 0.5mg

Appearance: A white to pale yellow powder.

Solubility: That is soluble inorganic solvents but not in water.

Melting point: 242°to250°C.

Boiling point: 620.3°Cat760 mmHg

Bioavailability: The oral bioavailability of dutasteride is about 60%.

Elimination Half-Life: About 4 to 5 weeks..

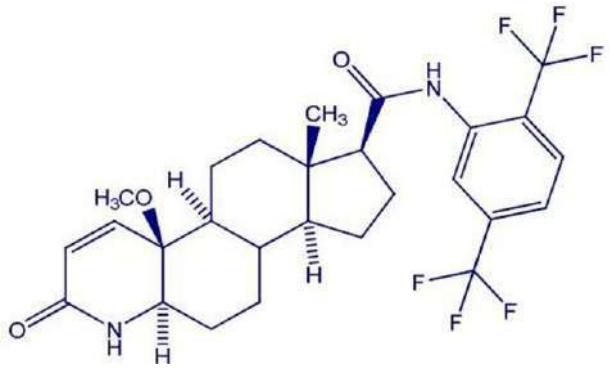

Fig: 1 Structure of Dutasteride

MATERIAL AND METHOD:

3.1 Chemicals:

Dutasteride was bought fromVridam Health care Private Limited, Nashik, Maharashtra. Tablet formulation of VRIDUTA 0.5 containing 0.5mg of Dutasteride was purchased from local pharmacy. Ethanol was purchased from online mart.

3.2 Instrumentation:

The multivariate technique was performed in Double beam UV-Visible spectrophotometer (UV 1700-Shimadzu – Japan) with 10 mm path length matched quartz cells was used for analytical purpose.

3.3 Preparation of standard solutions:

The standard solution was prepared by accurately weighed 0.5mg of Dutasteride raw material in 50ml standard flask, dissolved in Ethanol and made up to the volume with Ethanol which contains 1000µg/ml. From that the solution further dilutions were made by diluting 1ml to 100ml with the same solvent Ethanol to obtain 10µg/ml.

3.4 Selection of wavelength:

Dutasteride was transferred to a volumetric flask and diluted to mark with Ethanol. The resulting solution was scanned in the UV range of 265-273 nm i.e.,265, 267, 269, 271, 273 nm.

3.5 Preparation of sample solution:

For the analysis of marketing formulations, 5 tablets of VRIDUTA 0.5 were weighed accurately and powdered. Tablet powder equivalents to 5mg of Dutasteride was weighed and transferred into a 50ml volumetric flask and added a minimum quantity of Ethanol to dissolve the substance by using ultra sonicator for 15mins and made up to the volume with the same (1000µg/ml). Content was filtered through the wattmann filter paper No.41. From the clear solution further dilution 4ml to 100ml volumetric flask with solvent to obtain 40µg/ml of Dutasteride and determined by using multivariate equation. Procedure was repeated for 6 times.

3.6 Method Validation:

The method was validated according to International Conference on Harmonization (ICH) Q2A and Q2B guidelines for validation of analytical procedure to determine the linearity, limit of detection, limit of quantification, accuracy and precisions.

RESULT AND DISCUSSION:

Dutasteride was estimated by proposed multivariate UV spectrophotometric method in tablets. Dutasteride was found to be soluble in Ethanol. Hence Ethanol was selected for Dutasteride to obtain UV spectrum in the range of 265-273 nm. After the evaluation of the spectrum, Dutasteride presented maximum absorbance at 269 nm.

4.1 Linearity:

The linearity evaluation study is done by linear regression analysis. A validation sets consisting of six solutions in working range of 1-6µg/ml were freshly prepared. The absorbance was recorded and plotted calibration curve against concentration, which followed the beers law and gave a straight line. In order to improve this correlation and minimize instrumental fluctuations, absorbances of these solutions were measured over a range surrounding 269 nm i.e., 265, 267, 269, 271, 273 nm. The linearity range was found to be linear in the concentration range of 1-6 µg/ml Correlation coefficient value was found to (r2) greater than 0.99. Limit of detection (LOD) and Limit of Quantification (LOQ) value was found to be and The calibration curves of Dutasteride at different wave lengths are shown in Figure1.The reports were shown in table

4.2 Accuracy:

The accuracy of the method was confirmed by recovery studies. Recovery studies were carried out by spiking different concentrations of pure drug to the pre-analysed sample at different concentrations level (50%, 75%, and 100%). The percentage recovery was found to be in the range from 99.17 to 100.37%. The percentage RSD value was found to be 1.3196 to 1.6404%. The low percentage RSD value indicated there was no interference due to excipients used in formulation. The %RSD >2% (Table-) indicated that the proposed method was accurate. The reports of analysis were shown in table 9.

4.3 Precision:

Precision of the method was confirmed by the repeated analysis of formulation for 6 times. The percentage relative standard deviation values were found to be 1.37712%. The reports of analysis were shown in table 8. The low percentage RSD values indicate that the precision of the method was confirmed. The developed methods were applied to the quantification of Dutasteride in tablet dosage forms available in the local market. The results were tabulated in table 2. It can be seen that, the results obtained by proposed method was very much similar to that of established methods.

4.4 Optical Characteristics of Dutasteride:

Table: 1 Optical Characteristics of Dutasteride

Parameters	AT265nm	AT267nm	AT269nm	AT271nm	AT273nm
Beer's law limit(µg/mL)	1-5	1-5	1-5	1-5	1-5
LOD(µg/mL)	1.579	0.941	0.420	1.189	1.270
LOQ(µg/ mL)	4.785	2.850	1.272	3.602	3.848
Regression equation Y= mx+C	0.083X+0.082	0.086X+0.071	0.101X+0.049	0.086X+0.089	0.086X+0.100
Slope(m)	0.083	0.086	0.101	0.086	0.086
Intercept(c)	0.082	0.071	0.049	0.089	0.100
Correlation coefficient	0.9998	0.999	0.9936	0.9997	0.9995

4.5 Precision Study for Formulation (Vriduta0.5)

Table: 2 Precision Study for Formulation (Vriduta0.5)

Drug Name	Wavelength (nm)	Labeled Amount (mg/tablet)	Amount Found (mg)	Percentage Obtained (%)	Average (%)	SD	%RSD
Dutasteride	265	0.5	0.48875	97.75	99.1	1.36473	1.37712
	267	0.5	0.50625	101.2			
	269	0.5	0.49375	98.75			
	271	0.5	0.49125	98.25			
	273	0.5	0.4955	99.1			

4.6 Recovery Study Data of Pre-Analysed Formulation:

Table: 3 6 Recovery Study Data of Pre-Analysed Formulation

Wavelength (nm)	Amount present (µg/ml)	Amount added (µg/ml)	Amount recovered (µg/ml)	% Recovery	Average %	SD	% RSD

265	3	1	0.975	97.5	99.03	1.403	1.416
		2	2.005	100.25			
		3	2.9808	99.36			
267	3	1	0.9853	98.53	99.666	1.5024	1.5074
		2	2.0274	101.37			
		3	2.973	99.10			
269	3	1	1.012	101.2	100.07	1.3206	1.3196
		2	2.008	100.4			
		3	2.958	98.62			
271	3	1	0.9835	98.35	100.37	1.461	1.455
		2	2.002	100.11			
		3	3.0375	101.25			
273	3	1	0.975	97.50	99.16	1.447	1.459
		2	1.997	99.89			
		3	3.003	100.11			

4.7 Determination of Wave Length for Measurement (λmax):

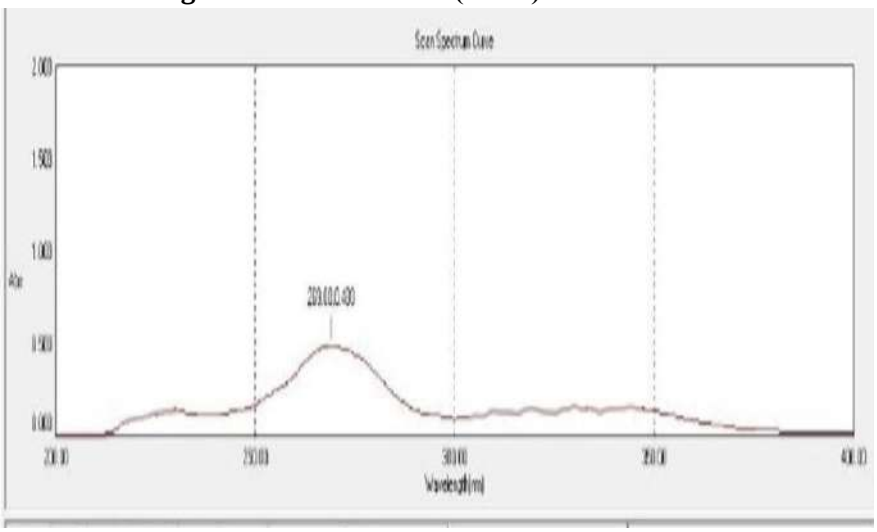

Fig: 2 Determination of Wave Length for Measurement

4.8 UV-Spectrum Of Dutasteride:

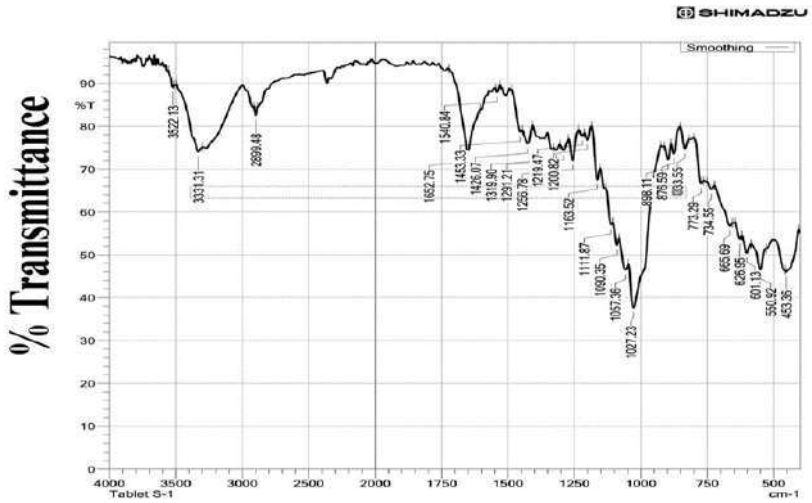

Fig: 3 Infra-Red Spectrum of Dutasteride

4.9 Calibration Graphs:

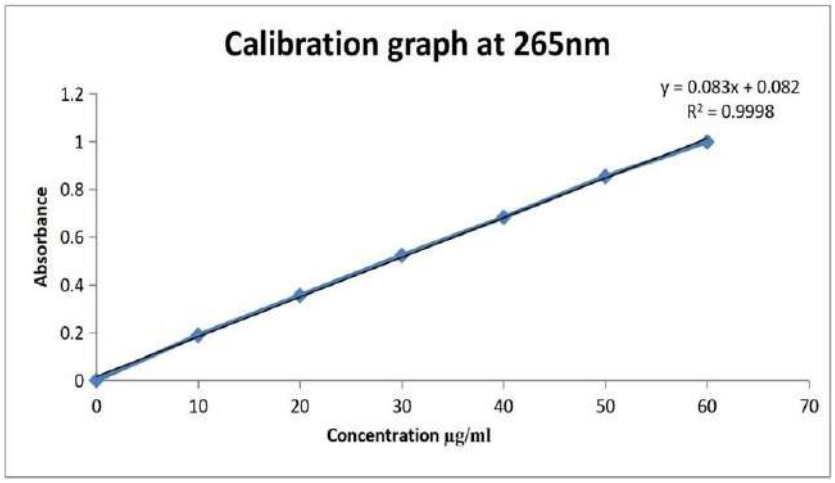

Fig: 4 Calibration Curve for Dutasteride at 265nm

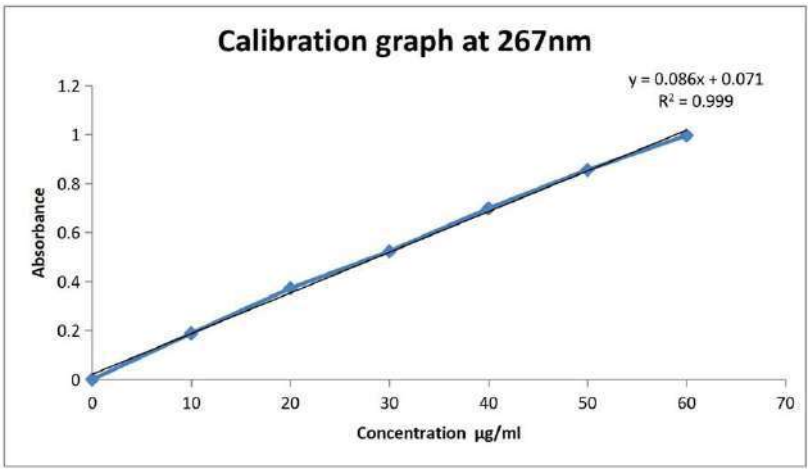

Fig: 5 Calibration Curve for Dutasteride at 267nm

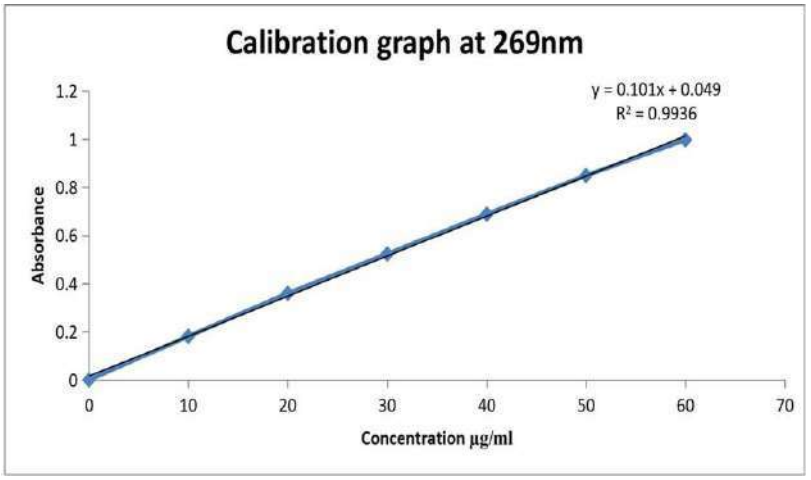

Fig: 6 Calibration Curve for Dutasteride at 269 nm

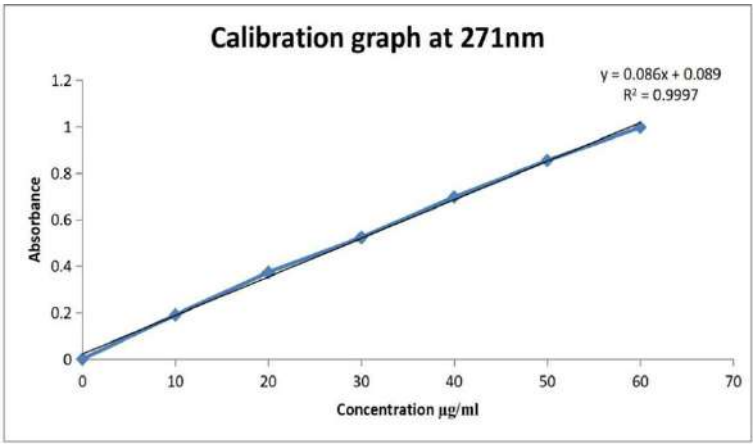

Fig: 7 Calibration Curve for Dutasteride at 271 nm

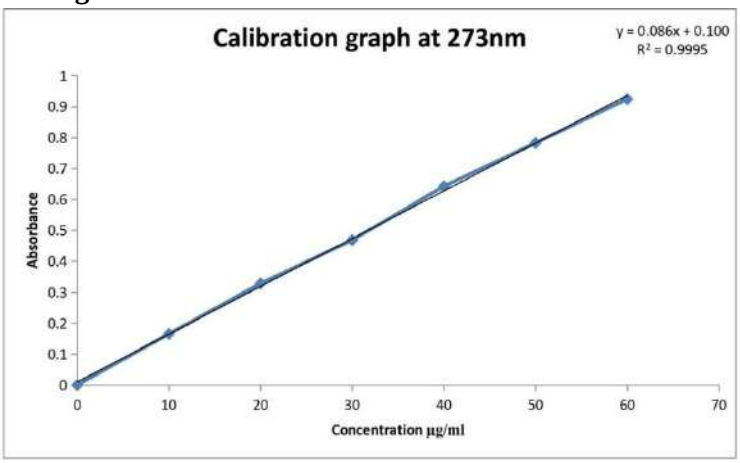

Fig: 8 Calibration Curve for Dutasteride at 273nm

CONCLUSION

The proposed method is simple, precise and accurate for the determination of Dutasteride in bulk and in pharmaceutical dosage forms by the multivariate spectrophotometric method. Hence this method is very useful with very simple mathematical contents is more reliable than the other spectrophotometric methods and strongly recommends the developed method can be effectively applied for the routine analysis of Dutasteride in tablet formulation In Conclusion, the development and validation of a multivariate spectroscopic method for estimating dutasteride using UV and IR spectroscopy have demonstrated significant advancements in pharmaceutical analysis. The integration of multivariate analysis techniques, such as Partial Least Squares Regression (PLSR) and Principal Component Analysis (PCA), has enhanced the accuracy and sensitivity of the estimation process. The method's validation, encompassing parameters like accuracy, precision, sensitivity, specificity, and robustness, confirms its reliability and suitability for routine quality control in pharmaceutical settings. The successful application of this method underscores its potential to streamline analytical procedures, reduce reliance on complex instrumentation, and offer a cost-effective alternative for the estimation of dutasteride in various formulations. Future research could focus on expanding the applicability of this method to other pharmaceutical compounds, further refining multivariate analysis techniques, and exploring the integration of this approach with other analytical platforms to enhance its versatility and robustness

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