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UV VISIBLE SPECTROPHOTOMETRIC METHOD FOR THE SIMULTANEOUS ESTIMATION OF FINASTERIDE AND DUTASTERIDE

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ABSTRACT

A simple, accurate, precise, and economical UV-visible spectrophotometric method was developed and validated for the simultaneous estimation of Finasteride and Dutasteride in bulk drug samples and pharmaceutical dosage forms. The method was developed according to International Council for Harmonisation guidelines. Methanol was selected as the solvent for the study of both drugs. Finasteride was having maximum absorbance at 240 nm, while Dutasteride was having maximum absorbance at 245 nm. The linearity range for both drugs was found to be 10–50 µg/mL with correlation coefficients of 0.9987 for Finasteride and 0.9999 for Dutasteride, indicating excellent linearity. Accuracy studies were performed by the recovery method at 80%, 100%, and 120% levels, and satisfactory percentage recoveries were obtained for both drugs. %RSD values of Precision studies, including intra-day and inter-day analysis were below 2%, confirming the reproducibility and reliability of the method. The developed method was successfully applied for the assay of tablet formulations of marketed products. The results demonstrated that the proposed UV spectrophotometric method is simple, sensitive, rapid, and suitable for routine quality control analysis of Finasteride and Dutasteride in pharmaceutical formulations.

KEYWORDS: Dutasteride, Finasteride, Simultaneous Estimation, UV-Visible Spectrophotometry, Benign prostatic hyperplasia, ICH Guidelines.

1. INTRODUCTION

1.1 Finasteride: Finasteride is a selective inhibitor of the type II 5α-reductase enzyme used in the treatment of benign prostatic hyperplasia and androgenetic alopecia. It reduces the conversion of testosterone into dihydrotestosterone (DHT), thereby decreasing prostate enlargement and hair loss. Finasteride is well absorbed, highly protein bound, and extensively metabolized in the liver. Its metabolites show low pharmacological activity, and the drug may cross the blood–brain barrier.[1]

1.2 Dutasteride: Dutasteride is a dual 5α-reductase inhibitor used in the treatment of benign prostatic hyperplasia and lower urinary tract symptoms. It inhibits the conversion of testosterone into dihydrotestosterone (DHT), the hormone mainly responsible for prostate enlargement. Dutasteride was approved by the USFDA in 2002 and is widely used worldwide.[2]

The combination dosage form of Finasteride and Dutasteride is not available in the market, hence the selection of this combination for the study is based on a clinical research where both Finasteride and Dutasteride is given in combination for better results and has obtained positive results in the study.[3,4]

1.3 Analytical method validation

When standard analytical methods were not available, new method is developed to evaluate Finasteride and Dutasteride. These techniques help reduce time and costs. The methods are optimized and validated through preliminary studies to ensure reliable results.[5]

The present work is to develop and validate UV Spectroscopic method for the determination of Finasteride Fig. 1 and Dutasteride Fig. 2 in API and pharmaceutical dosage forms as per ICH Guidelines for solubility, selection of solvent, selection of Wavelength, Linearity, Range, Accuracy, Precision, Limit of

Detection (LOD) and Limit of Quantification (LOQ) were assessed.[6]

1.4 Drug Structure

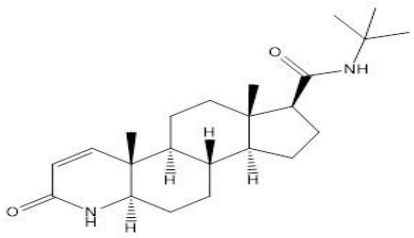

Fig. 1: Finasteride.[7]

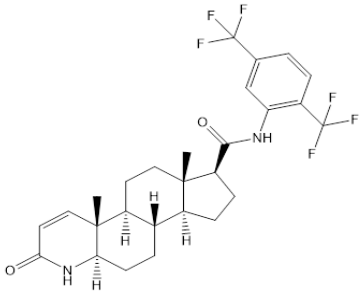

Fig. 2: Dutasteride.[8]

2. MATERIALS AND METHODS

2.1 Materials: The glassware and apparatus used were made of borosilicate glass and were calibrated before use. A calibrated digital weighing balance (Sartorius TE-214S, 200 g capacity) was used for weighing chemicals. UV-Visible analysis was performed using a Shimadzu UV-1700 Pharmaspec double-beam spectrophotometer with 10 mm quartz cells. FT-IR analysis was carried out using a Shimadzu FTIR-8400S with the KBr pellet method for API characterization. An ultrasonic bath (RC System MU1700) was used to ensure complete mixing of the samples. Finasteride and Dutasteride APIs were obtained as gift samples from CTX Life Sciences Pvt. Ltd., Surat, Gujarat, India. Commercial tablets, Finatoril 1 mg and Dutandro 0.5 mg, were purchased from a local pharmacy in Bangalore, India.

2.2 Solubility

Solubility of Finasteride: 10 mg of Finasteride was weighed and added to 4 different 10 ml volumetric flasks and add little amount of Water, Methanol, 0.1N NaOH and 0.1N Hcl respectively and shaken for 1-2 min and then made up the volume with respective solvents where results were found that the drug Finasteride was insoluble in water, slightly soluble in 0.1N NaOH and 0.1N Hcl and freely soluble in Methanol.

Solubility of Dutasteride: 10 mg Dutasteride was weighed and added to 4 different 10 ml volumetric flasks and add little amount of Water, Methanol 0.1N NaOH and 0.1N Hcl respectively and shaken for 1-2 min and then made up the volume with respective solvents where results were found that the drug Dutasteride was insoluble in water, slightly soluble in 0.1N NaOH and 0.1N Hcl and freely soluble in Methanol.

2.3 Selection of Solvent: From the above studies Finasteride and Dutasteride both were found to be soluble in Methanol. Hence Methanol was selected as solvent to carry the research work.

2.4 Selection of wavelength and Analytical Concentration Range for Finasteride

The standard stock solution-1 of Finasteride (1000 µg/mL) was prepared by dissolving 10 mg of pure drug in 10 mL of methanol. From this, 1 mL was transferred into a 10 mL volumetric flask and the volume was made up with water to obtain Stock Solution-2 (100 µg/mL). Further, working solutions in the range of 10–50 µg/mL were prepared from Stock Solution-2 and diluted up to volume with water. These solutions were scanned in the wavelength range of 200–400 nm fig no 1, and 240 nm was selected as the analytical wavelength based on maximum absorbance, which ranged from 0.172 (10 µg/mL) to 0.754 (50 µg/mL).

2.5 Selection of wavelength and Analytical concentration range for Dutasteride

The standard stock solution-1 of Dutasteride (1000 µg/mL) was prepared by dissolving 10 mg of pure drug in 10 mL of methanol. From this, 1 mL was transferred to a 10 mL volumetric flask and diluted to volume using a methanol: water mixture (50:50), as Dutasteride tends to precipitate when water content is increased. This gave Stock Solution-2 (100 µg/mL). Working solutions in the concentration range of 10–50 µg/mL were then prepared from Stock Solution-2 and making up the volume with methanol: water (50:50). These solutions were scanned between 200–400 nm fig no 2, and 240 nm was selected as the analytical wavelength, with absorbance values ranging from 0.166 (10 µg/mL) to 0.773 (50 µg/mL).

2.6 Analysis of Tablet Formulation

Since the combination tablets of Finasteride and Dutasteride were not available in the market, a synthetic mixture was prepared using individual marketed formulations of Finasteride (Finatoril 1 mg) and Dutasteride (Dutandro 0.5 mg). Ten tablets of each drug were accurately weighed and crushed together to obtain a fine powder. An amount of powder equivalent to 10 mg of Finasteride and 5 mg of Dutasteride was accurately weighed and transferred into a 100 mL volumetric flask. About 30 mL of methanol was added, and the mixture was sonicated for 10 minutes to ensure complete dissolution. The volume was then made up to the mark with methanol to obtain a stock solution containing 100 µg/mL of Finasteride and 50 µg/mL of Dutasteride. This solution was filtered through Whatman filter paper No. 41 and labelled as Sample Stock A. From Sample Stock A, 1 mL of aliquot was pipetted into a 10 mL volumetric flask and diluted with methanol to obtain the working sample solution containing 10 µg/mL of Finasteride and 0.5 µg/mL of Dutasteride. This was labelled as Sample

Stock B. The prepared sample solution was scanned at 240 nm and 245 nm, and the corresponding absorbance values were recorded.[9,10]

The concentration of two Drugs (X and Y) in sample solution was calculated by using Simultaneous equations: (Vierordt's Equation)

$C_x = A_2ay_1 - A_1ay_2 / ax_2ay_1 - ax_1ay_2$

$C_y = A_1ax_2 - A_2ax_1 / ax_2ay_1 - ax_1ay_2$

Where, ax_1, ax_2, ay_1 and ay_2 are the absorptivity's of X and Y at λ_1 and λ_2 respectively.

A_1 and A_2 are the absorbance of diluted sample at λ_1 and λ_2 respectively.

2.7 Validation of Spectrophotometric Method

2.7.1 Precision Study of Finasteride

Intermediate Precision

Intra-day Precision: To evaluate the variation in results, the absorbance of standard Finasteride solutions (10, 20, and 30 µg/mL) was measured at 240 nm at three different time intervals on the same day (0 h, 2 h, and 4 h). The % RSD was calculated to assess precision using the following formula: table no 3

$$\%RSD = (SD / mean) \times 100$$

Inter-day Precision: The variation in results was evaluated by measuring the absorbance of standard Finasteride solutions (10, 20, and 30 µg/mL) at 239 nm at the same time over three consecutive days. The % RSD was calculated to assess the reproducibility of the method using the following formula: table no 4

$$\%RSD = (SD / mean) \times 100$$

2.7.2 Precision Study of Dutasteride

Intermediate Precision

Intra-day Precision: The variation in results was evaluated by measuring the absorbance of standard Dutasteride solutions (10, 20, and 30 µg/mL) at 245 nm at different time intervals (0 h, 2 h, and 4 h) within the same day. The % RSD was calculated using the following formula: table no 5

$$\%RSD = (SD / mean) \times 100$$

Inter-day precision: The variation in results was assessed by measuring the absorbance of standard Dutasteride solutions (10, 20, and 30 µg/mL) at 245 nm at the same time over three consecutive days. The % RSD was calculated using the same formula [11] table no 6

$$\%RSD = (SD / mean) \times 100$$

2.7.3 Accuracy Studies of Finasteride and Dutasteride

Finasteride: To evaluate the accuracy of the method, the assay of the synthetic mixture was performed. Recovery studies were carried out using the standard addition method by spiking a known amount of Finasteride standard separately into the pre-analysed sample at three different levels, i.e., 80%, 100%, and 120% of the assay concentration. The percentage recovery was then calculated.

Dutasteride: The accuracy of the method was assessed by performing recovery studies on the synthetic mixture using the standard addition method. A known amount of Dutasteride standard was separately added to the pre-analysed sample at 80%, 100%, and 120% of the assay concentration, and the percentage recovery was calculated accordingly.

2.3.4 Limit of Detection (LOD) and Limit of Quantification (LOQ) of Dutasteride

The detection limit (LOD) and quantification limit (LOQ) were determined using the y-intercepts obtained from six calibration curves and the average slope of these calibration curves. The LOD and LOQ were calculated using the following equations:

LOD = 3.3 × (Standard Deviation of y-intercepts of six calibration curves) / (Average slope of six calibration curves) LOQ = 10 × (Standard Deviation of y-intercepts of six calibration curves) / (Average slope of six calibration curves).[12]

3. RESULTS AND DISCUSSION

3.1 Linearity studies of Finasteride

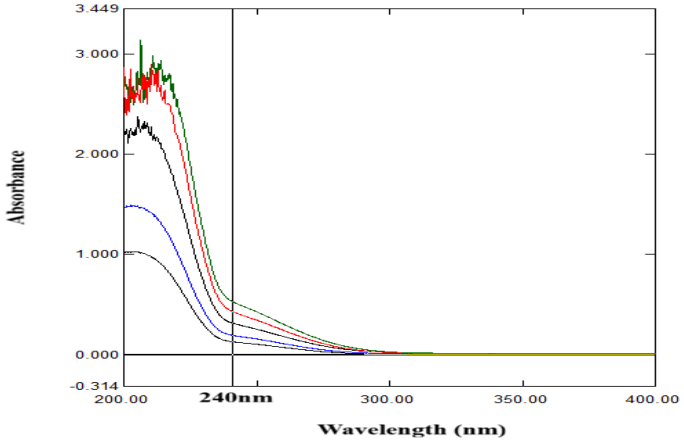

Fig. 3: The linearity of this method was determined at ranges from 10-50µg/ml for finasteride.

Table No. 1: Linearity range for Finasteride.

Conc µg/ml	Average Abs	SD	%RSD
10	0.172	0.001708	0.990
20	0.305	0.001972	0.645
30	0.450	0.003236	0.717
40	0.616	0.002134	0.346
50	0.754	0.003023	0.400

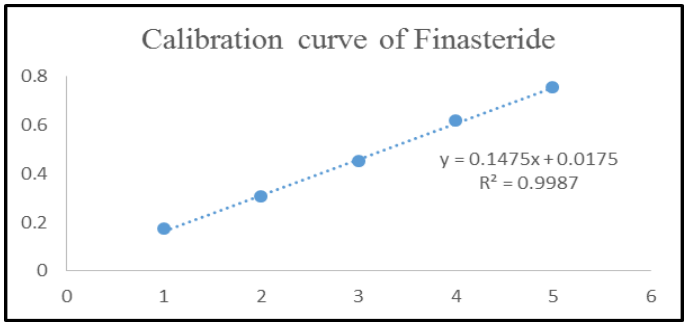

Fig. 4: Calibration curve of finasteride. [The Linearity for Finasteride was found to be linear in the range of 10-50 µg/ml with R^2= 0.9987 and the straight-line equation as Y=0.1475+ 0.0175 and R2=0.9987.]

3.2 Linearity studies of Dutasteride

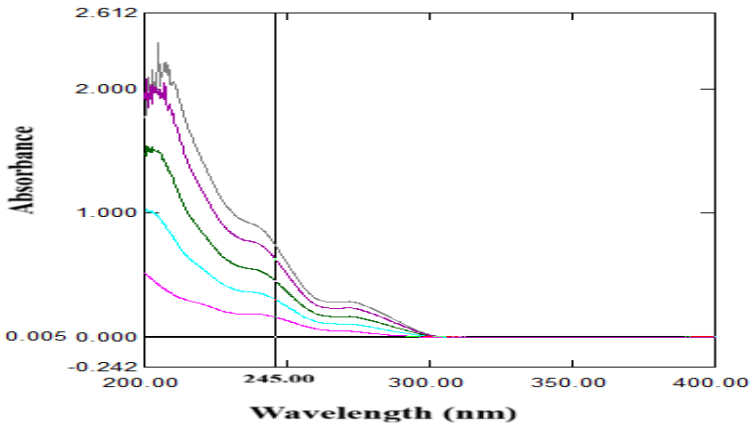

Fig. 5: The linearity of this method was determined at ranges from 10-50µg/ml for dutasteride.

Table No. 2: Linearity range for Dutasteride.

Conc µg/ml	Average Abs	SD	%RSD
10	0.169	0.002672	1.579
20	0.319	0.005336	1.668
30	0.474	0.002339	0.492
40	0.625	0.002544	0.406
50	0.773	0.002672	0.345

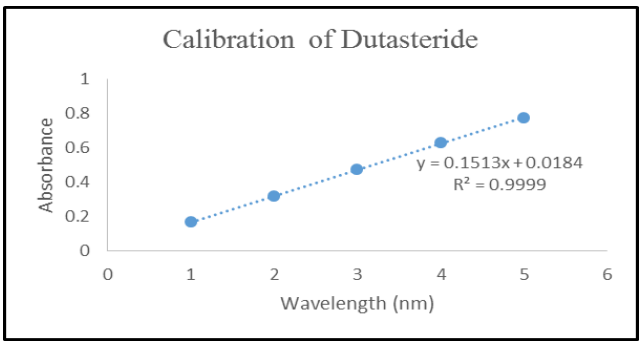

Fig. 4: Calibration curve of dutasteride. [The Linearity for Finasteride was found to be linear in the range of 10-50 µg/ml with R^2= 0.9999 and the straight-line equation as Y=0.1513+ 0.0184 and R2=0.9999.]

3.3 Overlay spectra of Finasteride and Dutasteride

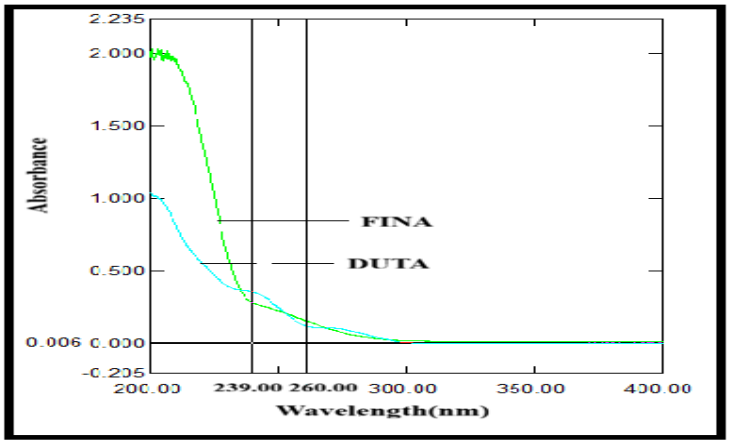

Fig. 5: Overlay spectra of Finasteride (40µg/ml) and Dutasteride (20µg/ml).

3.4 Precision studies

Table No. 3: Intraday studies if Finasteride.

Conc (µg/ml)	0 hr	2 hr	4hr	Average	SD	%RSD
10	0.175	0.177	0.178	0.176	0.001247	0.708
20	0.305	0.309	0.312	0.308	0.002867	0.930
30	0.443	0.447	0.441	0.443	0.002494	0.562

Table No. 4: Interday studies if Finasteride.

Conc (µg/ml)	Day 1	Day 2	Day 3	Average	SD	%RSD
10	0.175	0.179	0.181	0.178333	0.002494	1.398
20	0.305	0.309	0.306	0.306667	0.001700	0.554
30	0.443	0.449	0.453	0.448333	0.004110	0.916

Table No. 5: Intraday studies if Dutasteride.

Conc (µg/ml)	0 hr	2 hr	4hr	Average	SD	%RSD
10	0.168	0.167	0.169	0.168	0.000816	0.486
20	0.317	0.315	0.320	0.317	0.002055	0.647
30	0.474	0.471	0.477	0.474	0.002449	0.516

Table No. 6: Interday studies if Dutasteride.

Conc (µg/ml)	Day 1	Day 2	Day 3	Average	SD	%RSD
10	0.168	0.170	0.171	0.169	0.001247	0.735
20	0.317	0.320	0.322	0.319	0.002055	0.642
30	0.474	0.476	0.479	0.476	0.002517	0.528

3.5 Accuracy studies

Table No. 7: Accuracy results of Finasteride.

Level of recovery	Amount of std drug added(µg/ml)	Amount of sample added(µg/ml)	Total amount found(µg/ml)	Total amount recovered (µg/ml)	%Recovery
80%	8	10	17.864	7.864	98.30%
		10	17.924	7.924	99.06%
		10	18.045	8.045	100.56%
100%	10	10	20.116	10.116	101.16%
		10	20.058	10.058	100.58%
		10	19.941	9.941	99.41%
120%	12	10	22.180	12.180	101.50%
		10	22.009	12.009	100.07%
		10	22.123	12.123	101.02%

Table No. 8: Statistical validation data for Accuracy studies of Finasteride.

Level	Mean	SDV	%RSD
80%	99.31	1.148	1.156
100%	100.38	0.888	0.884
120%	100.86	0.723	0.717

Table No. 9: Accuracy results of Dutasteride.

Level of recovery	Amount of std drug added(µg/ml)	Amount of sample added(µg/ml)	Total amount found(µg/ml)	Total amount Recovered (µg/ml)	%Recovery
80%	8	10	17.864	7.864	98.30%
		10	17.924	7.924	99.06%
		10	18.045	8.045	100.56%
100%	10	10	20.116	10.116	101.16%
		10	20.058	10.058	100.58%
		10	19.941	9.941	99.41%
120%	12	10	22.180	12.180	101.50%
		10	22.009	12.009	100.07%
		10	22.123	12.123	101.02%

Table No. 10: Statistical validation data for Accuracy studies of Dutasteride.

Level	Mean	SDV	%RSD
80%	100.4453	1.16605	1.160
100%	100.4016	0.920196	0.916
120%	100.0855	1.067521	1.066

3.6 Assay results by Simultaneous Equation method

Table No. 11: Assay results of tablet formulation.

Amount Present (mg/tab)		Amount Found (mg/tab)		%Assay	
Duta	Fina	Duta	Fina	Duta	Fina
0.5	1	0.521	1.088	104.19%	108.82%
0.5	1	0.520	1.088	104.19%	108.80%
0.5	1	0.505	1.090	101.11%	109.52%
0.5	1	0.502	1.050	100.45%	105.33%
0.5	1	0.500	1.076	100.01%	107.60%
0.5	1	0.510	1.082	102.10%	108.21%
MEAN SD %RSD		0.509	1.079	102.01%	108.05%
		0.009031	0.013796	0.016712	0.013505
		1.771	1.278	1.638	1.249

Table 12: Summary of UV-Visible Spectrophotometric Method.

Parameters	FINA	DUTA
Wavelength (nm)	**240nm**	**245nm**
Linearity Range (µg/ml)	10-50µg/ml	10-50µg/ml
Regression Equation (y=mx+c)	Y=0.1475+0.0175	Y=0.1513x+0.0184
Correlation Coefficient (R^2)	0.9987	0.9999
LOD (µg/ml)	2.482	7.522
LOQ (µg/ml)	0.0792	0.2401
Analysis of Tablets (Mean %Assay)	102.01%	108.05%
% Recovery	100.86%	100.08%
Intra Day Precision (%RSD)	0.928%	0.647%
Inter Day Precision (%RSD)	1.398%	0.642%

4. CONCLUSION

The present study focused on the development and validation of a simple, economical, and reliable UV spectrophotometric method for the estimation of Finasteride and Dutasteride in both bulk drug samples and tablet formulations as per ICH guidelines. The method demonstrated good linearity, accuracy, precision, and sensitivity throughout the study. The obtained results showed that both drugs can be effectively and accurately estimated in pharmaceutical dosage forms as well as bulk

APIs. The lower %RSD values indicated that the method possesses good repeatability and intermediate precision, while the satisfactory recovery studies confirmed its accuracy. Hence, the developed method can be conveniently used for routine quality control analysis of Finasteride and Dutasteride in pharmaceutical industries.

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