METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF FINASTERIDE BY USING UV-VISIBLE SPECTROPHOTOMETER IN PHARMACEUTICAL FORMULATION

P. Venkata Kishore*[1], Dr.D. Narendra[2], G.S.N. Sirisha[3], G. Madhu Bhavya Sri[4], R. Keerthi[5], M. Supriya[6]

VJ's College of Pharmacy, Diwancheruvu, Rajahmundry-533296, Andhra Pradesh, India

*Corresponding author E-mail: **kishorepenumantra@gmail.com**

| ARTICLE INFO	ABSTRACT
Key words: Finasteride, UV-Spectrophotometer, Validation Access this article online Website: **https://www.jgtps.com/** Quick Response Code:	A simple, accurate, precise, reproducible, highly sensitive, an economic spectrophotometric method has been developed for the estimation of Finasteride. UV-Visible spectrophotometric method is based on the measurement of absorption at a maximum wavelength of 255 nm. The developed method was validated with respect to linearity, accuracy (recovery), precision (inter and intraday variations). Beer's law was obeyed in the concentration range of 5–25 µg/mL with a correlation coefficient of 0.9994. Results of the analysis were validated statistically and by recovery study. Hence the developed and validated method can be used for estimation of Finasteride.

INTRODUCTION

Finasteride, sold under the brand names Proscar and Propecia among others, is a medication used to treat hair loss and benign prostatic hyperplasia (BPH) in men. It can also be used to treat excessive hair growth in women and as a part of hormone therapy for transgender women. It is taken by mouth. Finasteride is a 5α-reductase inhibitor and therefore an antiandrogen. It works by decreasing the production of dihydrotestosterone (DHT) by about 70%, including in the prostate gland and the scalp. In addition to DHT, finasteride also inhibits the production of several anticonvulsant edrioasteroids including allopregnanolone, androstane diol. Adverse effects from finasteride are rare; however some men experience sexual dysfunction, depression, and breast enlargement. In some men, sexual dysfunction may persist after stopping the Medication. It may also hide the early symptoms of certain forms of prostate cancer.
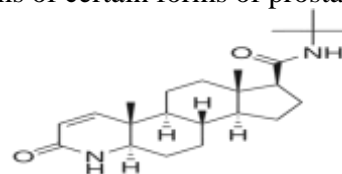
Fig.-01- Finesteride

Finasteride was patented in 1984 and approved for medical use in 1992. It is available as a generic medication. In 2020, it was the 90th most commonly prescribed medication in the United States, with more than 8 million prescriptions. Finasteride is used in the treat hair loss in men. It is used to increase hair growth and prevent further hair loss with male pattern baldness (gradual thinning of hair with receding hairline or thinning on the top of the head).

454

MATERIAL AND METHOD:

Instrumentation: Teccomp UV-2301 double beam UV-Visible spectrophotometer was used to carry out spectral analysis finasteride and the data was recorded by Hitachi software. Standard cuvettes of 10mm path length are used for analysis. Sonicator (1.5L) Ultrasonicator was used to sonicating the standard and formulation sample. Standard and sample drugs were weighed by using Denver electronic analytical balance (SI-234).

Reagents standard and samples: Working standard sample finasteride was obtained from well reputed research laboratory, formulation sample was purchased from local pharmacy. Spectrophotometric reagents i.e. methanol and colouring reagents like erichromo black t, methyl blue, bromocresol green and bromo thymol blue was purchased.

PROCEDURE

Preparation of standard stock solution: Take 0.01g of finasteride i.e., 10mg which is to be solubilized in the 10ml of methanol. So, 1000 µg/ml has been prepared as a stock. Then take 1ml stock solution and then add 9ml oh methanol so 100 µg/ml has been prepared. From 100 µg/ml take 1ml and make up with 9ml of methanol so 10 µg/ml has been prepared. So, find the λmax of 10 µg/ml I.e., 345.5

Preparation of dilutions: For 20 **µg/**ml we need to take 100 µg/ml in that we require 2ml of stock solution and we need to add 8ml of methanol. Same as prepare concentration of 40, 60, 80,100,120 µg/ml.

Preparation of formulation sample: We have obtained finasteride formulation here we have taken 3 brands. They are Finax, Finpecia, Finrest. The weight of the finax tablet is of 0.08gm the dosage of the tablet is of 1mg.The weight of the imperia tablet is of 0.07 gm dosage is about 1mg.The weight of the finrest is of 0.19gm dosage is about 1mg

Preparation of the sample: Take a complete tablet which means 1mg make it into fine powder then dissolve in 1ml of methanol by sonication. Repeat the same procedure for the remaining brands too. It is of 1000µg/ml.From this make 100 µg and further we ned to use 10 µg to find absorbance.

UV Spectrophotometric estimation:

Selection of solvent for solubility: The drug finasteride was practically soluble in Water and absorbance of solution was measured. Finally, dilutions with water were show improved absorbance compared to other solvents. Hence standard drug was soluble in water and necessary required dilutions were prepared with water as diluents for spectrophotometric estimation.

Selection of wavelength maxima: Suitable maximum absorbance for the estimation of finasteride was identified by scanning the absorbance in spectrum mode within the wavelength region of 400-200nm in three different dilute solutions. In all the solutions the drug absorbs maximum wavelength at 215nm. Hence 215nm was found to be suitable wavelength for the estimation of finasteride

Construction of calibration curve: From the prepared standard stock solution, a series of calibration standards were prepared by selected dilutions. From the stock solution, 20µg/ml, 40, 60, 80,100,120µg/ml was prepared. The absorbance of the prepared solutions was measured at 215nm against a regent blank. At each concentration triplet readings were measured and mean value was used for the Construction of calibration curve. Calibration curve was constructed by taking concentration of the prepared solution on x-axis and corresponding absorbance on y-axis.

Formulation analysis: The absorbance of the prepared formulation solution in all the brands was measured at 345.5nm in triplets separately. The average absorbance value was used for the formulation estimation of finasteride. The % assay estimated in the prepared sample solutions by substituting the absorbance values in the equation given.

$$\% \text{ Assay} = \frac{At}{As} \times \frac{Ws}{Ds} \times \frac{Dt}{Wt} \times \frac{P}{100} \times \frac{AW}{LC} \times 100$$

Where, At = Absorbance of the sample, As = Absorbance of the Standard, Ws = Weight of the Standard in mg, Wt = Weight of the Sample in mg, Dt = Dilution of the Sample Solution, Ds = Dilution of the Standard Solution, AW = Average Weight of the Tablet LC = Label Claim of the Tablet
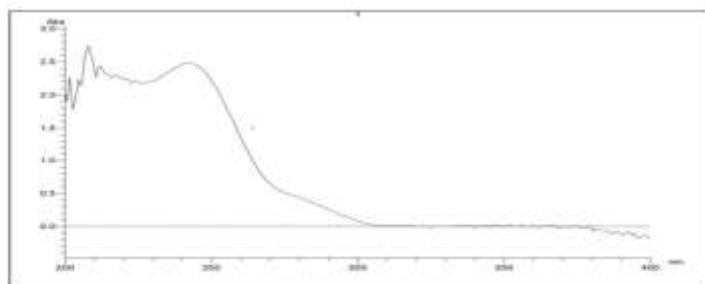P = % Purity of the Standard Drug

Fig.02 – wave length scanning spectrum of finasteride in UV region

S.No	Concentration	Average Absorbance
1	20μg/ml	0.352
2	40μg/ml	0.369
3	60μg/ml	0.382
4	80μg/ml	0.394
5	100μg/ml	0.417
6	120μg/ml	0.427

Table. 01- Calibration curve result
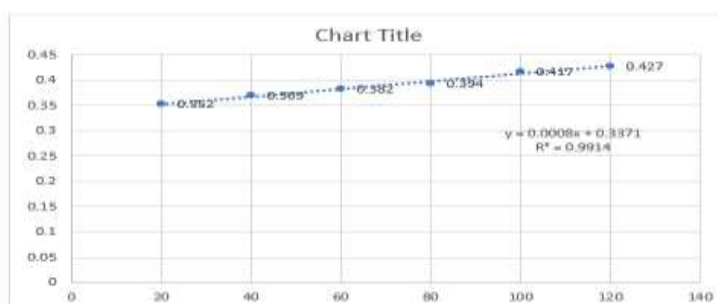
Fig. 03- Calibration curve of Finasteride in UV

S.no	Brand	Dosage	Amount Prepared	Absorbance Found	%Assay
1	Finpecia	1mg	10μg/ml	0.412	91.25%
2	Finax	1mg	10μg/ml	0.409	87.5%
3	Finrest	1mg	10μg/ml	0.405	82.5%

Table.02- Formulation result in UV

Visible Spectrophotometric estimation:
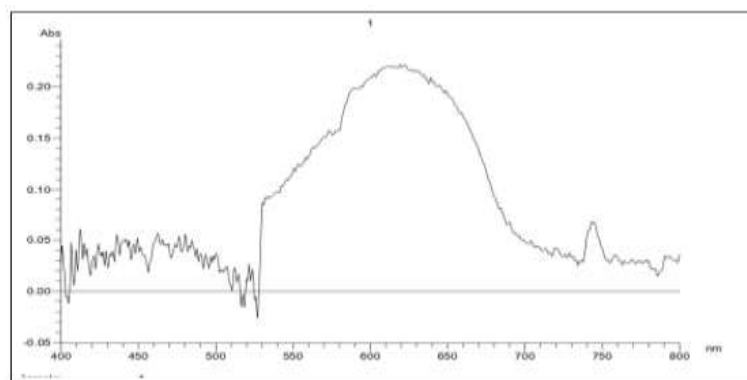
Fig.04- wavelength scanning spectrum of Finasteride in Visible region

S.NO	Concentration	Average Absorbance
1	0.2µg/ml	0.220
2	0.48µg/ml	0.257
3	0.68µg/ml	0.298
4	0.8µg/ml	0.324
5	1µg/ml	0.38
6	1.2µg/ml	0.446
	Slope, Intercept Correlation Coefficient	0.9913

Table.03-Calibration curve results
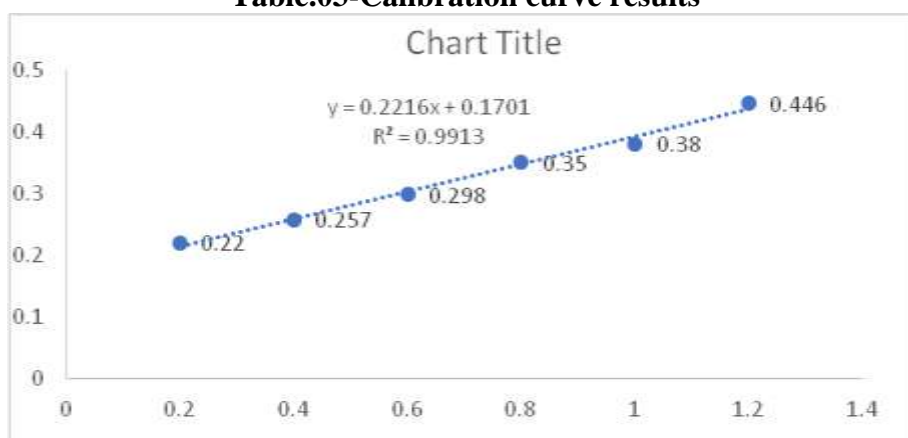
Fig. 05- Calibration curve of Finasteride in Visible method

S.no	Brand	Dosage	Amount Prepared	Absorbance Found	%Assay
1	Finrest	1Mg	10µg/ml	1.923	79.70%
2	Finpecia	1 Mg	10µg/ml	1.983	82.43%
3	Finax	1 Mg	10µg/ml	1.993	82.88%

Table.04 – Formulation results

VISIBLE SPECTROPHOTOMETRY:
Visible spectrophotometer estimation
Preparation of reagents: Eri chrome black-t -Take 0.1 ml of Eri chrome black -t dissolve in 100 ml of water. Methyl orange -take 0.1 ml of methyl orange dissolve in 100 ml of water. Bromothymol Blue-Take 0.1 ml of bromothymol blue in 100ml of water
METHOD PROCEDURE:
Preparation of standard solution: Stock solution of finasteride was prepared by dissolving 100mg of finasteride in 100ml of methanol. This solution was sonicated for 5 mins make up to the volume with methanol. From the above solution 0.2 ml was pippete out and add 0.5 ml of reagent. Dissolve in 9.3 ml of water so it is taken as a stock solution.

Same as prepare concentrations of 0.4, 0.6, 0.8, 1, 1.2 µg/ml.
Preparation of blank solution: Take 1 ml from standard stock solution add 0.5 ml of reagent and make up with 8.5 ml of water
Formulation Assay: From the prepared 10µg/ml of the sample solution, 1ml was taken and the method procedure as describes above was applied. After the development of the colour, the absorbance of the separated chloroform layer was measured at 482nm against a similar reagent blank. The resultant absorbance values were used for the estimation of finasteride in the formulation assay. The % assay estimated in the prepared sample solutions by substituting the absorbance values in the equation given below.

$$\% \ Assay = \frac{At}{As} \times \frac{Ws}{Ds} \times \frac{Dt}{Wt} \times \frac{P}{100} \times \frac{AW}{LC} \times 100$$

RESULT AND DISCUSSION:

UV-Method: Wavelength maximum were identified for the finasteride drug at dilute concentration. Specific wavelength maximum was identified at a wavelength of 345.5. Hence 345.5 were found to be most suitable wavelength for the estimation of finasteride Wavelength scanning result was shown in figure-02. Good linear relation was observed within the prepared concentrations of 20-120µg/ml regression equation was found to be y = 0.008x + 0.3371 with correlation coefficient of 0.9914. Results of calibration curve was shown in fig.03 and table.01

Formulation Assay: The absorbance of the prepared formulation solutions was measured and from the resultant sample values % assay was calculated. In the estimation of Ministered. Results of the essay studies were shown in table 02. From the prepared colour developed solution of the finasteride one solution was taken and the absorbance of the solution was scanned in the visible region i.e. 800nm-400nm against a similarly prepared reagent blank. At a wavelength of 482nm was found to be most suitable for the estimation of finasteride Wavelength scanning spectrum was shown in figure- 4. Six points calibration curve was constructed with in the concentration range of 0.2-1.2µg/ml. regression equation was found to be y = 0.022x + 0.1695 with a correlation of 0.9913. Results of the calibration curve were shown in table 3 and calibration curve was shown in figure-5.

Formulation Assay: The absorbance of the prepared formulation solutions was measured and from the resultant sample the absorbance of the prepared formulation solutions was measured and from the resultant sample values % assay was calculated. Results of the essay studies were shown in table 4

CONCLUSION: Finasteride is a medication used to treat hair loss and benign prostatic hyperplasia (BPH) in men. It can also be used to treat excessive hair growth in women and as a part of hormone therapy for transgender women. It is an oral administration drug. Finasteride is a 5α-reductase inhibitor and therefore an antiandrogen. It works by decreasing the production of dihydrotestosterone (DHT) by about 70%, including in the prostate gland and the scalp. In this thesis, we estimate the drug finasteride in market tablet brands like finrest, finpecia, finax of 1mg by UV and Visible spectrophotometry. In UV region drug was estimated at 345.5nm using methanol as diluents and in visible region the colour was developed using bromothymol blue reagent. The maximum absorbance of the developed light green colour was found to be 482nm. Beers law equation was found to be y = 0.008x + 0.3379 for UV and y = 0.022x + 0.1695 for Visible method. In both these methods the drugs were estimated more than 91%.

REFERENCES:

1. Lakshmi VN, Koteswara Rao GSN, . Development and Validation of UV Spectrophotometric Method for the Estimation of Finasteride in Tablets. International Journal of Pharma Sciences, 2013; 3(1): 123-125
2. Alaa S. Optimization and validation of spectrophotometric methods for determination of finasteride in dosage and biological forms. Pharm Methods, 2012; 3(1): 48–55.
3. Agarwal S et al. (2008) A new spectrophotometric method for the determination of finasteride in tablets. Chromatographia, 2008; 67: 778-783
4. Ilango K et al. Spectrophotometric determination of finasteride in tablet formulation. Indian Drugs, 2003;40 (2):122-123.
5. Manish Kumar Thimmaraju et al. (2011) UV spectrophotometric method for determination of finasteride in bulk and pharmaceutical dosage form. Int J Pharm Bio Sci. 1(1), 39-43.
6. Ilango et al. (2002) Spectrophotometric method for the estimation of Finasteride in Tablets. Indian J Pharm Sci. 174-17.