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UV SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF FINASTERIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Research Article

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ABSTRACT

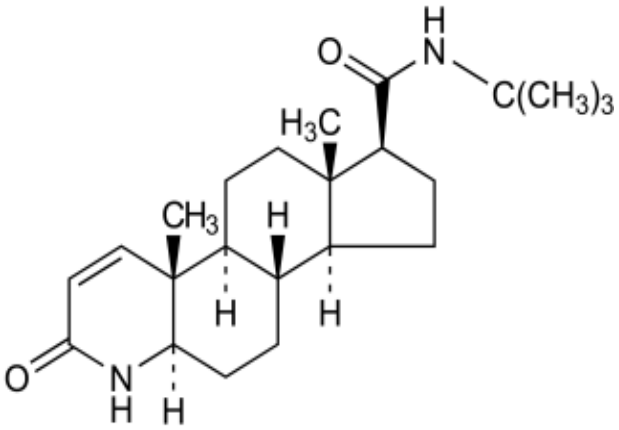
A Simple, rapid, accurate and economical UV Spectrophotometric method is developed for determination of finasteride in bulk and tablets. In chloroform, the λmax of the drug was found to be 245 nm. Using UV instrument (analytical), in this proposed method finasteride follows linearity in the concentration range 10 – 120 µg/ml with a correlation coefficient of 0.9993. Assay results were in good agreement with label claim. The methods were validated statistically and by recovery studies. The relative standard deviation was found to be 0.2319 with excellent precision and accuracy.

KEYWORDS: Finasteride, U.V.Spectrometry, chloroform.

Introduction

Finasteride , N- (1,1-dimethylethyl) –3-oxo-4-aza-5K-androst-1-ene-172-carboxamide. Finasteride, a type II 5 alpha reductase inhibitor, slowly reduces prostatic volume, Prostate growth and function is influenced by dihydrotestosterone.5alpha-reductase enzyme converts testosterone to dihydrotestosterone. Inhibition of 5 alpha reductase results in decreased level of dihydrotestosterone leading to reduction of prostate size. Finasteride has higher affinity for 5-R type II versus type I. According to the literature survey it was found that few analytical methods such as Visible, UV ,polarographic analysis, HPLC other methods were reported for Finasteride (Amer SM 2003, Amshumalli ,M.K et al., 2001 Constanzer ML et al., 1991 Carlucci G et al., 1997 ,Carlin JR et al.,1998,K.Ilango et al., 2002) .

The objective of the proposed methods to develop simple and accurate method for the determination of Finasteride by UV spectrophotometric method in Pharmaceutical dosages forms.



Structure Of Finasteride

METHODS AND MATERIALS:

Chemicals and Reagents

Finasteride, Chloroform (A.R.GRADE), Tablet formulation (FINAST)

Preparation of standard stock solution

100 mg of Finasteride was accurately weighed and dissolved in 100 ml of chloroform in 100ml volumetric flask to get the concentration about 1mg/ml stock solution. From the stock solution prepare serial dilutions from 0.1ml to 1.2 ml and transfer it to 10ml volumetric flasks. Dilute it with chloroform to get the concentrations ranging from 10µg/ml to 120µg/ml respectively. The absorbances were measured at λ_{max} 245 nm against chloroform as a blank. The spectra was shown in **FIG-1**

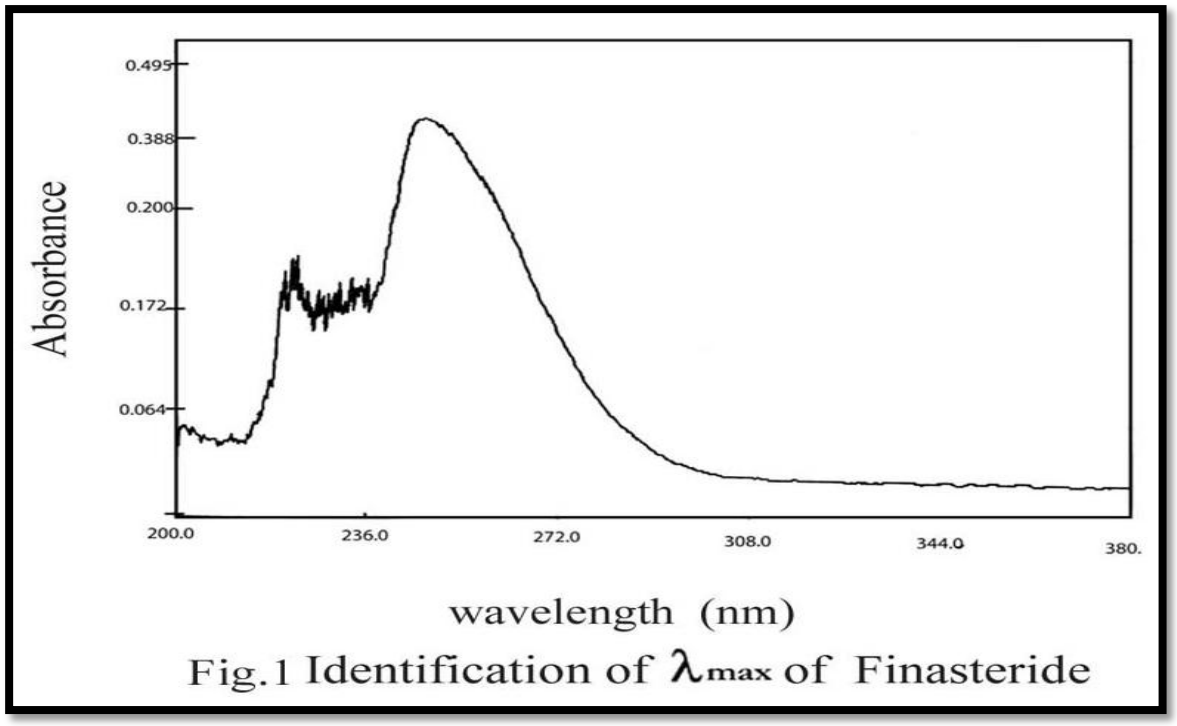


Fig.1 Identification of λ_{max} of Finasteride

Preparation of sample solution

20 tablets of marketed formulation containing Finasteride were taken and powdered. The powder equivalent to 100 mg of Finasteride was dissolved in 100 ml of chloroform, sonicated for 10 mins and filtered. From the above stock solution serial dilutions from 0.1 to 1.2ml were taken and transferred into 10ml volumetric flasks. The solutions were made up to the labelled volume with chloroform to get concentrations of about 10 to 120µg/ml respectively. The prepared solutions were measured at 245nm against chloroform as blank. Then the amount of drug present in the formulations was calculated. The results were shown in **Table-1**.

TABLE -1
RESULTS OF ASSAY

Drug	Sample no	Amount labeled (mg/tab)	Amount estimated (mg/tab)	% of label claim	% deviation
Finasteride	**1**	**5**	**4.92**	**98.4**	**(-) .6**
	2	**5**	**4.99**	**99.8**	**(-) 0.2**
	3	**5**	**4.95**	**99.1**	**(-) 0.9**

TABLE -2
SUMMARY OF UV METHOD

UV method	**Finasteride**
Absorption Maximum	245
Linearity Range (µg/ml)	10 - 120
Slope	0.0038
Correlation Coefficient (r)	0.9993
% RSD of slope	6.76
Label claim (mg/tablet)	5
Amount found	4.92
S.D	0.0104
RSD%	0.2319
Standard Error	0.00509
% Recovery	99.57

Recovery studies:

The recovery studies were carried out at three different levels i.e. 80%, 100% and 120% level. To ensure the reliability of the above method, recovery studies were carried out by mixing a known quantity of standard drug with the preanalysed sample formulation and the contents were reanalyzed by the proposed method. The percentage recovery was found and shown in **Table-3**

TABLE -3

Drug	Amount Added (µg/ml)	Amount recovered (µg/ml)	Percentage recovery (%)	Average Recovery	%RSD
Finasteride	**40** **50** **60**	**39.97** **49.52** **59.86**	**99.92** **99.09** **99.79**	**99.57**	**0.470**

RESULTS AND DISCUSSION

From the optical characteristics of the proposed method it was found that the drug obeys linearity within the concentration range of 10-120 µg/ml. From the results it was found that the percent RSD is less than 2% which indicates that the method has good reproducibility, the percent recovery values of pure drug from the preanalysed solutions of formulations were in between 99.09 -99.92%, which indicates that the method is accurate and which reveals the commonly used excipients and additives present in the pharmaceutical formulations did not interfere in the proposed method.

The proposed method was simple, sensitive and reliable with good precision and accuracy. The proposed method is specific while estimating the commercial formulations without interference of excipients and other additives. Hence, this method can be used for the routing determination of Finasteride in bulk samples and pharmaceutical formulations.

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