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UV SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS DETERMINATION OF FINASTERIDE AND TAMSULOSIN IN COMBINED DOSAGE FORM

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Research Article

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ABSTRACT

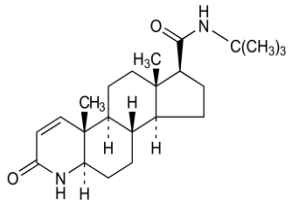
A specific, rapid and simple UV spectrophotometric method with good sensitivity was developed and validated for the simultaneous determination of finasteride and tamsulosin in standard solutions and tablets. In methanol, the λmax of finasteride and tamsulosin was found to be 219 and 224nm respectively. Using an Elico UV – Visible spectrophotometer (model SL – 159) with matched quartz cells, in this proposed method both these drugs obeyed linearity individually and in mixture with the concentration range of 12.5-62.5 µg/ml for finasteride and 1-5 µg/ml for tamsulosin with a correlation coefficient of 0.9981 and 0.9989. 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 0.5974 and0.4096 with excellent precision and accuracy.

KEYWORDS: UV spectrophotometric method, finasteride, tamsulosin, simultaneous determination, methanol

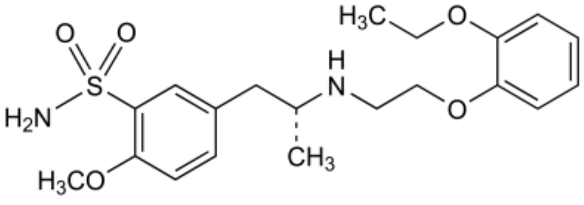
Introduction

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.5 alpha-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.Tamsulosin, 5-[(2R)-2[[2-(2-Ethoxy Phenoxy) ethyl] amino]Propyl}- 2-methoxy benzene sulfonamide. Tamsulosin is a selective alpha 1 adrenoceptor blocking agent. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha1 adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Blockade of these adrenoceptors can cause smooth muscles in the bladder, neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH. 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 and tamsulosin(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) Higuchi S et al., 1997, Soeishi Y et al., 1991. The objective of this study was to

develop and validate a simple and specific UV spectrophotometric method for the simultaneous determination of finasteride and tamsulosin in tablets. This method exhibited precise, accurate and cost effective assay for these drugs in mixture.



(1)



(2)

Fig 1. Chemical structures of Finastride (1) and Tamsulosin (2)

METHODS AND MATERIALS

Finasteride, Tamsulosin, Methanol, Double distilled water (DDW), Tablet formulation (VELTAM-F), Elico UV – Visible spectrophotometer (model SL – 159) with matched quartz cells.

Preparation of FSD Stock Solution

Standard finasteride stock solution was prepared by dissolving 125 mg of drug in methanol and volume make up to 100 ml with DDW to get concentration about of 1.25mg/ml (1250µg/ml stock solution). From stock solution take 1ml of this solution was taken and diluted to 10ml with DDW to get final concentration of 125µg/ml.

Preparation of TMS stock solution

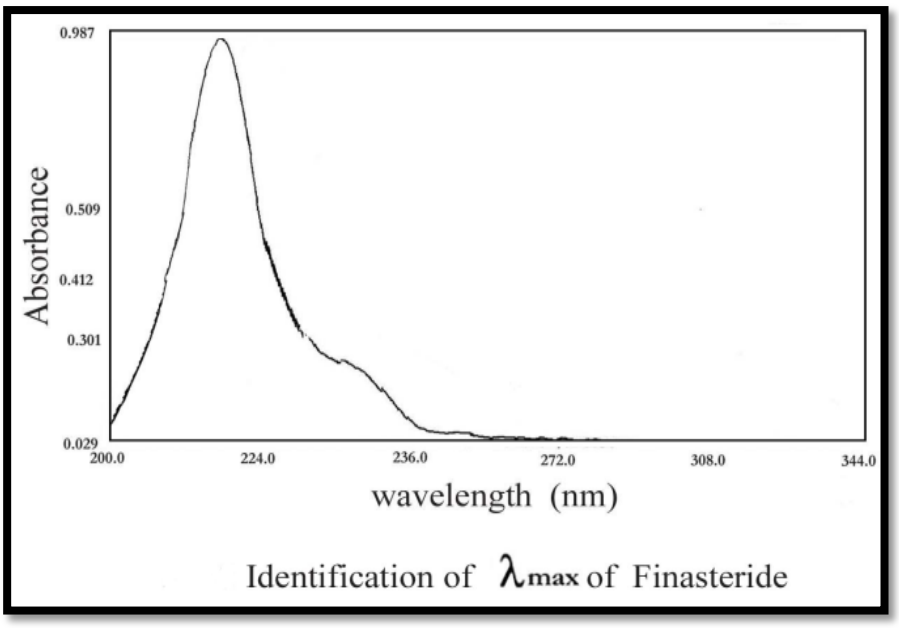
Standard tamsulosin stock solutions were prepared by dissolving 10mg drug in methanol and volume make up to 100ml with DDW to get concentration of 1mg/ml solutions. (100µg/ml)

Preparation of Linearity curve

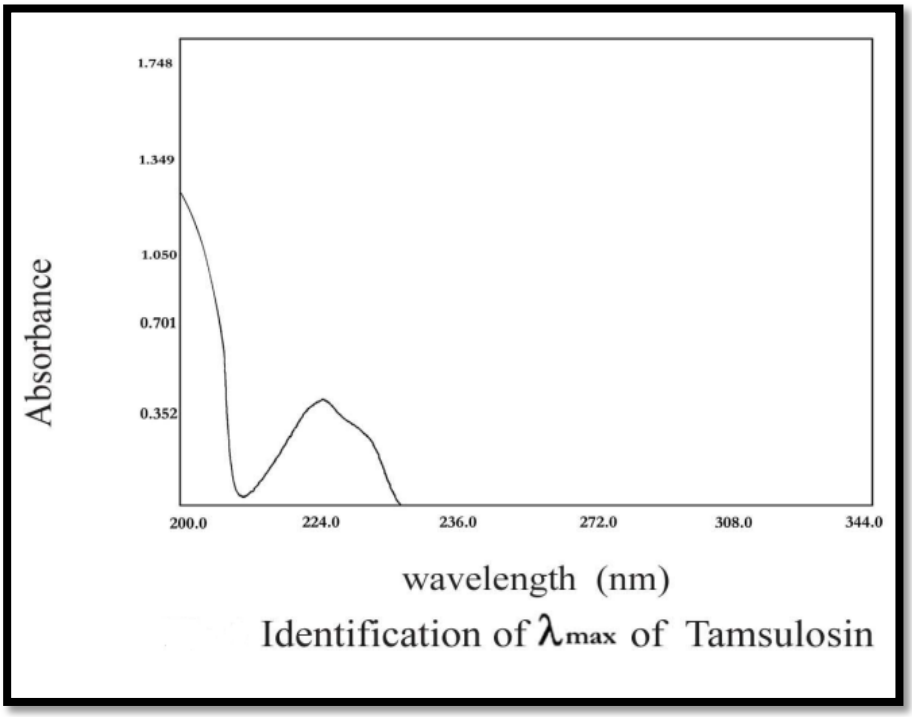
To construct Beer's law plot for finasteride and tamsulosin different aliquots of finasteride (1-5ml) with different concentrations (12.5, 25, 37.5, 50 and 62.5µg/ml) **fig-2** and tamsulosin (0.1-0.5ml) with different concentrations (1, 2, 3, 4 and 5µg/ml) **fig-3** were prepared by serial dilutions with DDW. Mixed standard solutions were prepared from working standard solutions of the two drugs .The spectra is shown in **fig-4**. Then absorbance of the solutions was measured at 219 nm for finasteride and 224 nm for tamsulosin, respectively. Both these drugs obeyed linearity individually and in mixture with the concentration range of 12.5-62.5 µg/ml for finasteride and 1-5 µg/ml for tamsulosin.

Preparation of Test Solutions and Estimation of Finasteride in Tablet formulations

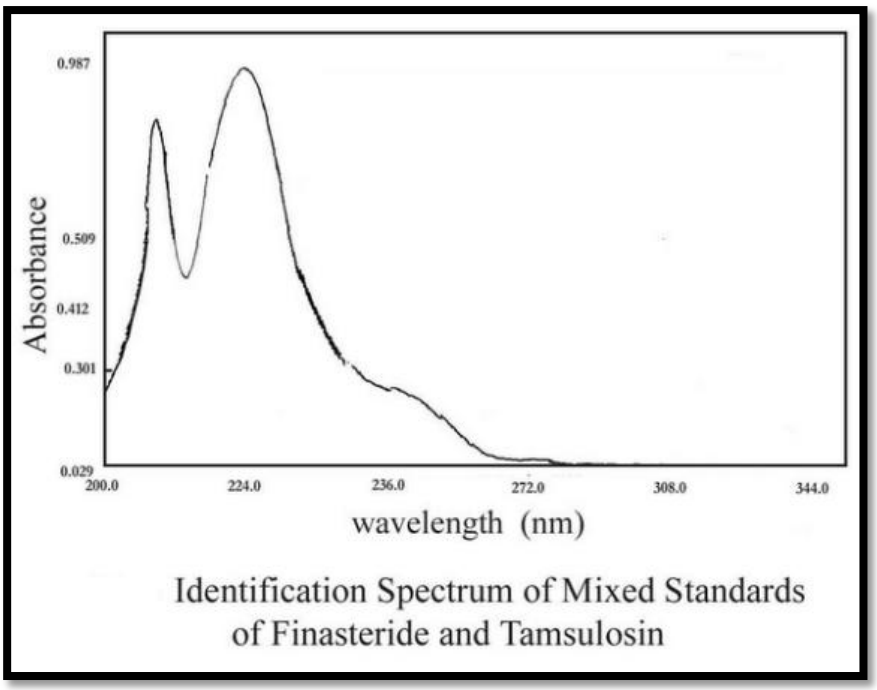
For analysis of commercial formulations of Tablets, 20 tablets were weighed, powdered and accurately weighed the equivalent to 125 mg of finsateride and 10mg of tamsulosin, which was transferred into 100 ml volumetric flask and in methanol and make up to 100ml with DDS, filtered and further diluted with DDW to get the concentrations within the linearity range of respective drugs and measured the absorbances at 219 nm for finsateride and 224 nm for tamsulosin, respectively. Then the amount of drug present in the formulations was calculated using calibration curve. The results were shown in **table-1.**


0.987
0.509
0.412
0.301
0.029
Absorbance
200.0
224.0
236.0
272.0
308.0
344.0
wavelength (nm)
Identification of λmax of Finasteride

(Fig-2)


1.748
1.349
1.050
0.701
0.352
Absorbance
200.0
224.0
236.0
272.0
308.0
344.0
wavelength (nm)
Identification of λmax of Tamsulosin

(Fig-3)



(Fig-4)

TABLE-I: Results of Assay

Drug	Sample No	Amount Labeled (mg/tab)	Amount Estimated	% of label Claim	% Deviation
Finasteride	1	5	4.89	97.8	(-)2.2
	2	5	4.87	97.4	(-)2.6
	3	5	4.90	98	(-)2.0
Tamsulosin	1	0.4	0.386	96.5	(-)3.5
	2	0.4	0.387	96.75	(-)3.25
	3	0.4	0.389	97.25	(-)2.75

TABLE-II: SUMMARY OF SIMULTANEOUS U.V METHOD

U.V Method (simultaneous)	Finasteride	Tamsulosin
Absorption Maximum	219	224
Linearity Range (µg/ml)	125 - 625	1 - 5
Slope	0.309	0.359
Correlation Coefficient (r)	0.9981	0.9984
% RSD of slope	0.51335	0.32156
Label claim (mg/tablet)	5	0.4
Amount found	4.89	0.386
S.D	0.0291	0.00158
RSD%	0.5974	0.4096
Standard Error	0.0130	0.00070
% Recovery	99.76	99.85

TABLE -III

PERCENTAGE RECOVERY

Drug	Amount Added (µg/ml)	Amount recovered (µg/ml)	% Recovery
Finasteride	12.5	12.47	99.76
	25	24.85	99.4
	37.5	37.3	99.46
Tamsulosin	1	0.975	97.5
	2	1.997	99.85
	3	2.983	99.63

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-III**

Results and Discussion

From the optical characteristics of the proposed method it was found that the drug obeys linearity with in concentration range 12.5-62.5µg/ml for FSD and 1-5µg/ml for TMS. From the results it was found that the percent RSD is less than 2% which indicates that the method has good reproducibility. From the results shown in accuracy **table-1** it was found that the percent recovery values of pure drug from the preanalysed solutions of formulations were in between 99.4 -99.76%, which indicates that the method is accurate and which reveals that 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 and tamsulosin in bulk samples and pharmaceutical formulations.

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