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Determination of Tamsulosin in bulk and pharmaceutical dosage forms by UV spectrophotometric method

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ABSTRACT

A Simple, rapid, accurate and economical UV Spectrophotometric method is developed for determination of tamsulosin in bulk and pharmaceutical dosage forms. In methanol, the λmax of the drug was found to be 224 nm. Using UV instrument (analytical), in this proposed method tamsulosin follows linearity in the concentration range 1 – 5µg/ml with a correlation coefficient of 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 0.23516 with excellent precision and accuracy.

Keywords: Tamsulosin, U.V. Spectrometry, Methanol.

INTRODUCTION

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 Tamsulosin, Matsushima H.., Takanuki K.Iet al.,2004[1], O'Neil MJ, Smith A, Heckelman PE, Budavari et al.,2001[2], ICH Q2 R11995[3], Nanda R K, Gaikwad J and Prakashet al.,2009[4], Chandorkar JG, Kotwal VB, Dhande et

al.,2009[5], Macek J, Klima J and Ptacek P et al.,2004[6], Matsushima H, Takanuki KI, Kamimura H et al.,2004[7], Nilam A.Gadhave Sanjay D. Sawant et al.,2011[8], Rao N, Talluri RK, Raju MVN, Shinde A[9], Rahkonen K, Parssinen P, Leppanen O et al.,2008[10]. The objective of the proposed methods to develop simple and accurate method for the determination of tamsulosin by UV spectrophotometric method in Pharmaceutical dosages forms.

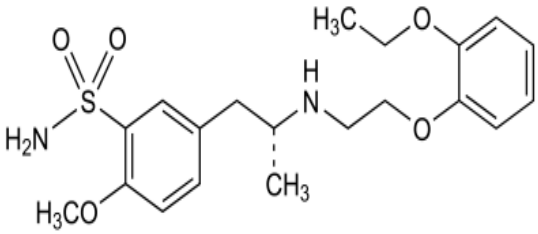

Fig-1 Tamsulosin

EXPERIMENTAL SECTION

Instrument

A double-beam Analytical Technologies Limited, model T60 UV-Visible spectrophotometer Connected to computer loaded with UV Win 5.0 software. The instrument has an automatic Wavelength accuracy of 1 nm and matched quartz cells of 10 mm path length.

Chemicals and Reagents

Tamsulosin, methanol (A.R.GRADE), Double distilled water (DDW), VELTAM (Formulation)

Preparation of Tamsulosin 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, different aliquots of tamsulosin (0.1-0.5ml) with different concentrations (1, 2, 3, 4 and 5µg/ml) were prepared by serial dilutions with DDW. Then absorbance of the solution was measured at 224 nm. The linearity range is shown in **Table- 1.** The linearity curve was shown in **fig-1**, U.v spectra was shown in **fig-2** optical characteristics and regression equation of tamsulosin were shown in **Table-2**

Table- 1 (Linearity)

Concentration(mcg/ml) (Tamsulosin)	Absorbance
1	**0.354**
2	**0.702**
3	**1.021**
4	**1.462**
5	**1.785**

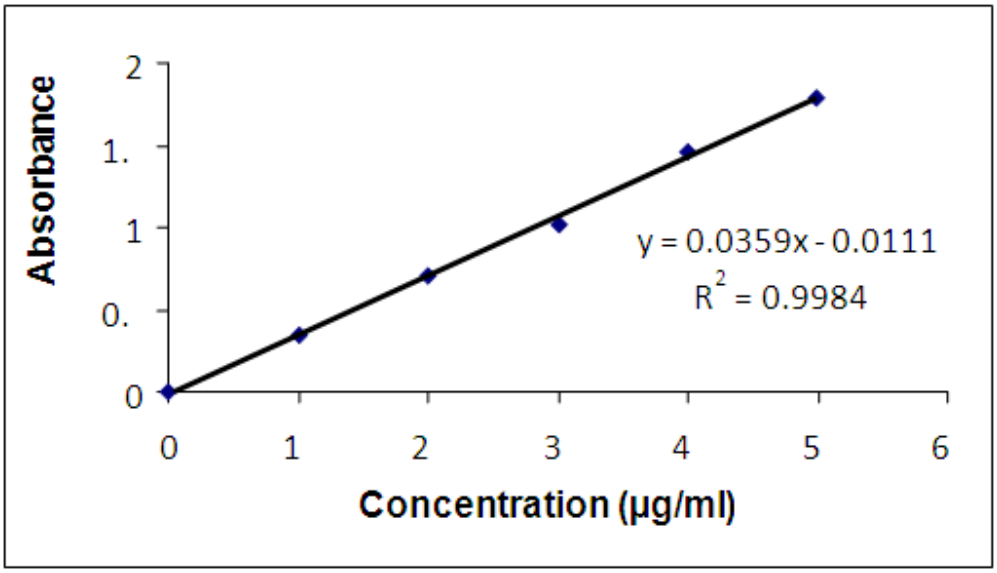

Fig-1 linearity curve of Tamsulosin

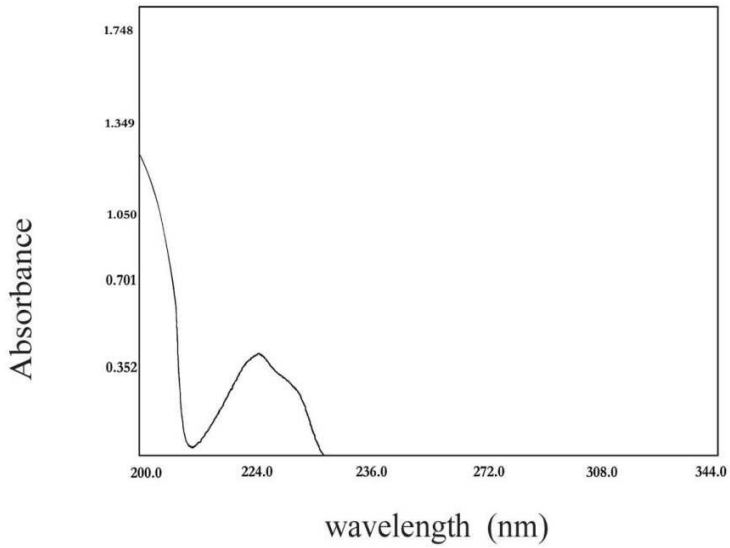

Fig-2 U.v spectra of Tamsulosin

TABLE-2 Optical Characteristics and Regression Equation of Tamsulosin

Parameters	Tamsulosin
Linearity range (µg/ml)	1-5
Correlation Coefficient	09984
Regression equation (Y) Slope (a) Intercept (b)	 0.0359 0.0111

Analysis of tamsulosin in its formulations

For analysis of commercial formulations of Tablets, 20 tablets were weighed, powdered and accurately weighed the equivalent to 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 and measured at 224 nm for Tamsulosin. Then the amount of drug present in the formulations was calculated .The results were shown in **Table-3.**

Table-3 Results of assay (Tamsulosin)

Drug	Sample No	Amount Labeled (mg/tab)	Amount Estimated (mg/tab)	% of label Claim	% Deviation
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

METHOD VALIDATION

Precision

The precision of the proposed method was ascertained by actual determination of eight replicates of fixed amount of the drug. Results given below in **Table-4**

Precision (Tamsulosin)

S.No	Concentration (µg/ml)	Absorbance	Average	S D	%RSD
1	1	0.354	0.3548	0.000835	0.23516
2	1	0.356			
3	1	0.355			
4	1	0.354			
5	1	0.354			
6	1	0.355			
7	1	0.356			
8	1	0.355			

The proposed method shows the precision with SD 0.000835 and %RSD 0.23516

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-4**

TABLE -4

Drug	Amount Added (µg/ml)	Amount recovered (µg/ml)	Percentage recovery (%)	Average Recovery	% RSD
Tamsulosin	1	0.975	97.5	98.99	1.311
	2	1.997	99.85		
	3	2.983	99.63		

RESULTS AND DISCUSSION

From the optical characteristics of the proposed method it was found that the drug obeys linearity within the concentration range of 1-5 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 97.5 - 99.63%, 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 Tamsulosin in bulk samples and pharmaceutical formulations.
Summary of proposed UV method for determination Tamsulosin in bulk and formulations was shown in **table-5**

Table-5 Summary of UV Method

UV METHOD	Tamsulosin
Absorption Maximum	224
Linearity Range (µg/ml)	1 - 5
Slope	0.0359
Correlation Coefficient (r)	09984
% RSD of slope	0.23516
Label claim (mg/tablet)	0.4
Amount found	0.386

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