ISSN 0974-4169 www.ajrconline.org

RESEARCH ARTICLE

Simultaneous Spectrophotometric Estimation of Tamsulosin in Pharmaceutical Dosage Form

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ABSTRACT
Three simple, precise and economical UV methods have been developed for the estimation of Tamsulosin in pharmaceutical dosage form. Tamsulosin has the absorbance maxima at 281.0 nm (Method A), and in the first order derivative spectra, showed sharp peak at 234.5 nm (Method B). Method C applied was area under curve (AUC), in the wavelength range of 286.0-276.0 nm. Linearity for detector response was observed in the concentration range of 5-25 µg/ml for all three methods. The proposed methods were successfully applied for the simultaneous determination of Tamsulosin in commercial pharmaceutical preparation. The results of the capsule analysis were validated statistically and by recovery studies. It was found to be satisfactory.

KEY WORDS Tamsulosin; Absorbance maxima; Derivative spectroscopy; Area under curve.

INTRODUCTION:
Chemically, Tamsulosin (TAM) is (-)-(R)-5-2-(2-(0-Ethoxyphenoxy)-ethyl)-amino)-propyl)-2-methoxy benzenesulphonamide. It is an α_1-adrenoceptor blocking agent and used in benign prostatic hyperplasia[1]. Capsules containing 0.4 mg TAM are available in the market. Literature survey revealed that it is estimated by HPLC[2-4] and mass spectroscopy[5-6]. No UV spectrophotometric methods have been reported for estimation of TAM in single component formulation. Hence, an attempt has been made to develop new UV methods for its estimation in pharmaceutical formulations with good accuracy, simplicity, precision and economy.

MATERIAL AND METHODS:
Instrument A double-beam Shimadzu UV-Visible spectrophotometer, with spectral bandwidth of 2 nm, wavelength accuracy ± 0.5 nm and a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution.

Materials Standard gift sample of Tamsulosin was provided by Cipla Pvt. Ltd., Mumbai, Tamsulosin capsules were purchased from local market.

Solvent Methanol was used as a solvent.
Stock solution: Standard stock solution of TAM (50 µg/ml) was prepared and used for the analysis.

Received on 14.02.2009 Modified on 21.03.2009
Accepted on 25.03.2009
Asian J. Research Chem. 2(1): Jan.-March, 2009;Page 63-65

Procedure
Method A: Absorption Maxima Method
For the selection of analytical wavelength, 20 µg/ml solution of TAM was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. From the spectra of drug (Fig. 1), λ_{max} of TAM, 281.0 nm was selected for the analysis. The calibration curve was prepared in the concentration range of µg/ml at 281.0 nm. By using the calibration curve, the concentration of the sample solution can be determined.

Method B: First Order Derivative Spectroscopy
In this method, 20 µg/ml solution of TAM was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. The absorption spectra thus obtained were derivatized from first to fourth order. First order derivative spectra were selected for analysis of drug. First order derivative spectra of drug (Fig. 2), showed a sharp peak at 234.5 nm, which was selected for its quantitation. The calibration curves for TAM was plotted in the concentration range of 5-25 µg/ml at wavelength 234.5 nm The concentration of the drug present in the mixture was determined against the calibration curve in quantitation mode.

Method C: Area Under Curve Method
For the selection of analytical wavelength, 20 µg/ml solution of TAM was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. From the spectra of drug, area under the curve in the range of 286.0-276.0 nm was selected for the analysis. The calibration curve was

prepared in the concentration range of 5-25 µg/ml at their respective AUC range. By using the calibration curve, the concentration of the sample solution can be determined.

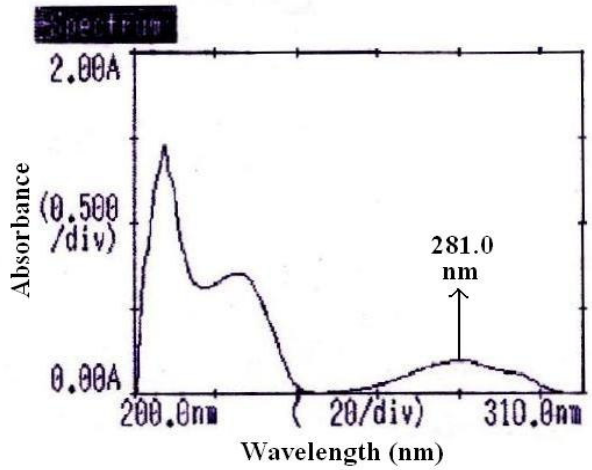

Fig. 1: Zero order spectra of Tamsulosin

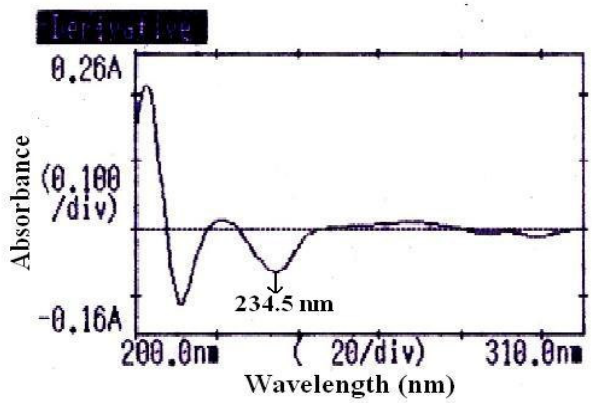

Fig. 2: First order derivative Spectra of Tamsulosin

Application of the proposed method for the determination of TAM in capsules

For the estimation of drugs in the commercial formulations, capsule powder equivalent to 5 mg TAM was transferred to 100.0 ml volumetric flask and volume was made up to the mark with Methanol and ultrasonicated for 10 minutes. The solution was then filtered through a Whatmann filter paper (No. 41). The filtrate was appropriately diluted with Methanol to obtain 10 µg/ml of TAM. In Method-A, the concentration of TAM was determined by measuring the absorbance of the sample at 281.0 nm in zero order spectrum mode. By using the calibration curve, the concentration of the sample solution can be determined. Method-B, the concentration of TAM was determined by measuring the absorbance of the sample at 234.5 nm, in first order derivative mode. The results of the capsule analysis were calculated against the calibration curve in quantitation mode. For Method-C, the concentration of TAM was determined by measuring area under curve in the range of 286.0-276.0 nm. By using the calibration curve, the concentration of the sample solution can be determined. Results of capsule analysis are shown in Table No. 1.

Validation

The methods were validated with respect to linearity, accuracy, precision and selectivity.

Accuracy: To ascertain the accuracy of proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% & 120%). Percent recovery for TAM, by all three methods, was found in the range of 98.33 % to 101.25 %.

Linearity: The linearity of measurement was evaluated by analyzing different concentration of the standard solution of TAM. Beer-Lambert's concentration range was found to be 5-25 µg/ml for all three methods.

Precision: The reproducibility of the proposed method was determined by performing capsule assay at different time intervals (morning, afternoon and evening) on same day (Intra-day assay precision) and on three different days (Inter-day precision). Result of intra-day and inter-day precision is expressed in % RSD. Percent RSD for Intraday assay precision was found to be 0.3069, 0.5050 and 0.2012 for Method A, B and C, respectively. Inter-day assay precision was found to be 0.3063, 0.4032 and 0.6127 for Method A, B and C, respectively.

RESULTS AND DISCUSSION:

The methods discussed in the present work provide a convenient and accurate way for simultaneous analysis of Tamsulosin in its pharmaceutical dosage form. Absorbance maxima of Tamsulosin at 281.0 nm (Method A); in the first order derivative spectra, sharp peak at 234.5 nm (Method B) and area under curve in range of 286.0-276.0 nm (Method C) were selected for the analysis. Linearity for detector response was observed in the concentration range of 5-25 µg/ml for all three methods. Percent label claim for TAM in capsule analysis, by all the methods, was found in the range of 98.80 % to 100.40 %. Standard deviation and coefficient of variance for six determinations of capsule sample, by all the methods, was found to be less than ± 2.0 indicating the precision of the methods. Accuracy of proposed methods was ascertained by recovery studies and the results are expressed as % recovery. Percent recovery for TAM, by all the methods, was found in the range of 98.33 % to 101.25 % values of standard deviation and coefficient of variation was satisfactorily low indicating the accuracy of all the methods. Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible & economical and can be employed for routine quality control of Tamsulosin in its pharmaceutical dosage form.

Table No. 1: Results of Analysis of Capsule Formulation

Method	Label Claim mg	Amount of drug estimated (mg/tab)	% Label Claim* ± S.D.	% Recovery*
A	0.4	0.3988	99.70 ± 0.4147	99.35
B	0.4	0.3981	99.53 ± 0.5164	99.64
C	0.4	0.3991	99.77 ± 0.5125	99.64

* indicates mean of six determinations.

ACKNOWLEDGEMENTS:

The authors are very thankful to Dr. Avinash D. Deshpande, Director of Pharmacy, Pad. Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune for providing necessary facilities. The authors are also thankful to Cipla Pvt. Ltd., Mumbai, for providing gift samples of Tamsulosin.

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