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Application of UV-Spectroscopy and First Order Derivative Method for Determination of Tamsulosin Hydrochloride in Bulk and Tablets

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Abstract

Two simple, rapid, sensitive and accurate UV-Spectrophotometry and First order derivative methods have been developed for estimation of tamsulosin hydrochloride in bulk and tablets. Methanol: water (2:8) was used as a solvent. In UV spectrophotometric method absorbance of samples are recorded at 280 nm. In first order derivative method the amplitude of trough was recorded at 298 nm. Tamsulosin follows linearity in the concentration range of 10-90 µg/ml. Assay results were in good agreement with label claim. These method were validated statistically and recovery studies.

Keywords: Tamsulosin hydrochloride (TMS); UV-Spectrophotometry; First order derivative

Introduction

Tamsulosin hydrochloride is a sulphonamide derivative used in the treatment of Benign Prostate Hyperplasia (BPH), synonymously known as elders disease.TMS is official in Martindale–The Extra Pharmacopoeia and Merck Index [1,2]. TMS, (R)-5-[2-[[2-(2-ethoxyphenoxy)ethyl] amino]propyl]-2-methoxy-benzenesulfonamide, is a subtype selective μ_{1A} and μ_{1D} adrenoceptor antagonist approved by the Food and Drug Administration (FDA), USA for treatment of BPH**.** It is a new type of highly selective α-1-adrenergic receptor antagonist for treatment of BPH. Compared to other α-antagonists, tamsulosin hydrochloride has greater specificity for α-1 receptors in the human prostate and does not affect receptors on blood vessels. Tamsulosin hydrochloride exists in two enantiomeric forms but only R-isomer is the pharmaceutically active component. Literature survey reveals the chiral separation by electrophoresis [3,4] and HPLC methods, coupled with ESI-MS-MS are reported for the estimation of tamsulosin hydrochloride with its impurities in bulk and pharmaceutical formulations [5] as well as in biological fluids [6-11]. According to our knowledge no method has been reported for TMS estimation by spectroscopic method. The present work deals with estimation of tamsulosin hydrochloride in bulk and pharmaceutical formulation by simple and derivative spectroscopy which is economical and intended for better reproducibility of product.

Material and Methods

Chemicals

All reagents used were of analytical grade.

Instrument and conditions

SHIMADZU AUX – 120 (Weighing Balance), UV Shimadzu 2450 (PC Series), UV-visible double beam spectrophotometer, Software UV Probe 2.21, Matched quartz cells 1 cm, Wavelength range 190 -900 nm, Lamp: 50 w, Deuterium Lamp, Detector: Silicon Photodiode, Cell holder: 1 mm wide, 12 mm high Resolution: 1 nm.

Parameter	At 280 nm	At 298nm
Linearity equation (Y= a+ bc)	Y=0.0107X+0.002	0.0046X+ 0.0027
Range(µg/mL)	10.00-90.00	10.00 - 90.00
Correlation Coefficient(r^2)	0.9993	0.9977

Table 1: Linear regression data for the calibration curves.

Results and Discussion

Tamsulosin hydrochloride in methanol: water (20:80) solvent system showed absorbance maximum at 280 nm. In 'first order

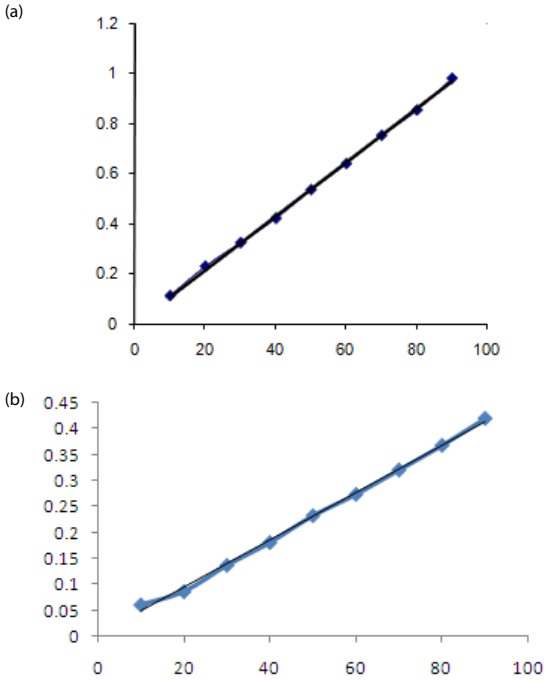

Figure 1: Calibration curve for TMS at 280 nm (a) 298 nm (b).

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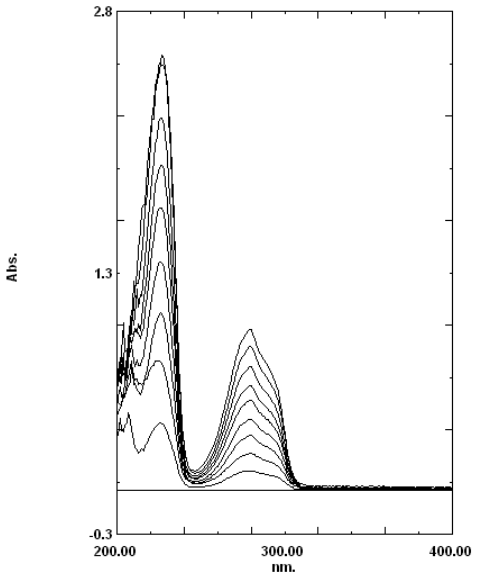

Figure 2: Zero Order UV Spectra of Tamsulosin hydrochloride in Methanol: Water (2:8) at 280 nm.

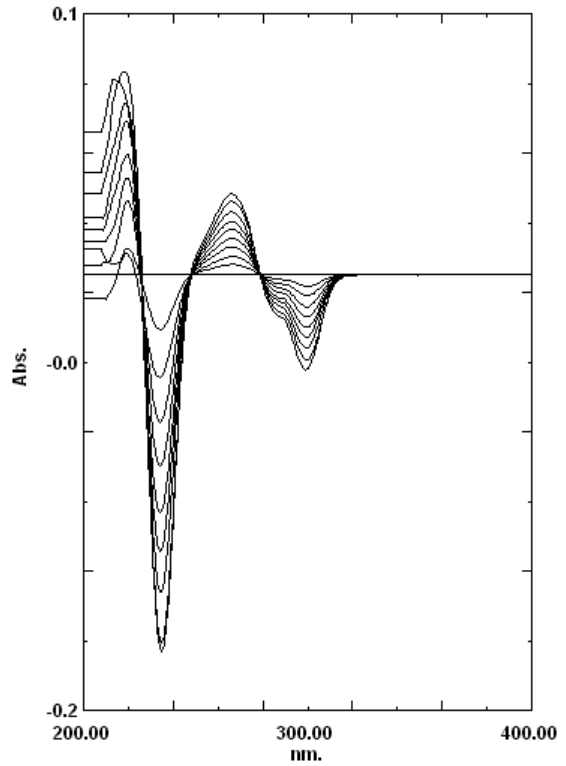

Figure 3: First Order UV Spectra of Tamsulosin hydrochloride in Methanol: Water (2:8) at 298 nm.

derivative' the amplitude of trough was recorded at 298 nm. In both the methods tamsulosin hydrochloride follows linearity in the concentration range 10-90 µg/ml. Amount of drug determined was in the good agreement with the label claim. The methods were validated for accuracy, precision and ruggedness. Accuracy of the methods was assessed by recovery studies. In both the methods, as %RSD values were found to be less than 2, indicative of accuracy of the method. Precision of the methods was studied as intra-day, inter-day and repeatability. The %RSD values less than 2 indicate the methods are precise. Ruggedness of the proposed methods was studied with the help of two analysts, the %RSD value less than 2 indicate methods are rugged. The results from validation studies are shown in Table 1. Both these methods are simple, rapid and accurate and precise and can be used for routine analysis of tamsulosin from tablet formulations.

Conclusion

The developed method is simple, economic specific and accurate. Statistical analysis proved the method is reproducible and selective for analysis of Tamsulosin Hydrochloride as the bulk drug and in tablet formulations. The method was validated in accordance with ICH guidelines. The method can be utilized to determine the purity of the commercially available drug by detecting the related impurities.

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