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Validated spectrofluorimetric method for the determination of Tamsulosin Hydrochloride in tablet dosage form

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ABSTRACT

A simple, precise, accurate and sensitive spectrofluorimetric method was developed for the determination of tamsulosin hydrochloride in tablet dosage form. The solvent systems and wavelengths of detection were optimized in order to maximize the sensitivity and minimize cost of analysis. The excitation and emission wavelengths were found to be 226 nm 322 nm respectively for tamsulosin hydrochloride in methanol. The calibration graph was linear over the range of 5-30 μ g/ml with high value of correlation coefficient. The percentage recovery was found to be 99.70%-99.92%. The developed method was validated statistically and was applied successfully for the routine analysis of tamsulosin hydrochloride in tablet dosage form.

Key words: Tamsulosin Hydrochloride, spectrofluorimetry, benign prostatic hyperplasia.

INTRODUCTION

Tamsulosin hydrochloride, (-) - (R) - 5 - [2 - [[2 - (o - ethoxy phenoxy) ethyl] amino] propyl] - 2methoxy benzene sulfonamide, monohydrochloride, is selective antagonist of α_1 -adrenoreceptor exhibits selectivity for α_{1-} receptors in the human prostate used in treatment of benign prostatic (BPH)[1]. Literature hyperplasia survey reveals various LC-MS[2-5], HPLC[6], spectrophotometric[7] and stability indicating HPTLC[8] methods for determination of TAM in biological fluid as well as in formulations. Also LC-MS-MS[9] and spectrophotometric[10] methods have been found for simultaneous estimation of tamsulosin hydrochloride and dutasteride. So it was thought of interest to develop a simple, sensitive and cost effective spectrofluorimetric method for determination of tamsulosin hydrochloride in pharmaceutical formulations.

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MATERIALS AND METHODS

Tamsulosin hydrochloride pure powder was obtained as a gift sample from Intaas Pharmaceutical Limited (Ahmedabad, India). All the reagents used were of AR grade and procured from S. D. Fine chemicals. Fluorescence intensity was measured on Spectrofluorophotometer, RF 1501 (Shimadzu, Japan) with single quartz cell of 1 cm pathlength. A Sartorius (CP224S) analytical balance and ultrasonic cleaner (Frontline FS-4) sonicator were used during the study. Tablets of tamsulosin hydrochloride were purchased from local pharmacy.

A standard stock solution of tamsulosin hydrochloride (100 μ g/ml) was prepared by dissolving 10 mg of pure drug to 100 ml volumetric flask with methanol. Aliquots of standard stock solution of tamsulosin hydrochloride were suitably diluted with methanol to obtain the final concentration in the range of 5-30 μ g/ml. The solution was scanned in the range of 200 nm to 400 nm against methanol as a blank, to obtain the excitation and emission wavelength. The excitation and the emission wavelength were found to be 226 nm and 322 nm, respectively. The fluorescence intensity of the resulting solutions was measured at emission wavelength 322 nm keeping excitation wavelength 226 nm. The calibration curve was prepared by plotting concentration of tamsulosin hydrochloride vs fluorescence intensity of solution.

For analysis of tamsulosin hydrochloride in tablet dosage form, twenty tablets were accurately weighed and powdered for analysis. A quantity of accurately weighed the tablet powder equivalent to 5 mg of tamsulosin hydrochloride was transferred to 25 ml volumetric flask containing 10 ml methanol, sonicated for 30 min. Finally volume was made up to the mark with methanol and further shaken for 15 min for complete extraction of from its matrix. The resulting solution was centrifuged for 20 min at 4,000 rpm and the supernant was diluted with methanol and filtered through whatman filter paper No.42 to obtain 50 μ g/ml solution of tamsulosin hydrochloride. Aliquot of above prepared sample solution was suitably diluted with methanol to obtain solution of tamsulosin hydrochloride (20 μ g/ml) and analyzed as discussed above.

RESULTS AND DISCUSSION

Tamsulosin hydrochloride showed stronger native fluorescence in methanol, hence it was selected as optimum solvent for spectrofluorimetric analysis. Tamsulosin hydrochloride exhibited maximum excitation and emission wavelengths at 226 nm and 322 nm, respectively (Fig. 1).

The developed method was validated as per ICH guideline^[9] and validation parameters are summarized in Table 1.

Recovery studies were done by standard addition method by adding known quantity of standard solution (50 %, 100 % and 150 % levels) to preanalyzed sample solution and the mixtures were reanalyzed by proposed method. The results are shown in Table 1.

The linearity was obtained in the concentration range of 5-30 μ g/ml with high value of correlation coefficient. The low values of % RSD for intraday and interday precision indicate that the method was precise and reproducible. The LOD and LOQ values were determined by

trial and error method by scanning a solution of relatively low concentration. Low value of LOD and LOQ describe the method as sensitive. The assay results obtained was 99.67 ± 1.093 (Table 2), indicate the excipients do not interfere during the analysis normally present in the tablet.



Fig. 1. Emission spectra of tamsulosin hydrochloride standard at 226 nm as excitation wavelength by proposed spectrofluorimetric method

 Table 1. Regression analysis data and summary of validation parameters by proposed spectrofluorimetric method

Parameters	Tamsulosin Hydrochloride
Linearity (µg/ml)	5-30 µg/ml
Regression equation $y = mx + c$	y = 12.32 x + 9.886
Slope (m)	12.32
Intercept (c)	9.886
Correlation coefficient (r ²)	0.9972
^a LOD (μg/ml)	1.36
^b LOQ (µg/ml)	4.92
Accuracy (% recovery) \pm ^c SD	$99.80\% \pm 0.10$
Repeatability (% d RSD) (n = 6)	0.59
Precision (% RSD)	
Interday (n = 3)	0.21 % -1.15 %
Intraday $(n = 3)$	0.08 % -1.62 %

^{*a}Limit of detection*, ^{*b}Limit of quantification*, ^{*c*}Standard deviation, ^{*d*}Relative standard deviation</sup></sup>

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Tablet	Labeled claim (mg/tab)	Amount found (mg/tab)	% Assay* ± SD	% RSD
1	0.4	0.399	99.75 ± 0.956	0.958
2	0.4	0.398	99.60 ± 1.122	1.126

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*Average of three determinations, ^aStandard deviation, ^bRelative standard deviation

CONCLUSION

The proposed spectroflourimetric method has linear response in the stated range and it is accurate, precise and sensitive. Tamsulosin hydrochloride itself fluorescent drug so it does not need to derivatization with other fluorescent dye. The proposed method is simple, rapid, inexpensive and measure the assay of TAM without interference from its excepients. Hence, it can be recommended for the routine quality control of TAM in its pharmaceutical tablet dosage form.

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