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NOTE

Reverse Phase HPLC Estimation of Tamsulosin Hydrochloride in Bulk and in Pharmaceutical Dosage Forms

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A simple, precise, rapid, reproducible and selective reverse phase HPLC method has been developed for the estimation of tamsulosin hydrochloride in bulk and pharmaceutical dosage forms. The analyte was resolved by using a mobile phase (acetonitrile, methanol and water in the ratio 37:13:50) at a flow rate of 1 mL/min. on an isocratic HPLC system consisting of LC-10 at liquid pump, SPD-10AVP UV-Visible detector, an ODS C-18 RP column (4.6 mmL.D x 250) at the wavelength of 232 nm. The linearity range is found to be 2-10 μg/mL.

Key Words: Estimation, Tamsulosine hydrochloride, HPLC.

Tamsulosin hydrochloride is chemically 5(2-((-(2-ethoxy phenoxy)amino)propyl)-2-methoxy bezene sulfonamide[1]. It is selective alpha adrenoreceptor blocking agent. These alpha 1 adrenoreceptors are most abundant in the prostate, prostatic capsule and bladder neck. Blockade of these adrenoreceptors can cause reduction of prostatic hyperplasia symptoms. An *in vitro* study revealed that the selectivity of this drug to prostate alpha 1 receptors was about 10 times higher than to aorta alpha1 adrenorerceptors[2,3]. A literature survey reveals the reports of HPLC[4,5], LCMS[6] methods for the estimation of tamsulosin hydrochloride in pharmaceutical dosage forms and in biological fluids. In this communciation we report a new reverse phase HPLC method for the determination of tamsulosin hydrochloride in bulk as well as in formulation.

An isocratic HPLC system (Shimadzu) consisting of LC-10 at liquid pump, SPD-10AVP UV-Visible detector, an ODS C-18 RP column (4.6 mmI.D x 250) 20 μL Hamilton injecting syringe and Spinchrome software was used. Shimadzu AS200 electronic balance was used for weighing the materials. A pure sample of tamsulosin hydrochloride was used;

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acetonitrile and methanol used were of HPLC grade and obtained from Merck (India) Ltd., Mumbai. Water used was triple distilled prepared by all-glass distillation apparatus.

Standard graph: Standard stock solution of tamsulosin hydrochloride was prepared by dissolving 25 mg of drug in 25 mL of methanol to get 1 mg/mL solution and this solution was suitably diluted with mobile phase. (acetonitrile, methanol, water in the ratio 37:13:50) to get a solution of concentration 100 µg/mL.

Working standard solutions containing tamsulosin in various concentrations in the range of 2-20 µg/mL were prepared with the mobile phase 20 µL of each solution was injected in the HPLC system to obtain the chromatogram. Calibration curve was constructed by plotting mean peak area against the corresponding drug concentrations. the detector response was found to be linear in the concentration range of 2-20µg/mL. The linearity plot is given in Fig. 1. Model chromatogram of tamsulosin is show in Fig. 2.

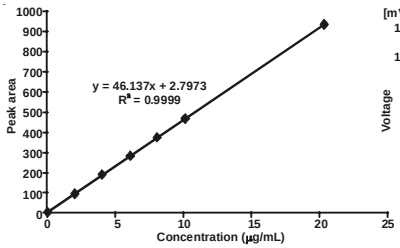

Fig. 1. Linearity plot of tamsulosin hydrochloride

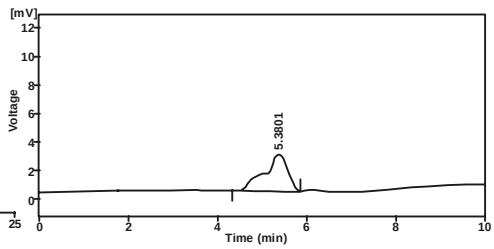

Fig. 2. Model chromatogram of tamsulosin

Estimation of tamsulosin hydrochloride in tablets and capsules: The quantity of formulation containing tamsulosin equivalent to 2.5 mg of tamsulosin hydrochloride was weighed accurately and taken into 25 mL volumetric flask. Tamsulosin was extracted into methanol and the volume was adjusted to 25 mL, mixed and filtered. From the filtrate 1 mL was pipetted in 25 mL volumetric flask and then volume was adjusted to 25 mL with mobile phase. 20 µg of this solution was injected into HPLC system to obtain the chromatogram and the concentration of tamsulosin was calculated from the standard graph. The results were given in the Table-1.

TABLE 1
ANALYSIS OF TAMSULOSIN HYDROCHLORIDE IN DOSAGE FORMS

Pharmaceutical formulation	Labeled amount mg	Amount found mg	(%) drug
Tablet (VELTAM)	0.4	0.396	99.00
Capsule (DYNAPRES)	0.4	0.397	99.25

Precision: The precision of the assay was determined in terms of

intra- and inter-day variation in the peak area for a set of drug solutions on three different days (n=5). The intra- and inter-day variation in the peak area of the drug solution (4 or 8 μg/mL) was calculated in terms of coefficient of variation and obtained by multiplying the ratio of standard deviation to the mean with 100[CV=±s.d./mean x 100]. The results are given in Table-2.

TABLE-2
PRECISION OF THE PROPOSED METHOD

Tamsulosin concentration (μg/mL)	Concentration of tamsulosin (μg/mL) found on			
	Intra-day		Inter-day	
	Mean	CV(%)	Mean (n=5)	CV (9 %)
4	3.98	0.65	3.99	0.92
8	7.96	1.21	7.98	1.35

Accuracy: Adding known amount of tamsulosin to the previously analyzed samples assessed accuracy of method. The results are given in Table-3.

TABLE-3
RECOVERY STUDIES

Drug content	Conc. of standard drug added	Amount drug found	(%) recovery
10	0	9.9996	99.99
10	4	13.9200	99.42
10	6	16.0400	100.28
10	10	19.9500	99.75

The absence of additional peaks in the chromatogram indicates non-interference of the common excipient in the formulations. The values of recovery studies are given in Table-2 indicate that the method is accurate. The run time is only 10 min. and the flow rate of the mobile phase is 1 mL/min. The method is rapid and economic. The proposed method was also validated for intra- and inter-day variation. The solutions containing 4 or 8 μg/mL of tamsulosin were repeatedly injected on the same day, the coefficient of variation (CV) in the peak area of the drug for five replicate injections was found to be less than 2.5%. Also inter-day variation (3 days and five injections) was found to be less than 2% (Table 3). Thus the results have shown that proposed HPLC method is highly reproducible. This method could be used for routine quality control analysis.

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