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Research Article

RP-HPLC method for the estimation of tamsulosin hydrochloride in bulk and tablet dosage form

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ABSTRACT

The Present work describes a simple reverse phase HPLC method for the estimation of Tamsulosin hydrochloride in bulk and tablet dosage form. The estimation was carried out on ODS,Phenomonex,C-18 (250x4.6 mm,5µ) column using a mobile phase consisting of sodium dihydrogen orthophosphate buffer-Acetonitrile (70:30).The eluent was monitored at 280 nm. The results have been validated statistically and recovery studies confirmed the accuracy of proposed method.

Keywords: HPLC estimation, Validation, Tamsulosin hydrochloride and Pharmaceutical formulation.

INTRODUCTION

Tamsulosin is a selective, potent and competitive α_1 – adrenoreceptor antagonist and has a greater affinity for these receptors, predominantly present in the human prostate. Chemically, Tamsulosin is 5 – [(2 R) – 2- [[2-(2-ethoxy phenoxy) ethyl] amino] propyl] – 2 – methoxy benzene sulfonamide hydrochloride. It is a white to slightly yellowish crystalline powder, freely soluble in methanol, ethanol and sparingly soluble in water. Literature survey reveals that several methods like HPLC,HPLC-MS and LC-MS were reported for the estimation of Tamsulosin hydrochloride in combination with other drugs as well as in biological fluids [1-3]. Recently, we reported the formulation and evaluation of Tamsulosin hydrochloride as an once daily sustained release matrix tablet[4]. The review of the literature revealed that no method is yet reported for the estimation of Tamsulosin hydrochloide in bulk and tablet dosage form by RP- HPLC.

MATERIALS AND METHODS:

Standard sample of Tamsulosin hydrochloride was obtained from Dr.Reddy's labs,Hyderabad,India .HPLC grade Acetonitrile, and AR grade sodium dihydrogen ortho phosphate were procured from Ranchem,RFCL ltd. Double distilled water was prepared in our laboratory. Fixed dose tablet formulation Veltam containing tamsulosin hydrochloride(0.4mg/each tablet) were obtained from local market.

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INSTRUMENTS USED:

Digital balance(Essae),pH meter(Elico),Ultrasonicator (Optics technologies),Millipore solvent filtration unit (Bros Scientifics),UV-detector,HPLC system (Shimadzu LC-20AT Prominence solvent delivery system), Analytical column-Phenomonex-ODS, C-18 (250x4.6mm id,5µ) were the instruments used in the present study.

RP-HPLC ASSAY METHOD:

The standard solutions of tamsulosin hydrochloride and veltam containg 0.4 mg/each tablet containing tamsulosin hydrochloride were prepared.From this solutions,20µl were injected and chromatographed. The mobile phase consisting of sodium dihydrogen orthophosphate buffer-acetonitrile(70:30) was pumped at a flow rate 1ml per min, the detection was monitored at 280 nm and the run time was 15 minutes.

METHOD VALIDATION[5,6,7]:

It is defined as the process of proving that an analytical method is acceptable for its intended use. It proves that the method developed is specific,linear,precise,accurate and sensitive. The different parameters of analytical method validation are discussed below.

Accuracy:

It is the measure of exactness of an analytical method, or the closeness of agreement between the value which is accepted either

Figure 1: Chromatogram of tamsulosin hydrochloride (Standard)

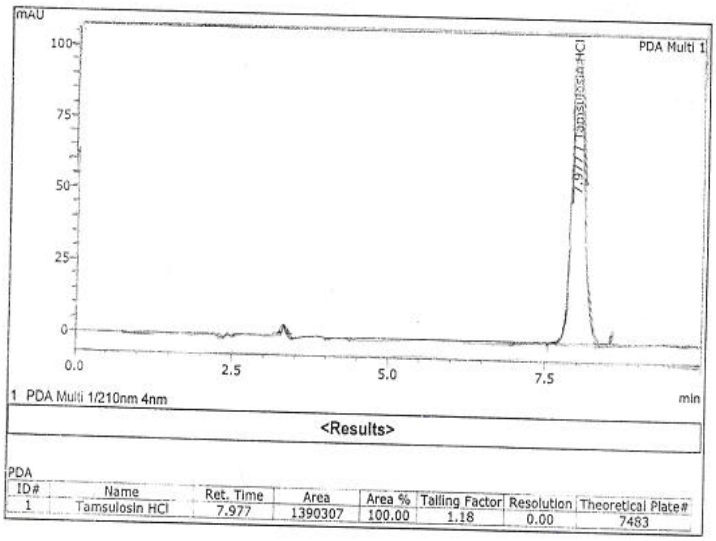
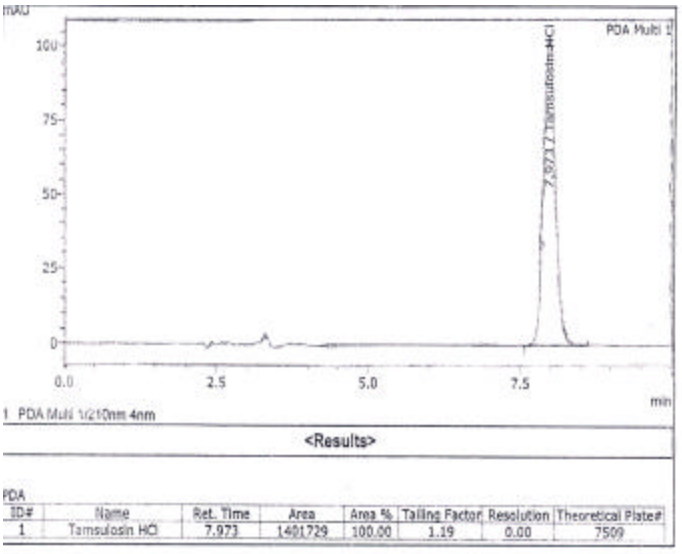


Figure 2: Chromatogram of tamsulosin hydrochloride(veltam)



as a conventional true value or an accepted reference value and the value found. Accuracy is evaluated by analyzing synthetic mixtures spiked with known quantities of components. For the quantitation of impurities,accuracy is determined by analyzing samples (drug substance or drug product) spiked with known amounts of impurities. To document accuracy[8]the ICH guideline on methodology recommends collecting data from a minimum of nine determinations over a minimum of three concentration levels covering the specified range, for example,three concentrations, three replicates each. The data should be reported as the percent recovery of the known, added amount, or as the difference between the mean and true value with confidence intervals.

Table-1:Recovery of Tamsulosin hydrochloride in commercial tablet dosage form

Formulation	Label content (mg/tablet)	Mean amount found(mg)	Mean (%)	Standard deviation found
Veltam	0.4	0.475	47.5	0.53

Table-2: Standard validation protocol

S.No	Parameters	Experiment	Acceptance Criteria
1.	System precision	Six replicate injections of standard solution	RSD should not be more than 1%.
2.	Method precision	Sample of one batch prepared and analysed separately six times as per the method.	RSD should not be more than 1%.
3.	Linearity	Linearity to be performed in the range of about 70-130% of standard/sample solution.	Correlation coefficient should not be less than 0.99.
4.	Ruggedness	Sample of the same batch, prepared and analysed separately six times by two different instruments,using to different columns on different days.	Overall RSD should not be more than 2%.

Precision[9]:

Precision is defined as the measure of the degree of repeatability and reproducibility of an analytical method under normal operation and expressed as the percent relative standard deviation for a statistically significant number of samples. According to ICH, it should be performed for repeatability, intermediate precision and reproducibility.

i) **System precision:**

The first type of precision study is instrument precision or injection repeatability. Repeatability should be assessed using a minimum of 9 determinations covering the specified range for the procedure (ex:3 concentrations/3 replicates each or a minimum of 6 determinations at 100% of the test concentration).

ii)**Method precision:**

The datas were obtained by repeatedly analyzing, in one laboratory on one day, aliquots of homogenous sample ,each of which independently prepared according to the following procedure.

Linearity[10]:

It is the ability of the method to elicit test results that are directly proportional to analyte concentration with in a given range.

Ruggedness[11]:

It is the degree of reproducibility of the results obtained under a variety of conditions, expressed as %RSD. An ICH chooses instead to cover the topic of ruggedness as part of precision (reproducibility).

Stability in analytical solution:

A sample solution containing 100 ppm of Standard Tamsulosin hydrochloride,Veltam was prepared and kept at room temperature and analyzed initially at different time intervals. As the cumulative RSD up to 12 hours meet the acceptance criteria , it is concluded that sample is stable in analytical solution for atleast 12 hours at room temperature.

RESULTS AND DISCUSSION:

The Chromatogram obtained for Tamsulosin hydrochloride (Standard) and Veltam were shown in the figures 1 and 2. Recovery of Tamsulosin hydrochloride in commercial tablet dosage form was shown in Table 1. Then the HPLC assay method was validated .The standard validation protocol was shown in Table 2. The validation results are as follows.

System Precision:

The RSD value was found to be 0.25 and 0.29 for Tamsulosin hydrochloride standard and Veltam respectively and the values were found to be present within the acceptable limits. The order of system precision is as follows :Tamsulosin hydrochloride standard>Veltam.

Method precision:

The RSD value was found to be 0.41 and 0.43 for Tamsulosin hydrochloride standard and Veltam respectively and the values were found to be present within the accepatable limits. The order of method precision is as follows: Tamsulosin hydrochloride standard>Veltam.

Linearity:

The correlation coefficient value was found to be 0.9996 and 0.9998 for Tamsulosin hydrochloride standard and Veltam respectively and the values were found to be present within the accepatable limits. The order of linearity is as follows: Tamsulosin hydrochloride standard>Veltam.

CONCLUSION:

From the above experimental data and validation results, the RP-HPLC assay method for the estimation of Tamsulosin hydrochloride in bulk and tablet dosage form is said to be rapid, simple, sensitive, precise, accurate and reliable for routine analysis in research institutions and quality control department in pharmaceutical industries.

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