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METHOD DEVELOPMENT AND VALIDATION OF TAMSULOSIN HCL IN BULK AND TABLET DOSAGE FORM BY UV SPECTROSCOPY METHOD

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ABSTRACT

A Simple, rapid, accurate and economical UV Spectrophotometric method is developed for determination of tamsulosin hydrochloride in bulk and pharmaceutical dosage forms. In Acetonitrile, the λ max of the drug was found to be 224 nm. Using UV instrument (analytical), in this proposed method tamsulosin hydrochloride follows linearity in the concentration range 0.5 – 1.50µg/ml with a correlation coefficient of 0.999. Assay results were in good agreement with label claim. The relative standard deviation was found to be 0.398272 with excellent precision.

KEYWORDS: Tamsulosin hydrochloride, U.V. Spectrometry, Acetonitrile.

INTRODUCTION

Tamsulosin, 5- [(2R)-2[[2-(2-Ethoxy Phenoxy) ethyl] amino] Propyl} - 2-methoxy benzene sulfonamide. Tamsulosin is a selective alpha 1 adrenoceptor blocking agent. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha1 adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Blockade of these adrenoceptors can cause smooth muscles in the bladder, neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH.

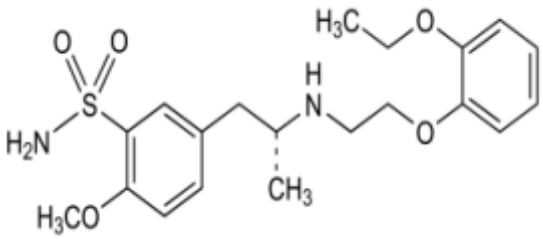


Fig-1 Tamsulosin

IUPAC NAME: 5 - [(2 R)- 2 - [[2 -(2 –Ethoxyphenoxy) ethyl] amino] propyl]- 2 – methoxy benzene sulfonamide.

MATERIALS USED: Drug sample and formulation used Tamsulosin hydrochloride bulk drug gifted by Medreich limited, Bengaluru. Karnataka. Tamsulosin hydrochloride (Urimax 0.4mg) tablet purchase in local pharmacy.

CHEMICALS AND SOLVENTS USED: All the chemicals used were of analytical grade procured from great scientific Tiruvannamalai. The chemicals used for the study were, Acetonitrile (Analytical Grade) Distilled water.

INSTRUMENTS USED

Instruments employed for the study were,

1. Digital balance
2. SHIMADZU – 1700 Double beam UV –Visible spectrophotometer with pair of 10mm matched Quartz cell
3. Sonica Ultra Sonic cleaner – model 2200MH
4. Melting point apparatus (Laboratory setup).

PREPARATION OF STANDARD STOCK SOLUTION

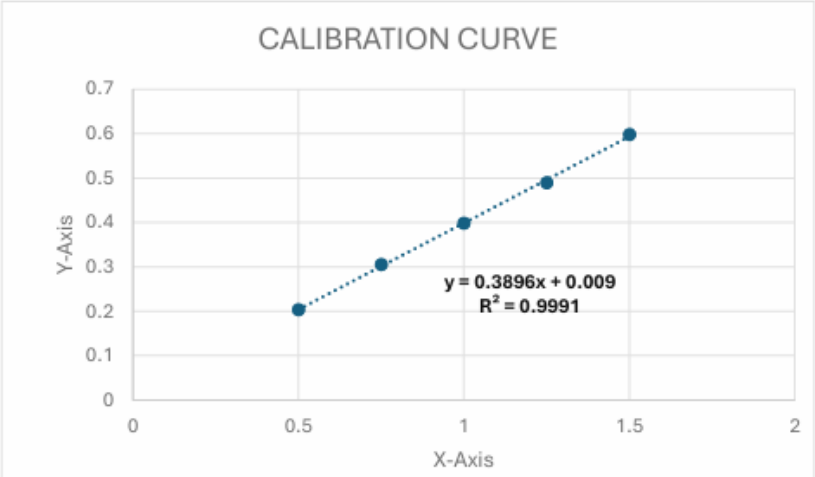
Standard Tamsulosin stock solutions were prepared by dissolving 10mg drug in Acetonitrile and volume make up to 100ml with DW to get concentration of 1mg/ml solutions. (100µg/ml).

PREPARATION OF LINEARITY CURVE

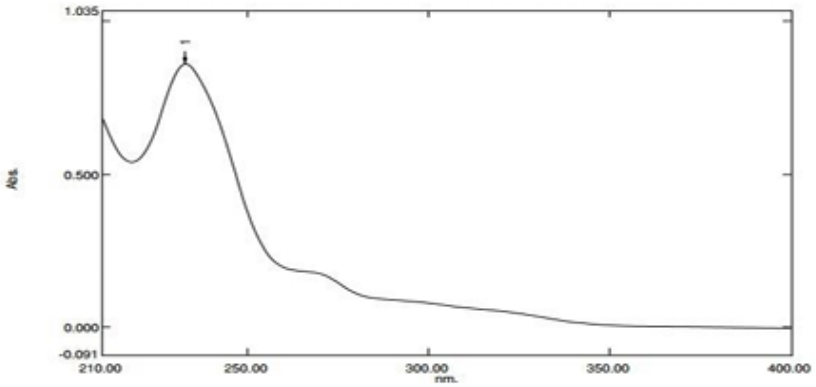
To construct Beer's law plot, different aliquots of tamsulosin (0.1-0.5ml) with different concentrations (0.50, 0.75, 1.0, 1.25and 1.50µg/ml) were prepared by serial dilutions with DW. Then absorbance of the solution was measured at 224 nm. The linearity range is shown

in Table- 1. The linearity curve was shown in fig-1, UV spectra was shown in fig-2 optical characteristics and regression equation of tamsulosin were shown in Table-2

s. no	CONC(mcg/ml)(Tamsulosin)	Absorbance
1	0.5	0.203
2	0.75	0.305
3	1.00	0.398
4	1.25	0.489
5	1.50	0.598



SPECTRUM PEAK PICK REPORT:



S.no	Wavelength in nm	Absorbance at 224nm
1	215	0.249
2	216	0.269
3	217	0.284
4	218	0.312
5	219	0.357
6	220	0.364
7	221	0.378
8	222	0.390

9	**224**	**0.398**
10	225	0.404
11	226	0.438

PARAMETERS	TAMSULOSIN HYDROCHLORIDE
LINEARITY RANGE	0.5-1.50
CORRELATION COEFFICIENT	0.999
REGRESSION EQUATION (Y) SLOPE(a) INTERCEPT(b)	 0.3896 0.009

ASSAY

The developed method can be used to successfully for the assay of tamsulosin hydrochloride in bulk and pharmaceutical dosage form without any interference the assay show the drug content of this product to be in concordance with the label claim of 0.4 mg and the value are given in the table.

S.no	Standard Absorbance	Sample Absorbance	Percentage purity	Average percentage purity	Std Deviation	%RSD
1.	0.398	0.384	96.4%			
2.	0.397	0.382	96.2%			
3.	0.399	0.390	97.7%	97.24%	0.004219	1.093006
4.	0.396	0.385	97.2%			
5.	0.397	0.392	98.7%			

METHOD VALIDATION

PRECISION

The precision of the proposed method was ascertained by actual determination of five replicates of fixed amount of the drug.

INTER DAY PRECISION

S.no	Absorbance	Average	SD	%RSD
1	0.402	0.403	0.001581	0.392342
2	0.401			
3	0.403			
4	0.405			
5	0.404			

INTRA DAY PRECISION

S.no	Absorbance	Average	SD	%RSD
1	0.397	0.397	0.001581	0.398272
2	0.395			
3	0.398			
4	0.399			
5	0.396			

RUGGEDNESS

The ruggedness of the proposed method was evaluated by applying the developed procedure to assay of 10µg/ml of Tamsulosin using the same instrument by two different analyzed under the same optimized conditions at different days. The results are shown in table,

S.no	Analysts	Conc(µg/ml)	Absorbance	SD	%RSD
1	Analysts-1	10µg/ml	0.396	0.003536	0.899627
		10µg/ml	0.397		
		10µg/ml	0.393		
		10µg/ml	0.390		
		10µg/ml	0.389		
2	Analysts-2	10µg/ml	0.398	0.00503	1.278574
		10µg/ml	0.389		
		10µg/ml	0.397		
		10µg/ml	0.387		
		10µg/ml	0.396		

ROBUSTNESS

Wavelength	Abs 1	Abs 2	Abs 3	Mean	SD	%RSD
222nm	0.390	0.392	0.390	0.390		
224nm	0.398	0.397	0.398	0.397	0.0065	1.6430
226nm	0.402	0.403	0.403	0.402		

The robustness of the method was determined by introducing small changes in UV parameter such as changing in the wavelength. The results are shown in table.

CONCLUSION

From the optical characteristics of the proposed method it was found that the drug obeys linearity within the concentration range of 0.50-1.50 µg/ml. From the results it was found that the percent RSD is less than 2% which indicates that the method has good reproducibility, which indicates that the method is accurate and which reveals the commonly used excipients and additives present in the pharmaceutical formulations did not interfere in the proposed method.

The proposed method was simple, sensitive and reliable with good precision and accuracy. The proposed method is specific while estimating the commercial formulations without interference of excipients and other additives. Hence, this method can be used for the routing determination of Tamsulosin in bulk samples and pharmaceutical formulations.

UV METHOD	TAMSULOSIN
Absorption maximum	218
Linearity range	0.5-1.50
Slope	0.3896
Correlation Coefficient	0.999
Label Claim(mg/tablet)	0.4

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