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Analytical Method Development and Validation for Estimation of Tamsulosin Hydrochloride by UV-Spectroscopic Method

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ABSTRACT: Tamsulosin Hydrochloride is a medication primarily used in men to treat the symptoms of an enlarged prostate, also known as benign prostatic hyperplasia (BPH). It belongs to a class of drugs called alpha – blocker. A simple, specific, rapid, precise and accurate UV Spectroscopic method have been developed and validated for determination of Tamsulosin Hydrochloride. Drug showed the absorption maxima at 280 nm and was linear for a range of 10 – 50 µg/ml with a correlation coefficient 0f 0. 9944.The validation of the above proposed method was done by carrying out precision and accuracy studies. The percentage recovery at three different levels i.e. 80%, 100% and 120% was found to be 99.8%, 99.9% and 99.9% respectively. The analytical method showed good Intra precision (repeatability) with relative standard deviation 1.445% and Inter precision with relative standard deviation is 1.939% which is less than 2. The proposed method was validated for the parameter Precision, Linearity and range, Accuracy, Robustness, Ruggedness, LOD, and LOQ. Hence proposed analytical method for estimation of Tamsulosin Hydrochloride formulation drug by UV spectrophotometer in pharmaceutical can be applied for the routine quality control analysis.

KEYWORDS: Validation, Tamsulosin Hydrochloride, UV Spectrophotometer.

I. INTRODUCTION

Tamsulosin is a selective, potent and competitive α1 – adrenoreceptor antagonist and has a greater affinity for these receptors, predominantly present in the human prostate. Chemically, Tamsulosin is 5 – [(2R) – 2- [[2-(2-ethoxy phenoxy) ethyl] amino] propyl] – 2– methoxy benzene sulfonamide hydrochloride. Tamsulosin is used in men to treat the symptoms of an enlarged prostate which includes difficulty in urination, painful urination, and urinary frequency and urgency. 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 works by relaxing the smooth muscles in the prostate and the bladder neck. This relaxation helps to improve the flow of urine and reduce the symptoms associated with BPH. It selectively targets alpha$_1$-adrenergic receptors, which are more prevalent in the prostate, minimizing effects on blood pressure compared to non-selective alpha-blockers.

Tamsulosin HCl is only for use in men for BPH. It does not shrink the size of the prostate gland but helps manage the symptoms. It is usually taken once daily, about 30 minutes after the same meal each day. Dizziness, light headedness, and a drop in blood pressure upon standing (orthostatic hypotension) can occur, especially when starting the medication or with dosage changes. It's important to get up slowly from a sitting or lying position. Alcohol can worsen these side effects.

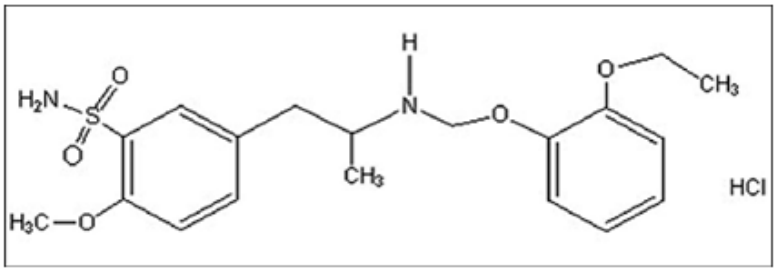

Fig.1 Molecular structure of Tamsulosin Hydrochloride

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Table .1. Drug Profile of Tamsulosin Hydrochloride

Sr. No.	Parameters	Tamsulosin Hydrochloride
1.	Molecular Formula	$C_{20}H_{29}ClN_2O_5S$
2.	Synonyms	5-(2-((2-(2-ethoxyphenoxy) ethyl) amino) propyl)-2-methoxybenzenesulfonamide Flomax LY-253352 tamsulosin hydrochloride. YM 617
3.	Molecular Weight	444.97 g/mol
4.	Category	Alpha-1 adrenergic receptor antagonist.
5.	Solubility	Sparingly soluble or slightly soluble in water and more soluble in organic solvents like methanol and DMSO.
6.	Mechanism of Action	Tamsulosin HCl works by selectively blocking alpha-1A and alpha-1D adrenoceptors, primarily located in the prostate gland, prostatic capsule, prostatic urethra, and bladder. This selective blocking action leads to relaxation of the smooth muscle in these areas.
7.	Uses	It is used to treat the symptoms of benign prostatic hyperplasia (BPH).
8.	Adverse Effects	• Sudden swelling of the face, lips, tongue, or throat • Difficulty breathing or swallowing • Severe allergic reaction • Priapism (painful, long-lasting erection) • Low blood pressure

II. MATERIALS AND METHODS

➢ Materials

1. Drug sample used

Pharmaceutically pure sample of Tamsulosin Hydrochloride were obtained from Alkem Laboratories, Mumbai.

2. Chemicals and Solvents

All the chemicals and solvents used were of analytical grade. The solvent system used for the study composed of–

- Methanol
- Water

3. Marketed Drug Formulation

The 0.4 mg of Tamsulosin Hydrochloride Tablet were purchased from local market.

4. Instrument

Double beam UV-Visible Spectrophotometer Shimadzu 1900 using UV Probe Software. The spectra were recorded over range 200 - 400 nm against solvent in 1 cm Quarts cells.

➢ Method Development

In the present work, an attempt was made to develop and validate a simple, precise and accurate method for the estimation of Pioglitazone and Metformin HCl in pure bulk form and in combined tablet dosage form by UV - Visible Spectroscopy.

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1. Selection of solvent system: -

The solubility of drugs was determined in a variety of polar to non-polar solvents as per Indian Pharmacopeial standards. We performed trial and error method to select the best possible solvent which can dissolve both drugs and tablet formulation.By performing solubility studies of Tamsulosin HCL in different solvents and its ratios, such as 0.1 N NaOH, Methanol: water (25:75), Methanol: water (50:50), Methanol: water (75:25). Observing results, we concluded best solvent system was Methanol: water in the ratios 1:1 respectively.

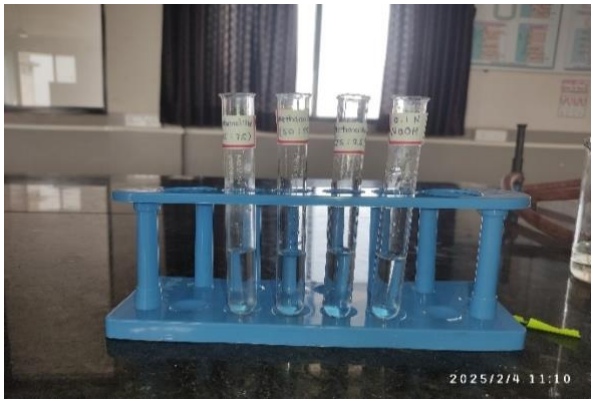

Fig.2 Selection of Solvent System (Trial & ErrorBasis)

2. Preparation of Standard Stock Solution: -

Accurately weighed 10 mg of Tamsulosin HCl were transferred into a clean & dried 100 ml volumetric flasks separately and then volume was made up to the mark with solvent Methanol: water (1:1) to get a standard concentration of 100 µg/ml. This standard stock solution (100 µg/ml) was further diluted with solvent system to obtain a series of dilution - 10, 20, 30, 40, and 50µg/ml for Tamsulosin HCl.

Fig.3 Standard Stock Solution of API & Series of dilution

3. Determination of Maximum Wavelength (λmax):

The standard solution having highest concentration was scanned at 200 nm to 400 nm with diluent as the blank to detect maximum wavelength (Fig.4).

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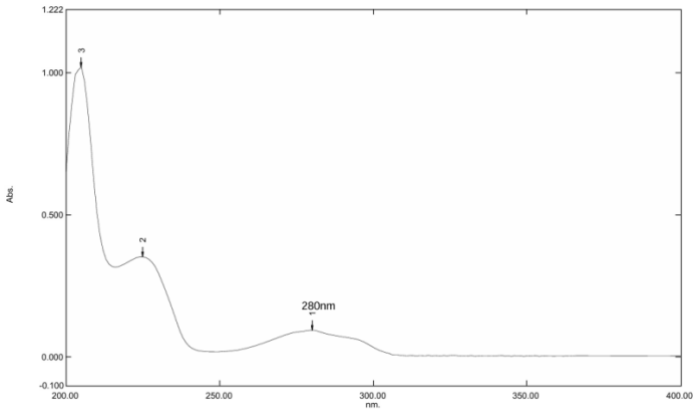

Fig.4 Estimation of Maxima of Tamsulosin Hydrochloride

From the above (Fig.4) spectra of Tamsulosin Hydrochloride wavelength maxima identified for quantification were 280 nm (λmax).

- **Method validation**

1. Linearity & Range

Prepare a series of standard solutions of Tamsulosin HCl having concentration of 10 µg/ml,20 µg/ml,30 µg/ml,40 µg/ml, and 50 µg/ml. Measure the absorbance of each standard solution at the determined **(**λmax**)**. Plot the absorbance values against the corresponding concentrations. A linear regression curve was constructed, the correlation coefficient (R^2) and assessment value calculated. The correlation coefficient (R^2) for Tamsulosin Hydrochloride obtained is 0.9944. The plot is a straight line and the results are tabulated in the Table 2 and Curve shown in the Figure 8.

Table 2. Linearity and Range

Sr. No.	Standard Concentration (µg/ml)	Absorbance@280nm	CorrelationCoefficient
1	10	0.099	0.9944 Limit ≥ 0.999
2	20	0.153	
3	30	0.223	
4	40	0.31	
5	50	0.378	

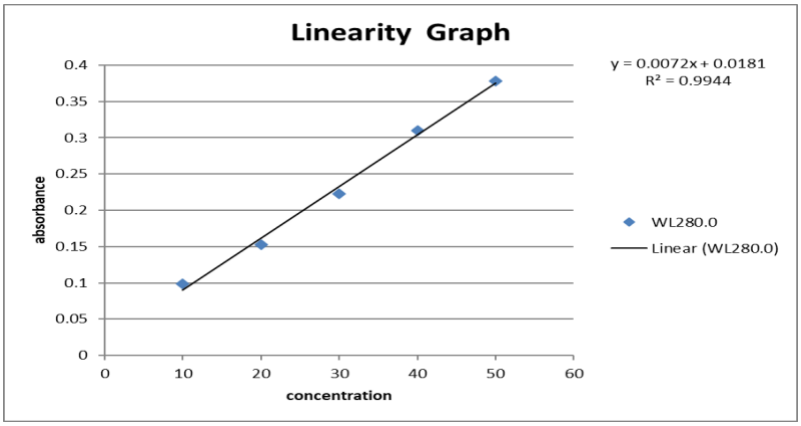

Fig.5 Linearity and Range of Tamsulosin Hydrochloride

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2. Precision

Express the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision is usually expressed as the standard deviation (SD) or relative standard deviation (%RSD).

1. Intra-day precision (Repeatability):

Assessed by analyzing multiple replicates of the same sample on the same day, under the same conditions. The % RSD due to Tamsulosin Hydrochloride concentration for samples was found to be 1.445%. The % RSD due to Tamsulosin Hydrochloride concentration for the assay meets the requirements. Results are tabulated in the Table 3.

Table 3. Intra Precision (Repeatability) Results

Sr. No.	Sample reading	Sample concentration	Absorbance	Mean	Standard Deviation	%RSD
1.	Morning	10 µg/ml	0.104	0.105	0.001	1.445% Limit < 2%
2.	Afternoon	10 µg/ml	0.106			
3.	Evening	10 µg/ml	0.107			

2. Inter-day precision (Intermediate Precision):

Assessed by analyzing multiple replicates of the same sample on different days, by different analysts, or using different equipment within the same laboratory. The %RSD due to Tamsulosin Hydrochloride concentration for the three samples was found to be 1.939%. The % RSD due to Tamsulosin Hydrochloride concentration for the assay meets the requirements. Results are tabulated in the Table 4.

Table 4. Inter-day Precision (Repeatability) Results

Sr. No.	Sample reading	Sample concentration	Absorbance	Mean	Standard Deviation	%RSD
1.	Day 1	10 µg/ml	0.105	0.107	0.001	1.939% Limit < 2%
2.	Day 2	10 µg/ml	0.107			
3.	Day 3	10 µg/ml	0.109			

3. Accuracy

This parameter determines the accuracy of the assay results under the same operating conditions test. A sample was constituted analysed for the accuracy with known quantity of standard samples of Tamsulosin Hydrochloride at 80%,100%, 120% concentration levels and assayed as per the method stated under analytical Methods respectively. Three determinations were performed under each concentration levels respectively. Results are shown in Tables 5, 6,7. The % RSD due to recovery of Tamsulosin Hydrochloride at 80%,100%, 120% concentration levels were found to be 1.875 %, 1.538% and 1.752% respectively. Nine sample preparations were analysed according to the proposed method of analysis. The % RSD due to Tamsulosin Hydrochloride concentration for the assay meets the requirements and within 98.0% to 102%. Results are tabulated in the Table 5, 6, 7.

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Table 5. Accuracy and Recovery Results @ 80 % Concentration level

Sr. No.	Accuracy @ 80% level	Amount Added	Absorbance	Amount Recovered	% Recovery	% RSD
1	Sample Preparation -1	20 µg/ml	0.160	1.99	99.8%	1.875% Limit < 2%
2	Sample Preparation -2		0.157	1.96		
3	Sample Preparation -3		0.163	2.04		

Table 6. Accuracy and Recovery Results @ 100 % Concentration level

Sr. No.	Accuracy @ 100% level	Amount Added	Absorbance	Amount Recovered	% Recovery	% RSD
1	Sample Preparation -1	25 µg/ml	0.195	2.50	99.9%	1.538% Limit < 2%
2	Sample Preparation -2		0.198	2.54		
3	Sample Preparation -3		0.192	2.45		

Table 7. Accuracy and Recovery Results @ 120 % Concentration level

Sr. No.	Accuracy @ 120% level	Amount Added	Absorbance	Amount Recovered	% Recovery	% RSD
1	Sample Preparation -1	30 µg/ml	0.230	2.99	99.9%	1.752% Limit < 2%
2	Sample Preparation -2		0.235	3.06		
3	Sample Preparation -3		0.227	2.94		

4. Robustness

Assess the capacity of the method to remain unaffected by small but deliberate variations in method parameters (e.g., wavelength, solvent composition, temperature). Make small changes to the method parameters and observe the effect on the absorbance of a standard solution. The method should remain reliable even with these small variations. The respective test assay results of Tamsulosin Hydrochloride having concentration as 10 µg/ml was illustrious. The result is expressed as shown in table 8.

Table 8. Robustness

Sr. No.	Wavelength(nm)	Absorbance	Mean	Standard Deviation	%RSD
1.	245nm	0.486	0.482	0.003	0.632
		0.482			
		0.480			
2.	271nm	0.086	0.085	0.001	1.783
		0.084			
		0.087			
3.	295nm	0.091	0.091	0.001	1.259
		0.091			
		0.093			

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5. Ruggedness

The degree of reproducibility of test results obtained by the analysis of the same sample in different laboratories, by different analysts, using different instruments, different reagents, and/or different days. The respective test assay results of Tamsulosin Hydrochloride having concentration as 10 µg/ml was illustrious. The result is expressed as shown in table 9.

Table 9. Ruggedness

Sr. No.	Analyst	Absorbance	Mean	Standard Deviation	%RSD
1.	Analyst - I	0.104	0.104	0.001	0.961 Limit < 2%
2.	Analyst - II	0.105			
3.	Analyst - III	0.103			

6. Limit of Detection (LOD)

The lowest amount of analyte in a sample that can be detected but not necessarily quantitated as an exact value. It can be calculated using the formula: LOD = 3.3 × (SD/Slope), where SD is the standard deviation of the response (y-intercepts of regression lines or standard deviations of blank determinations) and Slope is the slope of the calibration curve.
LOD = 3.3 × (0.0005/0.0127) = 0.130 µg/ml.

7. Limit of Quantitation (LOQ)

The lowest amount of analyte in a sample that can be quantitatively determined with suitable precision and accuracy. It can be calculated using the formula: LOQ = 10 × (SD/Slope), where SD is the standard deviation of the response (y-intercepts of regression lines or standard deviations of blank determinations) and Slope is the slope of the calibration curve.
LOQ = 10 × (0.0005/0.0127) = 0.394 µg/ml.

Assay of Tamsulosin HCL in its formulation

For analysis of commercial formulations of Tablets, 30 tablets were weighed, powdered and accurately weighed the equivalent to 10mg of Tamsulosin, which was transferred into 100 ml volumetric flask and make up to 100ml with methanol: water (1:1), filtered and further diluted with methanol: water (1:1) to get the concentrations within the linearity range 10-50 µg/ml and measured at 280 nm for Tamsulosin. Then the amount of drug present in the formulations was calculated. The results were shown in Table 10.

Table 10. Results of Assay

Drug	Label Claim (mg/tab)	Amount Estimated	%Label Claim	%Deviation
Tamsulosin	0.4	0.367	91.75%	-8.25%

III. RESULTS AND DISCUSSION

The method discussed in the present work provides a simple, stable, rapid, accurate, precise, reliable, less expensive (Economical), time saving and convenient method for the analysis of Tamsulosin Hydrochloride using U.V. Spectrophotometry. The results were shown in Table 11.

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Table 11. Results of Tamsulosin HCL

Sr. No.	Parameter	Results
1.	Absorbance Maxima (nm)	280nm
2.	Linearity & Range	10-50 µg/ml
3.	Regression equation	Y=0.071x+0.018
4.	Correlation Coefficient (R^2)	0.9944
5.	Intra precision %RSD	1.445%
6.	Inter-day precision %RSD	1.939%
7.	% Recovery at 80%	99.8%
8.	% Recovery at 100%	99.9%
9.	% Recovery at 120%	99.9%
10.	Robustness %RSD at 245nm	0.632%
11.	Robustness %RSD at 271nm	1.783%
12.	Robustness %RSD at 295 nm	1.259%
13.	Ruggedness %RSD	0.961
14.	LOD	0.130 µg/ml
15.	LOQ	0.394 µg/ml
16.	%Label Claim	91.75%

IV. CONCLUSION

Based on the outcome of analytical method development and analytical validation study test results, it was found that, the proposed analytical method for estimation of Tamsulosin Hydrochloride by UV Spectrophotometry is Accurate, Precise, Reproducible, Stable, Simple, Rapid Time saving and less expensive (Economical). The analytical method can be employed for routine quality control of Tamsulosin Hydrochloride in pharmaceutical analysis.

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