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A Elementary and Delicate Spectrophotometric Method for Resolution of Tamsulosin from Pharmaceutical Formulation

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ABSTRACT

Pharmaceutical formulations may now be accurately and quickly measured for Tamsulosin concentrations using a new spectrophotometric approach. Chloroform extractable ion pair complex of Tamsulosin and Phenol red was the basis of the suggested approach. Reagent blank is used to evaluate the absorbance of extractable Ion pair complexes at their maximal absorbance wavelength (510nm). There is statistical proof that the results achieved can be reproduced.

Key words: Spectrophotometry, Tamsulosin, Phenol red, Pharmaceutical and Formulation

MATERIALS AND METHOD

Instrument:

A Lab India 3000 plus UV Visible Spectrophotometer with a double-beam UV Visible detector was used for all measurements.

Hydrochloric acid (0.1N):

10 g of 36% HCl (Merck) is dissolved in 1000ml of distilled water.

1.1 M Potassium Hydrogen Phthalate : In 100 cc of purified water, dissolve 2.0422 grams of Fischer Scientific Potassium Hydrogen Phthalate.

Buffer solution (pH 3.6):

0.1 M potassium hydrogen phthalate (20.422 gram of Potassium Hydrogen Phthalate (Fischer scientific) in 1000 ml of distilled water) is mixed with 12.6 ml of 0.1M HCl and the pH of the solution is adjusted to pH3.6.

Phenol Red (100µg/ml):

After dissolving 80 mg of Phenol Red (Fischer Scientific) in Methanol 100 mL, 5 mL of this solution as a starting point is added to 40 mg of the same solution and stirred until the mixture is uniform.

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Preparation of standard stock solution: Tamsulosin, distilled water, and a stock solution of 1mg/ml were used to make it. Tamsulosin working standard solution (50 g/ml) was created by diluting the standard stock solution with Methanol.

INTRODUCTION

Tamsulosin is a 5-(2-{[2-(2-ethoxyphenoxy)ethyl] amino}propyl)-2-methoxybenzenesulfonamide that has (R)-configuration. Tamsulosinhas the following structural formula Fig.1

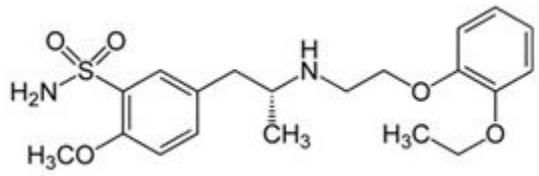

Fig: 1. Structure of Tamsulosin

For the testing of Tamsulosin, a number of analytical techniques have been published, including spectrophotometric methods1-15, emission spectra methods16, the vierordt method 17, UPLC methods 18 and HPLC methods 19. The spectrophotometric approach of Tamsulosin measurement has not been attempted in this novel.

As a secondary amine, the tamsulosin medication reacts with phenol red in the presence of chloroform at pH 3.6, resulting in the chloroform extraction described below. It is possible to detect spectrophotometrically by extracting the chloroform extractable layer, which contains the ion pair complex of Tamsulsin-Phenol red.

The determination of Tamsulosin in pharmaceutical formulations may be made using a spectrophotometer using a quick, simple, sensitive, and affordable approach described in this study. Tamsulosin in pharmaceutical dosage forms was to be determined using visible spectrophotometric procedures that were easy, sensitive, and verified.

Procedure:

Allotment 10 ml of deionized water to the volumetric flask, add 0.5 mL of Phenol red solution and 1.o mL of pH3.6 buffer solution, and let to stand for 5 minutes before using the volumetric flask. The flask's contents are poured into a separating funnel, which is then filled with chloroform and agitated. The aqueous

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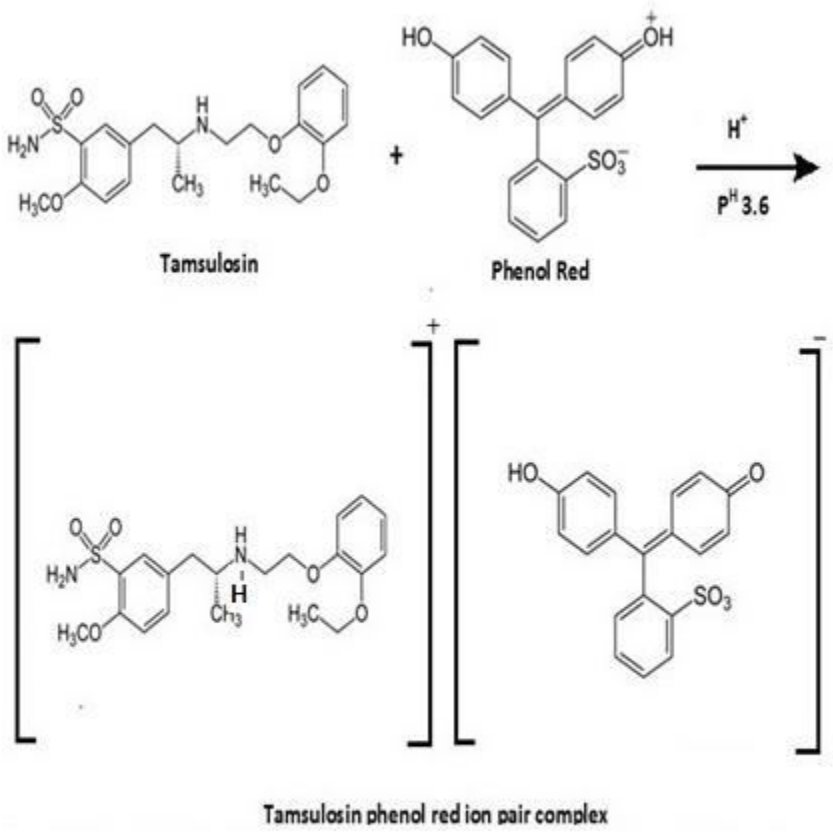
and chloroform layers are separated after 5 minutes of agitation in the separation funnel. Stored in conical flasks, the chloroform layer. Once again, chloroform is added to the volumetric flask, which is then poured through the separation funnel and extracted once again. It is collected in the same conical flask as chloroform. The combined chloroform layer is used to measure absorbance at 510 nm, which is used to compare the reagent blank against. This chloroform layer is used to test the absorbance of 510 nm against the reagent blank. You must repeat this process until you have utilized all of the Tamsulosin solutions.

Tamsulosin, in the presence of a chloroform-soluble buffer solution, forms an ion pair complex with Phenol red and is subsequently extracted on an organic layer. The reaction chain is shown in the diagram. 1



Scheme.1: Reaction sequence of ion pair complex between tamsulosin and phenol red

Absorbance graph of Tamsulosin - Phenol red ion pair complex is presented in following Fig.2. The perfect circumstances have arrived.

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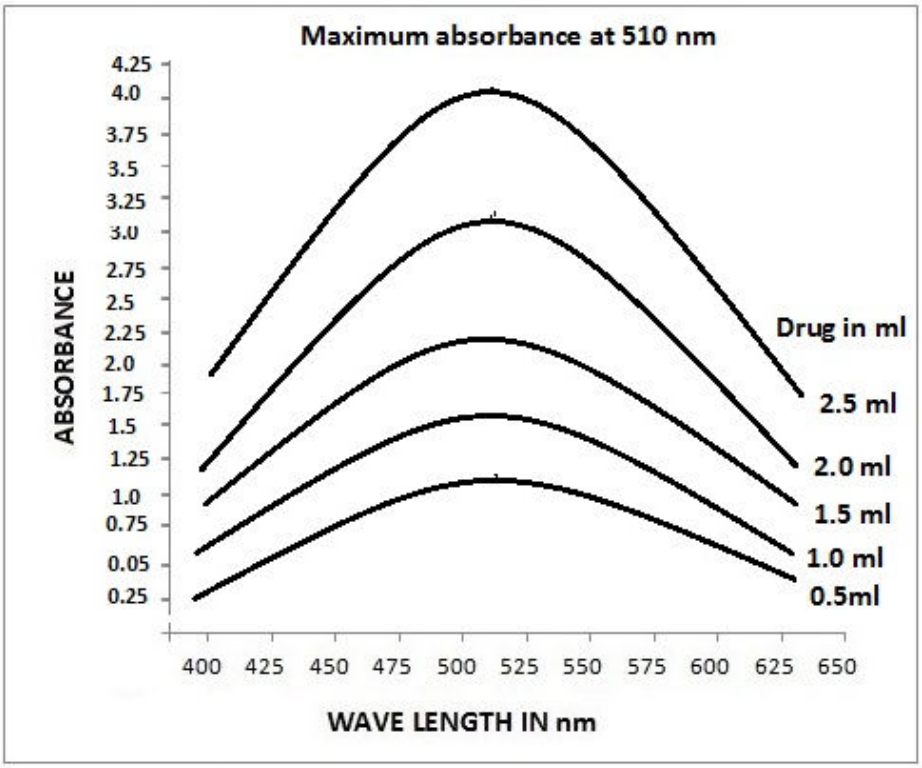

Fig. 2: Absorption spectrum of Tamsulosin-Phenol red complex

Construction of Calibration graph:

Tamsulosin (Pure medication donated by M/s. Dr. Reddy's Lab Ltd.) standard solution aliquots of 0.5-2.5ml are transferred into 10ml volumetric flasks. Add 0.5 milliliters of phenol red and 1.0 milliliters of buffer solution to each flask before filling it up with distilled water to the mark. Separation is accomplished by adding two volumes of 5 ml chloroform to a funnel and shaking gently for five minutes, then allowing the mixture to rest for five minutes to enable the aqueous and chloroform layers to separate. The aqueous layer is extracted with 5 ml of chloroform after the chloroform layer has been removed. After a second extraction, the combined chloroform layer is collected in a 50 ml conical flask and analyzed. At 510 nm, the reagent blank is made in the same way as the drug solution, but without the drug solution. Table 1 displays the drug's absorbance and concentration together with the related absorbance. All Tamsulosin solutions are subjected to the same rigorous testing procedure.

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Table.1: Construction of Calibration curve with the following values

Volume of Tamsulosin drug in ml	Amount of Tamsulosin in µg	Absorbance at 510 nm
0.5	20	0.092
1.0	40	0.162
1.5	60	0.243
2.0	80	0.323
2.5	100	0.409

Absorbance measurements are plotted against Tamsulosin concentration in order to create a calibration graph. When Tamsulosin is used at concentrations ranging from 20 to 100 g/mL, the calibration curve is found to be linear. Estimating Tamsulosin content is based on the calibration graph. Figure 3 shows the findings.

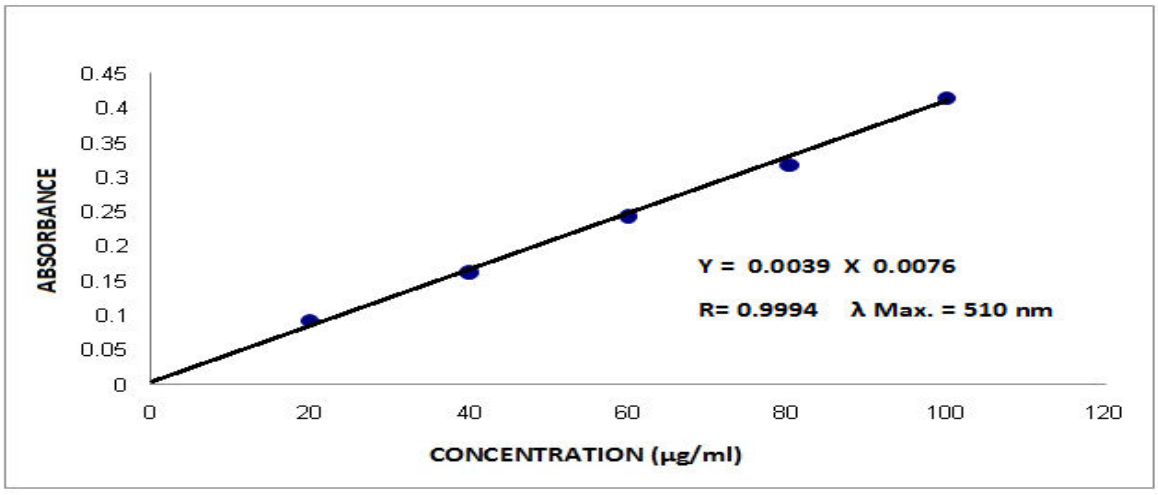

Fig. 3: Calibration curve of Tamsulosin

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Assay of pharmaceutical Formulations:

20 Tamsulosin pills are meticulously weighed and finely ground. To get the 50 mg of Tamsulosin, samples were taken in a 50-ml volumetric flask and sonicated for 20 minutes. After filtering using Whatman filter paper No. 41, the filtrate is collected in a second 50-ml volumetric flask. Numerous times, methanol washed the filter paper with it. The washings were added to the filtrate and the final volume was brought up to the mark with Methanol as part of the calibration curve procedure. The drug concentration in the sample was determined using calibration curves. Table 2 has all the information you need.

Results and discussions:

Tamsulosin, pH 3.6, dyed with Phenol red. Chloroform is used to extract the resulting solution. An extractable layer of Chloroform is used to form the ion pair complex. Measurement of absorbance at 510 nm against reagent blank of the extractable ion pair complex (prepared in a similar manner devoid of drug solution). Within a concentration range of Tamsulosin of 20-100 g/mL, the calibration curve is linear. Factors such as Beer's laws, molecular absorption, and Sandell's sensitivity are all examples of optical parameters.of the proposed approach are shown in Table 2. Measurements such as those using Sandell's and molecular absorbance reveal how sensitive the procedure is. As shown in Table 2, a least-squares regression analysis was performed on the slope, intercept, and correlation values obtained from varied concentrations. Linearity in calibration lines was shown by a correlation coefficient of 0.9994. Table 2 shows the % relative standard deviation based on the five Tamsulosin readings. Good repeatability may be shown by the fact that the percentage of RSD is less than 2. Standard deviation numbers are minimal, indicating that the procedure is accurate and replicable. There is no substantial difference between the suggested and official methods, as shown in table 3, when the estimated values of 't' are compared to the theoretical value of 2.78. If you're looking for an additive or excipient that doesn't have an influence on the dosage of a drug, you're better off looking for anything else.

An advantage of the suggested approach is that it is easy to implement for regular examination of estimate of Tamsulosin in bulk pharmaceuticals samples and pharmaceutical formulations, as well as repeatable.

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Table. 2:

Optical characteristics of proposed method

parameters	Proposed method
λmax (nm)	510
Beer's law limit (µg/ml)	20-100
Molar absorbitivity (l mole-^{1} cm-^{1})	1.66X10^{4}
Sandell's sensitivity (µg cm-^{2} / 0.001 absorbance unit)	0.0602
Regression equation (Y = bx+a)	Y=0.0039 x+ 0.0076
Slope (b)	0.0039
Intercept (a)	0.0076
Correlation coefficient (r)	0.9994

*Y = bx+a, where Y is the absorbance and X concentration in µg / ml.

Table. 3:

Assay of Tamsulosin in tablets

S.No	Tablets (mg)	*Amount Found(mg) ±S.D*	% Label claim	*t_{cal}
1	0.4	0.3979±0.006	99.48	0.2859
2	0.4	0.3984±0.0015	99.6	0.2985

*Average of five determination based on the label claim

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