Original Article

Spectrophotometric estimation of tamsulosin hydrochloride by acid-dye method

Abstract

A new spectrophotometric method for the estimation of tamsulosin hydrochloride in pharmaceutical dosage forms has been developed and validated. The method is based on reaction between drug and bromophenol blue and complex was measured at 421 nm. The slope, intercept and correlation coefficient was found to be 0.054, -0.020 and 0.999, respectively. Method was validated in terms of specificity, linearity, range, precision and accuracy. The developed method can be used to determine drug in both tablet and capsule formulations. Reaction was optimized using three parameters i.e., concentration of the dye, pH of the buffer, volume of the buffer and shaking time. Maximum stability of the chromophore was achieved by using pH 2 and 2 ml volume of buffer. Shaking time kept was 2 min and concentration of the dye used was 2 ml of 0.05% w/v solution. Method was validated in terms of linearity, precision, range, accuracy, LOD and LOQ and stochiometry of the method was also established using Mole ratio and Job's method of continuous variation. The dye benzonoid form (blue color) of dye ionized into quinonoid form (purple color) in presence of buffer and reacts with protonated form of drug in 1:1 ratio and forms an ion-pair complex (yellow color).

Key words: Bromophenol blue, method development and validation, spectrophotometric estimation tamsulosin hydrochloride

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INTRODUCTION

Tamsulosin hydrochloride 5-[(2R)-2-[2-(2-ethoxyphenoxy)ethylamino]propyl]-2-methoxybenzenesulfonamide hydrochloride [Figure 1] is a uroselective α_{1A} ($\alpha_{1A:}$ α_{1B} affinity 7-38-fold) antagonist which is used in benign prostatic hyperplasia (BPH). The α_{1A}-receptors are prominent in prostate, prostatic capsule, prostatic urethra and bladder where it acts by relaxation of prostate and bladder smooth muscles helps to urine flow, reduction of lower urinary tract symptoms and decrease urinary hesitancy/urgency. The medication is available in single or in combination with dutasteride or finasteride.[1] Tamsulosin is official in European pharmacopoeia.[2]

Various analytical methods reported are HPLC-UV method for estimation of TAM and its impurity (J.G. Chandorkar *et al*.),[3] LC/ESI-MS–MS method (R. Nageswara Rao *et al*.)[4] for assay and related substance estimation, LC-MS for determination of tamsulosin in human aqueous humor and serum (Pekka Keski-Rahkonen *et al*.).[5] In plasma estimation by LC–ESI-MS reported by Li Ding *et al*.,[6] estimation of drug in dog plasma by LC-MS,[7] chiral separation by its *S*-isomer by HPLC-UV[8] and HPLC with fluorescence estimation in human plasma[9] is also reported. Other methods include voltametry[10] and chiral separation by capillary electrophoresis[11] is also available in the literature. HPTLC[12] and radioreceptor analysis[13] of TAM alone and in combination with 5 α_1-reductase inhibitor like dutasteride[14] and finasteride[15] such as UV spectroscopy, ratio derivative spectroscopy, LC–MS–MS[16], HPLC-UV[17] and LC-TMS[18] methods are also developed and reported so far. Methods in combination with tolterodine tartrate by UV[19] and HPLC-UV[20] methods are available in the current scientific communications. But to the best of our knowledge there is no single method

available for the estimation by UV spectroscopy which is far simpler, economical and less time consuming as compared to above-mentioned methods.

The acid-dye method can provide a more sensitive technique for certain amines and quaternary ammonium compounds that absorb weakly in the ultraviolet region. In such methods addition of an amine in its ionized form to an ionized acidic dye, yields a salt (ion-pair) that may be extracted into an organic solvent such as chloroform or dichloromethane. The indicator dye is added in excess and the pH of the aqueous solution is adjusted (if necessary) to a value where both the amine and dye are in ionized forms. The ion-pair is separated from the excess indicator by extraction into the organic solvent, and the absorbance is measured at the λ_{max} of the indicator in the solvent.[21] TAM exist as secondary ammonium salt, thus acid-dye method is found suitable for increasing the sensitivity of the drug. Hence this forms sufficient basis for the development of such type of method for Tamsulosin also. Further validation of the proposed method was planned to be performed as per ICH guidelines[22].

MATERIALS AND METHODS

Pure tamsulosin hydrochloride was received as gift sample by Aurobindo Pharma Ltd., Hyderabad, India. UV-Visible spectrophotometer of Shimadzu Corporation model UV-1800 was used in the estimation. Methanol, bromophenol blue, potassium chloride, concentrated HCl and chloroform were purchased from Loba Chemie Pvt. Ltd. and were of GR grade.

Preparation of reagents and solutions

Dye solution

0.05% w/v dye solution was freshly prepared by dissolving the dye in distilled water.

HCl-KCl buffer

Buffer was prepared according to I.P. method by mixing 0.2 M KCl and a suitable amount of 0.2 M HCl to obtain the buffer of required pH.

Standard solution of drug

Standard stock of drug was prepared by dissolving 50 mg of pure drug in methanol and diluted 10 ml to obtain a standard solution of 5000 µg/ml. 2.5 ml of this stock was diluted 50 ml to obtain a working standard of 250 µg/ml.

Optimization of the reaction conditions

Reaction was optimized using three parameters i.e., concentration of the dye, pH of the buffer, volume of the buffer and shaking time. Maximum stability of the chromophore was achieved by using pH 2 and 2 ml volume of buffer. Shaking time kept was 2 min and concentration of the dye used was 2 mL of 0.05% w/v solution. Figure 2 clearly indicate the increase in absorbance of TAM after reaction with dye.

Choice of concentration of dye

From the literature it was revealed that in acid dye complexation method the amount of dye should be in excess. The ion-pair between the drug and dye formed is in 1:1 ratio. Thus, 2 ml of 0.05% w/v solution of dye will be sufficient for the proposed method.

Shaking time

As the drug was soluble in methanol and dye in water, so ion-pair was formed in aqueous layer. Therefore, the shaking time should be sufficient enough to extract the ion-pair of drug and dye from the aqueous layer to organic layer and 2 min shaking time was selected for extraction.

Volume and pH of buffer

HCl-KCl buffer was selected for the purpose, different pH and volume was used to optimize this parameter. The condition showing maximum absorbance and stability is the basis of selection of optimized condition. This is obvious from the results

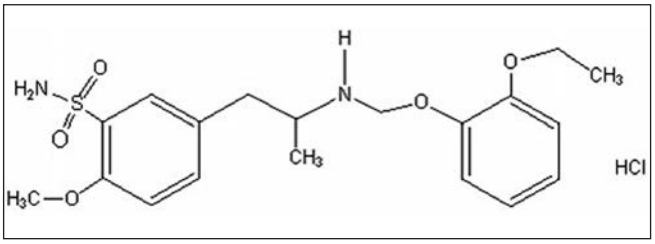

Figure 1: Chemical structure of tamsulosin hydrochloride

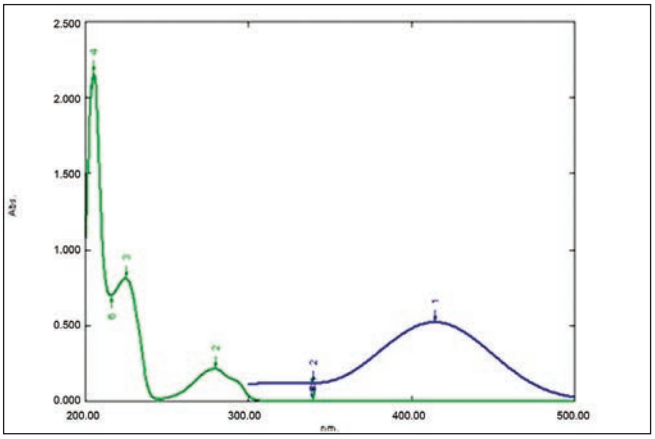

Figure 2: Overlay spectra of pure TAM (a) 200 µg/ml in methanol and (b) Ion-pair complex (10 µg/ml with BPB in chloroform)