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Novel Spectroscopic Methods for the Determination of Tamsulosin in Bulk and Capsules

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Abstract:
Four simple, sensitive and accurate visible spectrophotometric methods (A, B, C & D) are developed for the determination of tamsulosin in pure and tablet dosage forms. The methods A, B and C are based on the coupling of the drug with 4 amino antipyrine, orcinol and resorcinol in alkaline medium, respectively. The resulting colored complexes showed absorbance maxima at 400, 440 and 430 nm for 4 amino antipyrine, orcinol and resorcinol, respectively. The method D is based on the formation of a purple colored ion-pair complex of tamsulosin & eriochrome black T and extracting in chloroform. The extracted complex shows absorbance maxima at 520 nm. The calibration curves were found to be linear in the range of 4-20 µg/mL for all the proposed methods. Apparent molar absorpitivities were 2.658×10^4, 1.407×10^4, 1.874×10^4 and 1.579×10^4 L/mol/cm; Sandell sensitivities were 0.0167, 0.0316, 0.0024, and 0.0321 µg/cm^2/0.001 absorbance, for methods A, B, C and D, respectively. The proposed methods have been applied successfully to the assay of tamsulosin in capsule dosage forms. 2.658×10^4, 1.407×10^4, 1.874×10^4 and 1.579×10^4 L/mol/cm, whereas Sandell sensitivities are 0.0167, 0.0316, 0.0024, and 0.0321 µg/cm^2/0.001 absorbance unit for methods A, B, C and D, respectively

Key words: Tamsulosin, 4 Amino Antipyrine, Orcinol, Resorcinol, Eriochrome black T, Spectrophotometric analysis.

INTRODUCTION

Tamsulosin (TSN), chemically known as (*R*)-5-(2-{[2-(2-ethoxyphenoxy) ethyl] amino}propyl)-2-methoxybenzene-1-sulfonamide (Figure 1) , belongs to a class of medications called uroselective α_{1a}- adrenergic receptor antagonist used in the treatment of symptoms of enlarged prostate (benign prostatic hyperplasia) which include difficulty urinating, painful urination, and urinary frequency and urgency [1-4]. TSN works by relaxing the muscles in the prostate and bladder so that urine can flow easily.

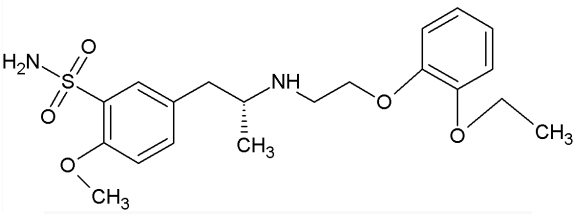

Figure 1. Chemical Structure of Tamsulosin

Several analytical techniques have been described for the determination of TSN in bulk, pharmaceutical formulations biological samples which include HPLC [5-10], stability indicating HPLC [11], stability indicating HPTLC [12,13], LC-MS-MS [14-20], radioreceptor assay [21,22], potentiometry [23], voltametry [24], capillary electrophoresis [25], spectroflorimetric [26], UV [27] and visible spectrophotometry [28,29].

No visible spectrophotometric method has been reported for quantification of TSN in bulk and pharmaceutical formulations using 4-aminoantipyrine, orcinol, resorcinol and eriochrome black T as chromogenic reagents. The purpose of the present work is to develop four simple, sensitive, and rapid spectrophotometric methods for the determination of TSN in bulk and capsule dosage forms. The methods A, B and C are based on the coupling of TSN with 4 amino antipyrine (method A), orcinol (method B) and resorcinol (method C) under alkaline condition. The method D was based on the extraction of TSN into chloroform as purple colored ion pair with eriochrome black T. The proposed methods were applied for the determination of TSN in capsule dosage forms.

MATERIALS AND METHODS

Instrumentation:

After due calibration of the instrument, spectral and absorbance measurements were made using Elico UV-Visible spectrophotometer model SL-159, Mumbai, India.

Preparation of Reagents:

All the chemicals used were of analytical grade. All solutions were freshly prepare with distilled water and always used for analysis. Following aqueous solutions were prepared:

Method A:

- 0.3 % 4-Aminoantipyrine (oxford laboratory chemicals, Mumbai, India)
- 0.5 % Ammonia (Merck Specialties Private Ltd, Hyderabad, India)

Method B:

- 0.5 % Orcinol (Merck Specialties Private Ltd, Hyderabad, India)
- 0.5 % Ammonia (Merck Specialties Private Ltd, Hyderabad, India)

Method C:

- 0.5 % Resorcinol (Merck Specialties Private Ltd, Hyderabad, India)
- 0.5 % Ammonia (Merck Specialties Private Ltd, Hyderabad, India)

Method D:

- 0.1 % Eriochrome black T (Merck Specialties Private Ltd, Hyderabad, India)
- Chloroform (Sdfine-Chem limited, Mumbai, India)

Standard solution of Tamsulosin:

About 100 mg of tamsulosin was accurately weighed on a digital single pan balance, dissolved in a volumetric flask containing 50 mL of methanol (Rankem laboratories, Mumbai, India) and made upto the mark with the same solvent to prepare a standard solution with a concentration equal to 1mg/mL. Further dilution (100 µg/mL) of the standard solution was made with the methanol for the proposed methods A, B, C and D.

Capsule dosage form of Tamsulosin:

Urimax (Cipla Ltd., Mumbai, India) capsules containing 0.4 mg of TSN were purchased from local pharmacy store.

Assay procedure:

Method A:

Aliquots (0.4-2.0 mL) of the standard TSN solution (100 µg/mL) were transferred into a series of 10 mL calibrated flasks and then solutions of 0.3 % 4-aminoantipyrine (0.5 mL) and 0.5 % ammonia (2.0 mL) were added successively. The total volume in each flask was brought to 10 mL with methanol. The absorbance of the yellowed colored complex was measured after 5 min at 400 nm against a reagent blank prepared similarly. The content of the drug was computed from the calibration graph.

Method B:

Aliquots (0.4-2.0 mL) of the standard TSN solution (100 µg/mL) were transferred into a series of 10 mL calibrated flasks and then solutions of 0.5 % orcinol (0.5 mL) and 0.5 % ammonia (2.0 mL) were added successively. The total volume in each flask was brought to 10 mL with methanol. The absorbance of the orange colored complex was measured after 5 min at 440 nm against a reagent blank prepared similarly. The content of the drug was computed from the calibration graph.

Method C:

Aliquots (0.4-2.0 mL) of the standard TSN solution (100 µg/mL) were transferred into a series of 10 mL calibrated flasks and then solutions of 0.5 % resorcinol (0.5 mL) and 0.5 % ammonia (1.0 mL) were added successively. The total volume in each flask was brought to 10 mL with methanol. The absorbance of the yellowed colored complex was measured after 5 min at 430 nm against a reagent blank prepared similarly. The content of the drug was computed from the calibration graph.

Method D:

Aliquots (0.4-2.0 mL) of the standard TSN solution (100 µg/mL) were transferred into a series of 100 mL separating funnels. The volume in each separating funnel was adjusted to 2.0 mL with methanol. 2.0 mL of 0.1% eriochrome black T were transferred to each funnel and mixed well. The funnels were shaken vigorously with 5 mL of chloroform for 2 min and then allowed to stand for clear separation of the two phases. The chloroform phase thus separated was transferred into a 10 mL volumetric flask, made up to the mark with chloroform and mixed well. The absorbance of the purple colored chloroform phase was measured at 520 nm against a reagent blank prepared similarly. The content of the drug was computed from the calibration graph.

Analysis of Capsule dosage forms:

The contents of capsule dosage forms of urimax, for TSN (100 mg), were weighed and then transferred to a 100 mL beaker containing 50 mL of methanol. The solution was shaken thoroughly for about 15–20 min. The solution was filtered in Whatman No 1 filter paper, washed well, and the filtrate was transferred into a 100 mL volumetric flask and completed to the mark with methanol. An aliquot of the solution containing 50 and 70 µg/mL of the drug was transferred to a 10mL calibrated flask and analyzed applying methods A, B, C or D.

RESULTS AND DISCUSSION

The results obtained in the methods A, B and C involves the coupling of TSN with 4 amino antipyrine (method A), orcinol (method B) and resorcinol (method c) in alkaline medium. The absorption spectra of the chromogens formed between TSN-4 amino antipyrine, TSN-orcinol and TSN-resorcinol showed absorption maxima at 400, 440 and 430 nm respectively (Figures 2, 3 and 4). The results obtained in the method D was based on the reaction between TSN and eriochrome black T resulting in the formation of an purpled colored ion-pair complex which could be extracted into chloroform. The ion-pair complex has an absorption maximum at 520 nm (Figure 5). The proposed mechanism of the proposed methods A, B, C and D are shown in Figures 6, 7, 8 and 9, respectively.

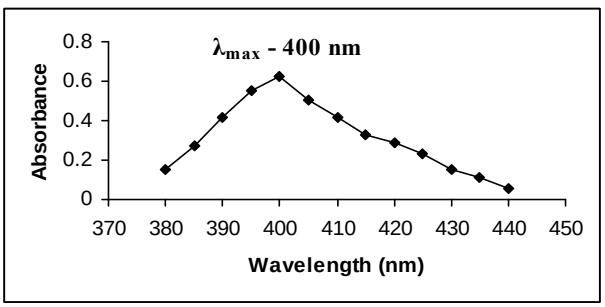

Figure 2. Absorption spectrum of Tamsulosin-4 Amino antipyrine complex

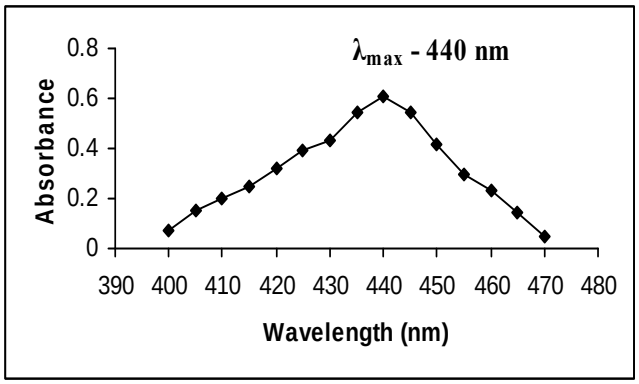

Figure 3. Absorption spectrum of Tamsulosin-orcinol complex

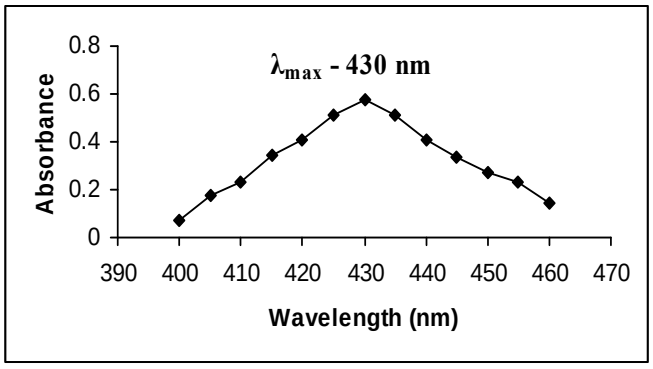

Figure 4. Absorption spectrum of Tamsulosin-resorcinol complex

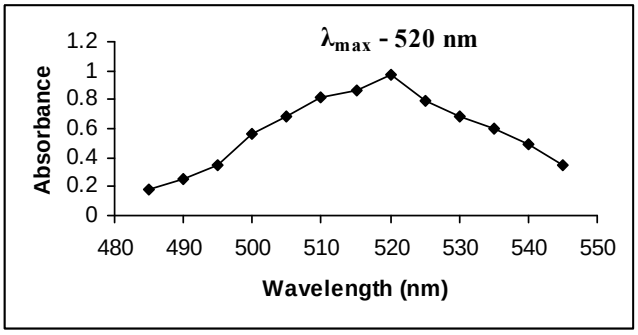

Figure 5. Absorption spectrum of Tamsulosin-eriochrome black T complex

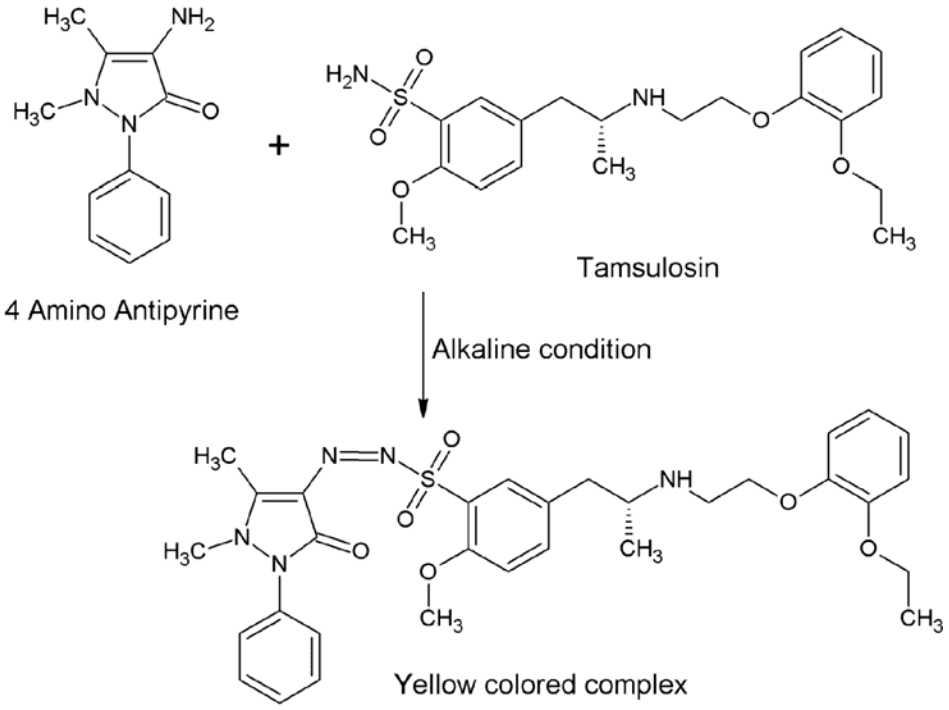

Figure 6. Proposed mechanism of coupling of Tamsulosin with 4 Amino antipyrine

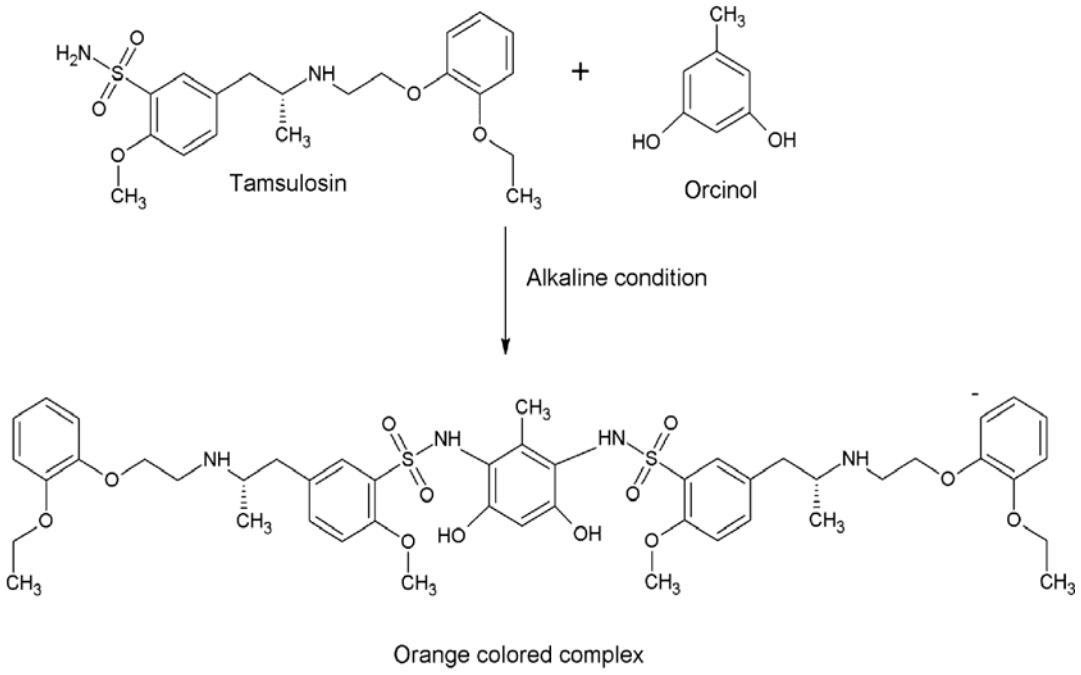

Figure 7. Proposed mechanism of coupling of Tamsulosin with Orcinol

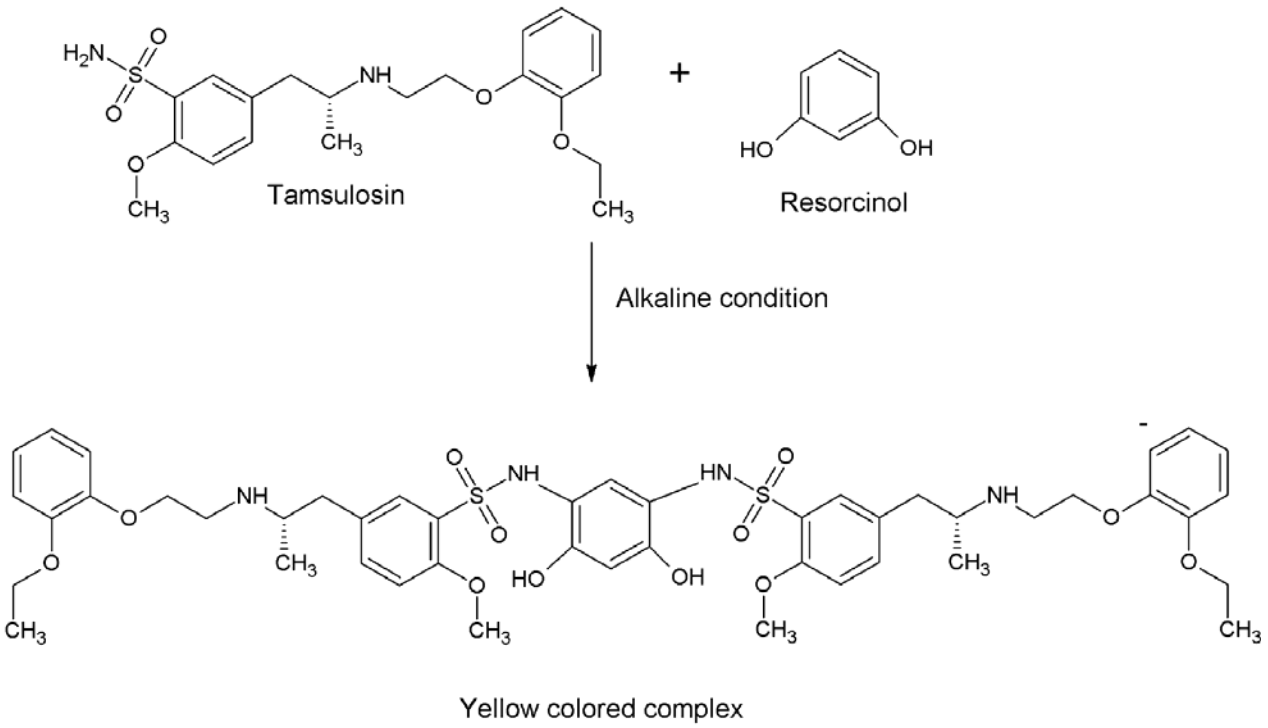

Figure 8. Proposed mechanism of coupling of Tamsulosin with Resorcinol

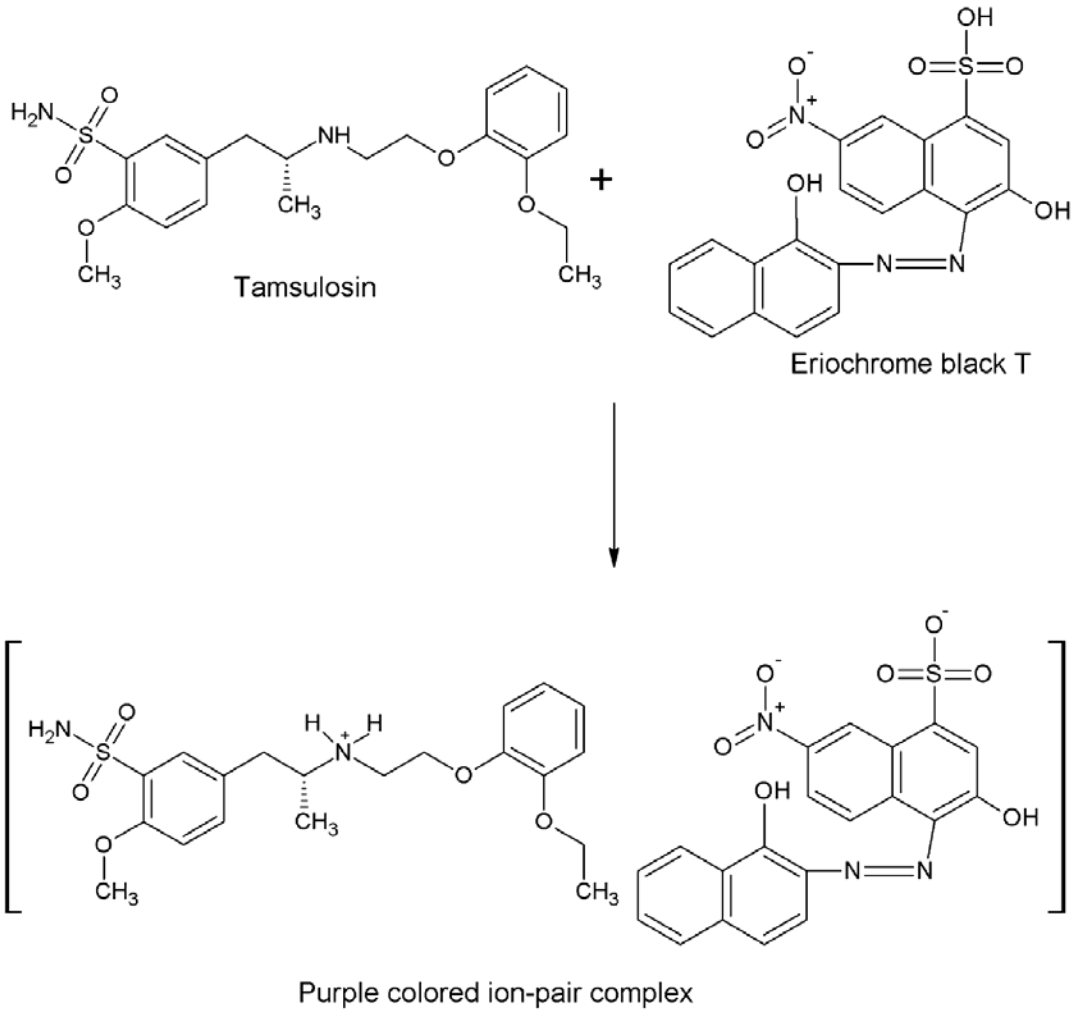

Figure 9. Proposed mechanism of ion-pair formation between Tamsulosin and Eriochrome black T

Table 1.Optical and Regression characteristics, Precision and accuracy of the proposed methods for Tamsulosin

Parameters	Method A	Method B	Method C	Method D
λ_{max} (nm)	400	440	430	520
Beer's Limit (µg/mL)	4-20	4-20	4-20	4-20
Molar Absorbitivity (L/mole/cm)	2.658×10^4	1.407×10^4	1.874×10^4	1.579×10^4
Sandell's sensitivity (µg/ cm^2/0.001 Absorbance unit)	0.0167	0.0316	0.0024	0.0321
Regression equation (Y= a + bx)*				
Slope (b)	0.0262	-0.0820	0.107	0.009
Intercept (a)	0.0443	0.0378	-0.0302	0.0621
Regression coefficient (r^2)	0.9998	0.9998	0.9998	0.9998
Standard deviation@	8.90×10^{-3}	9.72×10^{-3}	9.98×10^{-3}	1.10×10^{-3}
Relative standard deviation (%)	1.22	1.89	1.47	1.95
Range of errors (%)				
0.05 significance level	±1.020	±1.580	±1.229	±1.631
0.01 significance level	±1.509	±2.338	±1.819	±2.410

* Y= a + bx, where'Y'is the absorbance and x is the concentration of tamsulosin in µg/mL
@ For five replicates

Table 2. Assay and recovery of Tamsulosin in capsules

Brand name of TSN Capsule	Amount of TSN taken (µg/mL)	Amount of TSN found (µg/mL)*				Recovery (%)			
		Method A	Method B	Method C	Method D	Method A	Method B	Method C	Method D
Urimax	50	48.0	48.0	49.0	46	96.0	96.0	98.0	92.0
Urimax	70	66.0	67.0	67.0	62	94.0	95.7	95.7	91.0

* Average of five determinations

A linear correlation was obtained between absorbance and the concentration over the range 4-20 µg/mL of TSN in the methods A, B, C and D. The apparent molar absorptivity, Sandell sensitivity and regression equation for each method was calculated and is tabulated in Table 1. The apparent molar absorptivity of the resultant colored products was found to be 2.658×10^4, 1.407×10^4, 1.874×10^4 and 1.579×10^4 L/mol/cm, whereas Sandell's sensitivities are 0.0167, 0.0316, 0.0024, and 0.0321 µg/cm^2/0.001 absorbance unit for methods A, B, C and D, respectively. The high value of molar absorptivity and low value of Sandell sensitivity indicated the fair sensitivity of the proposed methods. The correlation coefficient for the methods A, B, C and D was found to be 0.9998.

The precision and accuracy of the proposed methods were found by analyzing five replicate samples containing known amounts of the drug and the results are summarized in Table-1. The accuracy of these methods in the case of capsules was thoroughly studied by recovery experiments and the results were presented in Table-2. The low values of standard deviation, relative standard deviation, percent range of error and high values of recovery indicate the high accuracy, precision, and reproducibility of the proposed methods to determine TSN.

Application of the proposed methods to capsules containing TSN:

The proposed methods were successfully applied to determine TSN in its capsule dosage form. The results are summarized in Table 2. The proposed methods were more accurate with high recoveries indicating the absence of any interference from the excipients.

CONCLUSION

Four visible spectophotometric methods were developed for the quantification of tamsulosin in bulk and dosage forms. The proposed methods were found to be simple, rapid and economical. The statistical parameters and recovery study data obviously indicate the reproducibility and accuracy of the method. So the proposed methods can be recommended for routine analysis of TSN in pure and dosage forms in the majority of drug quality control laboratories.

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