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NOTE

New Spectrophotometric Methods for the Estimation of Tolterodine Tartarate in Pharmaceutical Formulations

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Two simple and sensitive visible spectrophotometric methods (methods A and B) have been developed for the estimation of tolterodine tartarate in pure as well as in pharmaceutical formulations. Method A is based on the oxidative coupling reaction with 3-methyl-2-benzothiazolinone hydrazone (MBTH) in the presence of ceric ammonium sulphate (CAS) to form a coloured species with λ_{max} at 555 nm. Method B is based on the oxidation of the drug with ferric chloride followed by complexation with 1,10-phenanthroline (1,10-PTL) to form a blood red coloured chromogen with λ_{max} at 520 nm. Beer's law is obeyed in the range of 10–50 and 2.5- 12.5 μg/mL for methods A and B respectively. The results obtained are reproducible and statistically validated and also found to be suitable for the assay of tolterodine tartarate in bulk as well as in pharmaceutical formulations.

Key Words: 3-Methyl-2-benzothiazolinone hydrazone, 1,10-Phenanthroline, Tolterodine tartarate.

Tolterodine tartarate[1, 2] (TLD) is a urogential antispasmodic; chemically it is phenol, 2-[(1R)-3-[bis(1-methylethyl)amino]-1-phenylpropyl]-4-methyl-(2R,3R)-2,3-dihydroxybutane dioate (1 : 1). Literature survey reveals that no method was reported; hence an attempt has been made to develop two simple and sensitive visible spectrophotometric methods for the estimation of TLD in bulk as well as in pharmaceutical dosage forms.

Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells. All the chemicals used were of analytical grade.

3-Methyl-2-Benzothiazolinone hydrazone (MBTH) (0.2%): 200 mg of MBTH dissolved in 100 mL of distilled water.

Ceric ammonium sulphate (CAS) (1%): 1g of CAS dissolved in 100 mL of 0.72 M sulphuric acid.

1,10-phenanthroline (1,10-PTL) (0.2%): 200 mg of 1,10-PTL dissolved in 100 mL of distilled water.

Ferric chloride (0.5%): Freshly prepared by dissolving 500 mg of $FeCl_3$ in 100 mL of distilled water.

Preparation of standard and sample solutions: Accurately weighed 100 mg of TLD was dissolved and diluted with distilled water stepwise so as to obtain a concentration of 200 μg/mL. Sample solution was prepared by taking an amount equivalent to 100 mg of capsule powder, dissolved in 100 mL of water, then diluted stepwise so as to obtain a concentration of 200 μg/mL.

Assay procedures

Method A: Aliquots of standard drug solution ranging from 0.5–2.5 mL (1 mL = 200 μg) were transferred into a series of 10 mL graduated test tubes. 1.5 mL of MBTH and 1 mL of CAS were added to each of the test tubes and kept aside for 5 min at room temperature. The solutions were made up to volume with distilled water. The absorbance of the coloured species was measured at 555 nm. The amount of drug in the sample was computed from the calibration curve.

Method B: Aliquots of standard drug solution ranging from 0.5–2.5 mL (1 mL = 50 μg) were transferred to a series of 10 mL graduated test tubes. To each of the tubes, 0.5 mL of $FeCl_3$ and 2.5 mL of 1,10-PTL were added and kept in a water bath for 10 min, cooled and 1 mL of orthophosphoric acid was added. The solutions were made up to volume with distilled water. The absorbance of the coloured species was measured at 520 nm against reagent blank. The amount of drug in the sample was computed from the calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limits) were calculated and the results are summarized in Table-1. Regression characteristics like standard deviation of slope (S_b), standard deviation of intercept (S_a), standard error of estimation (S_e), % range of error (0.05 and 0.01 confidence limits) were also calculated (Table-1).

TABLE-1
OPTICAL CHARACTERSTICS AND PRECISION OF THE PROPOSED METHODS A AND B

Parameter	Method A	Method B
λ_{max} (nm)	555	520
Beer's law limits (μg/mL)	10–50	2.5–12.5
Molar absorptivity (L mol^{-1} cm^{-1})	9.5×10^4	2.682×10^4
Sandell's sensitivity (μg cm^{-2}/0.001 absorbance unit)	0.00493	0.01773
Regression equation (Y = a + bC):		
Slope (b)	2.02×10^{-1}	5.5×10^{-2}
Intercept (a)	1.0×10^{-3}	2.0×10^{-3}
Correlation coefficient (r)	0.9999	0.9999
Relative standard deviation (%)*	0.35	0.32
% Range of error (Confidence limits)*:		
0.05 level	0.292	0.266
0.01 level	0.432	0.393

* Average of eight determinations.

Pharmaceutical formulation of TLD was successfully analyzed by the proposed and reference methods. The results obtained by the proposed and reference methods are presented in Table-2. To evaluate the validity and reproducibility of the method, known amounts of pure drug were added to the previously analyzed samples and the mixtures were analyzed by the proposed method; there is no interference of other ingredients present in formulations. These results indicate that the method is simple, rapid with reasonable precision and accuracy and applicable to various formulations of tolterodine tartarate.

TABLE-2
ASSAY AND RECOVERY OF TOLTERODINE TARTARATE IN DOSAGE FORMS

Name of the dosage form	Labelled amount (mg)	Content of drug found (mg) by			%Recovery by	
		proposed methods		Reference method [R]	proposed methods†	
		A	B		A	B
Capsules I	2	2.02	1.98	1.98	101.0	99.0
Capsules II	2	1.99	2.01	2.01	99.5	100.5

R Reference was UV method developed in the laboratory.
†Recovery amount was the average of five determinations.

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