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NOTE

Spectrophotometric Determination of Tolterodine Tartarate and Repaglinide

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Simple and sensitive spectrophotometric methods has been developed for the estimation of tolterodine tartarate and repaglinide in pure as well as in pharmaceutical formulations. These methods are based on the oxidation of drug with ferric chloride followed by complexation with 2,2-bipyridyl to form a blood red colored chromogen, exhibiting maxiumum absorbance at 530 nm and obeyed Beer's law in the concentration range of 5-20 μg/mL. These methods were extended to pharmaceutical formulations. There was no interference from any common pharmaceutical excepients and diluents.

Key Words: Spectrophotometric determination, Tolterodine tartrate, Repaglinide.

Tolterodine tartarate (TLD)[1] is an urogenital antispasmodic agent and is chemically phenol, 2-[(1R)-3-[bis(1-methyl ethyl)amino]-1-phenyl propyl]-4-methyl-(2R, 3R)-2,3-dihydroxy butanedioate (1:1) (salt). Repaglinide (RPG)[2] is a non-sulfonylurea antidiabetic drug, chemically, it is 2-ethoxy-4-[2-[[(1S)-3-methy-1-[2-(1-piperidinyl)phenyl]butyl]amino]-2-oxoethyl]benzoic acid. Literature survey reveals that a few methods have been reported for the determination of TLD[3] and RPG[4-7] which includes UV, HPLC and colorimetry.

The present method describes the reaction of TLD or RPG with ferric chloride and 2,2 bipyridyl to develop a blood red colored species, which exhibits absorption maximum at 530 nm.

All the measurements were made using Systronics visible spectrophotometer model 167 with 10 mm matched quartz cells.

All the chemicals used were of analytical grade. 0.05 M of freshly prepared ferric chloride, 0.01 M of 2,2 bipyridyl and 2×10^{-2} of orthophospheric acid were prepared.

Preparation of standard solutuions: Accurately weighed 100 mg of TLD was dissolved in 100 mL of distilled water to obtain 1 mg/mL stock solution and the stock solution was further diluted with distilled water to

obtain a working standard solution of 100 μg/mL. The stock solution (1 mg/mL) of RPG was prepared by dissolving 100 mg of drug in 5 mL of methanol and then make up to 100 mL with distilled water. This solution was diluted with distilled water to obtain the working standard solution of concentration 100 μg/mL.

Preparation of sample solution: An accurately weighed amount of capsule powder (TLD) equivalent to 100 mg was dissolved in 100 mL of distilled water and filtered if necessary. This solution was further diluted with distilled water so as to obtain a concentration of 100 μg/mL of TLD. An accurately weighed amount of tablet power of RPG equivalent to 100 mg of the drug was dissolved in 5 mL of methanol and then makes up to 100 mL with distilled water and filtered if necessary. This solution was further diluted with distilled water to obtain a concentration of 100 μg/mL.

Assay procedure: Aliquots of standard drug solution ranging from 0.5-2.5 mL (100 μg/mL for TLD or RPG were transferred to a series of 10 mL-graduated test tubes. To each of test tubes, 1.5 mL of ferric chloride and 2.0 mL of 2,2´bipyridyl were added and heated on a boiling water bath for 20 min. cooled then 2.0 mL of orthophosphoric acid was added. The solutions were made up to volume with water. The absorbance was measured at 530 nm against a reagent blank. The coloured species were stable for 1 h. The amount of the drug in the sample was computed from the Beer-Lambert plot.

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 slope, intercept, correlation coefficients and % range of error (0.05 and 0.01 confidence limits) were calculated are shown in Table-1.

Commercial formulations of TLD and RPG were successfully analyzed by the proposed and reference methods. The values obtained by the proposed and reference methods[R] are presented in Table-2. As an additional demonstration of accuracy, adding a fixed amount of the drug to the pre-analyzed formulations performed recovery experiements. These results are summarized in Table-2. There is no interference in the proposed analytical methods.

In conclusion the proposed spectrophotometric method for the estimation of TLD and RPG are simple, sensitive, accurate and can be used for the routine quality control of these drugs in bulk as well as in pharmaceutical formulations.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHOD FOR TLD AND RPG

Parameters		TLD	RPG
λ_{max} (nm)		530	530
Beer's law limits ($\mu g/mL^{-1}$)		5-25	5-25
Molar absorptivity ($L\ mol^{-1}\ cm^{-1}$)		1.724×10^4	1.816×10^4
Sandell's sensitivity ($\mu g\ cm^{-2}$/0.001 absorbance unit)		0.0275	0.0249
Regression equation (Y = a + bC)	Slope (b)	0.03477	0.03970
	Intercept (a)	-4×10^{-3}	1.9×10^{-3}
Correlation coefficient (r)		0.9921	0.9998
Relative standard deviation (%)*		0.2834	0.2500
% Range of error (Confidence limits)*	0.05 level	0.2369	0.2090
	0.01 level	0.3505	0.3092

*Average of eight determinations

TABLE-2
ASSAY AND RECOVERY OF EZM AND RPG IN DOSAGE FORMS

Name of the dosage form	Labeled amount (mg)	Content of drug found		(%) Recovery by proposed method**
		Proposed method	Reference method[3,4]	
Tolterodine tarataratе				
Capsule I	2	1.99	1.98	99.50
Capsule II	2	2.00	2.01	100.00
Repaglinide				
Tablets I	2	1.98	2.01	99.00
Tablets II	2	2.01	1.99	100.50

** Recovery amount was the average of five determinations.

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