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NOTE

UV and Visible Spectrophotometric Methods for the Determination of Roxatidine Acetate Hydrochloride in Pharmaceutical Formulations

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Two simple and reproducible spectrophotometric methods have been developed for the estimation of roxatidine acetate hydrochloride. In the UV region, the drug showed maximum absorption at 208 nm in distilled water. In the proposed visible spectrophotometric method, the drug is made to react with Folin-Ciocalteu (FC) reagent under alkaline conditions, when it forms a blue coloured chromogen having absorption maximum at 750 nm. These methods obey Beer's law in the concentration range 5-40 μg/mL and 25-100 μg/mL respectively. The methods are statistically evaluated for accuracy and precision.

Key Words: Spectrophotometric determination, Roxatidine acetate hydrochloride, Pharmaceutical formulations.

Roxatidine acetate hydrochloride (RAH) is a H2-receptor antagonist used in patients with peptic ulcers. Chemically, it is 2-(acetyloxy-N-(3-(1-piperidinyl-methyl) phenoxy) propyl) acetamide[1]. A survey of literature revealed that a few analytical methods[2-4] based on HPLC and spectrophotometry have been reported earlier for the determination of RAH. The present work deals with the determination of RAH in bulk samples and dosage forms by UV and visible (using Folin-Ciocalteu reagent and sodium hydroxide) spectrophotometric methods.

All the chemicals used were of analytical grade. Solutions of sodium hydroxide (1 N) and FC reagent (1 N) were prepared in distilled water. Spectral and absorbance measurements were made on a Systronics UV/Vis spectrophotometer (model 117) with 10 mm-matched quartz cells.

Standard and sample solutions

About 100 mg of RAH (pure) was accurately weighed and dissolved in 100 mL of water. This stock solution was further diluted with distilled water to get a working standard solution of 100 μg/mL for method A. Similarly, the stock solution of the sample was prepared by dissolving in water a quantity of the finely ground tablet powder equivalent to 100 mg of the drug.

Method A: Aliquots of working standard solution of RAH ranging from 0.5 to 4.0 mL were transferred into a series of 10 mL graduated test tubes and the final volume was brought to 10 mL with distilled water. The absorbance was measured at 208 nm against a blank and the amount of RAH present in the sample solution was computed from the calibration curve for the standard.

Method B: To a series of 10 mL volumetric flasks, aliquots of the original drug solution (1 mg/mL) ranging from 0.25–1.0 mL, 1 mL of FCR and 1.5 mL of NaOH were added. The solution in each flask was made up to 10 mL with distilled water. The absorbance of the blue coloured complex was measured at 750 nm against a reagent blank. The amount of the RAH present in the sample solution was computed from its calibration curve. The coloured chromophore was stable for about 4 h.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation and per cent range of error were calculated for both the methods and the results are summarized in Table-1. The values obtained for the determination of RAH in tablets by the proposed methods are compared with those of the reported methods (Table-2). To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to the pseviously analysed pharmaceutical preparations and the mixtures were analysed by the proposed methods and the per cent recoveries are given in Table-2. Studies revealed that the common excipients and other additives usually present in the dosage forms did not interfere in the proposed methods.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION DATA

Parameters	Method A	Method B
Beer's law limit (μg/mL)	5–40	25–100
Sandell's sensitivity (μg/cm^2/0.001 absorbance unit)	0.0503	0.1515
Molar extinction coefficient (1 mole^{-1} cm^{-1})	6.9223×10^3	2.2991×10^3
% Relative standard deviation	0.5406	0.9472
% Range of error:		
0.05 confidence limits	±0.4523	±0.7918
0.01 confidence limits	±0.6687	±1.1752
Correlation coefficient	0.9998	0.9989
Regression equation (*Y**):		
Slope (a)	0.0201	0.0066
Intercept (b)	–0.0032	–0.0065

Y* = b + aC, where C is concentration in μg/mL and Y is absorbance unit.

The formation of the colour by FC reagent with RAH in method B may be explained in the lines according to Folin and Ciocalteau[5] and Peterson[6]. The mixed acids in the FC reagent contain the following chemical species.

$$3H_2O{\cdot}P_2O_5{\cdot}13WO_3{\cdot}5MoO_3{\cdot}10H_2O$$

and

$$3H_2O{\cdot}P_2O_5{\cdot}14WO_3{\cdot}4MoO_3{\cdot}10H_2O$$

TABLE -2
ASSAY OF ROXATIDINE ACETATE HYDROCHLORIDE IN TABLETS

Sample	Labelled amount (mg)	Amount obtained (mg)			Recovery (%) by the proposed methods	
		Reported method[4]	Proposed methods			
			A	B	A	B
1	150	149.4	150.6	149.7	100.40	99.80
2	150	150.2	149.9	150.8	99.93	100.53
3	75	74.9	75.5	74.9	100.60	99.86

RAH probably affects a reduction of 1, 2 or 3 oxygen atoms from the tangstate and/or molybdate in FC reagent thereby producing one or more of the possible reduced species which have a characteristic intense blue colour.

The results indicate that the proposed methods are sensitive, precise and reproducible and can be used for the routine determination of RAH in bulk as well as in pharmaceutical preparations.

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