Asian Journal of Chemistry Vol. 21, No. 9 (2009), 7419-7421

NOTE

Spectrophotometric Estimation of Roxithromycin in Bulk and Pharmaceutical Formulations

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A simple and sensitive spectrophotometric method has been developed for the estimation of roxithromycin in bulk as well as pharmaceutical formulation. Roxithromycin obeyed Beer's law in a concentration range of 10-150 µg/mL exhibiting maximum absorption at 205 nm. This method is extended to pharmaceutical formulation and there is no interference from any pharmaceutical additive and diluent. The results have been validated statistically and recovery studies confirmed the accuracy of the proposed method.

Key Words: Spectrophotometric estimation, Roxithromycin.

Roxithromycin[1] is a macrolide antibiotic which acts on gram-positive bacteria and gram-negative bacteria. Chemically[1,2] it is (3R,4S,5S,6R,7R,9R,11S,12R,13S, 14R)-4-[(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-10-[(E)-[(2-methoxy ethoxy)methoxy]-imino]-3,5,7,9,11, 13-hexamethyl-6-[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo- hexopyranosyl]oxy]-oxacyclotetradecan-2-one. It is used in respiratory tract infections[2] like pharyngitis, pneumonia, chronic bronchitis and bronchopneumonia. The recommended dosage for roxithromycin is 150-300 mg per day. Roxithromycin is official in British Pharmacopoeia[2] and European Pharmacopoeia[3] and it is assayed by high-performance liquid chromatographic method. Literature survey reveals that roxithromycin is estimated in pharmaceuticals and biological fluids by spectrophotometric[4-7], HPLC[8-11] and microbiological methods[12]. These methods are too expensive and time consuming. An attempt has been made to develop a simple, economical, accurate and reproducible spectrophotometric method for estimation of roxithromycin in bulk as well as pharmaceutical formulations.

Spectral and absorbance measurements were made on Elico SL-159 UV/Visible spectrophotometer with 1 cm matched quartz cells. Roxithromycin was obtained from Dr. Reddy's laboratories private limited, Hyderabad, India. The tablets were obtained commercially. All the chemicals used were of analytical grade.

Preparation of standard solution: Accurately weighed 25 mg of roxithromycin was dissolved in 25 mL of 0.1 N HCl to get a concentration of 1 mg/mL. The stock solution is further diluted with 0.1 N HCl to obtain working standard solutions of 10 and 100 µg/mL.

Assay procedure for roxithromycin: Aliquots of solution 0.5 to3.0 mL were transferred into a series of 10 mL volumetric flasks and the volume is make up to 10 mL with 0.1 N HCl. The absorbance of the prepared solutions was measured at 205 nm for roxithromycin against 0.1 N HCl as blank. The amount of roxithromycin present in the sample solution was computed from its calibration curve. The Beer's law limit, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation, regression equation are calculated as shown in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF PROPOSED METHOD

Parameter	Roxithromycin
λ_{max} (nm)	205
Beer's range (µg/mL)	10-150
Sandell's sensitivity (µg/cm^2/0.001 AU)	0.2298
Molar extinction coefficient	0.003431 x 10^6
Regression equation (Y*)	
Slope (a)	0.0040
Intercept (b)	0.0009
Correlation coefficient (r)	0.9990
% RSD*	0.6980

Y* = a + bC, where Y* = absorbance at reseptive λ_{max} and C = concentration of roxithromycin in µg/mL. *Average of six determinations.

Analysis of commercial formulations: Twenty tablets of each brand were accurately weighed and finely powdered. The powder equivalent to 25 mg of roxithromycin was transferred into 25 mL volumetric flask and dissolved in 0.1 N HCl. Then the solution was filtered and further diluted with 0.1 N HCl to get 150 µg/mL of working standard solution. The absorbance was measured at 205 nm for roxithromycin and the quantity was determined from the standard graph and the results are shown in Table-2.

TABLE-2
ASSAY AND RECOVERY OF ROXITHROMYCIN IN DOSAGE FORMS

Name of the dosage form	Labeled amount (mg)	Amount found (mg)	Recovery by proposed method* (%)
Tablet 1 Roxibest-A (Blue Cross)	150	150.00	100.00
Tablet 2 Roxid-M (Alembic)	150	149.75	99.83

*Recovery amount is the average of five determinations.

To evaluate validity and reproducibility of the methods, known amounts of pure drug were added to previously reported pharmaceutical preparations and the mixtures were analyzed by the proposed method and the results are presented in Table-2.

The proposed method for the determination of roxithromycin in bulk and pharmaceutical dosage forms was found to be simple, rapid, accurate and economical and is applicable to the determination of roxithromycin in pure and pharmaceutical formulations.

ACKNOWLEDGEMENTS

The authors are thankful to M/s Dr. Reddy's Laboratories Pvt. Ltd., Hyderabad, India, for providing Roxithromycin sample and Management of Sri Padmavathi School of Pharmacy, Tiruchanur, Tirupathi for providing facilities to carry out this work.

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(*Received*: 21 August 2008; *Accepted*: 25 August 2009) AJC-7784