



UV SPECTROPHOTOMETRIC DETERMINATION OF RANITIDINE HYDROCHLORIDE IN PURE AND PHARMACEUTICAL FORMULATION

AMUL N. MISHRA* and A. C. RANA

*B. N. Girls College of Pharmacy, UDAIPUR – 313001 (Raj.) INDIA

ABSTRACT

Simple and sensitive method has been developed for determination of ranitidine hydrochloride (RHCl) in both pure and pharmaceutical formulation. This method obeys Beer's law in the concentration range of 10 to 70 µg/mL, exhibiting maximum absorption at 313 nm. In this method no interference from the common pharmaceutical excipients was observed.

Key words : Spectrophotometric, Ranitidine hydrochloride

INTRODUCTION

Ranitidine is a synthetic H₂ receptor antagonist¹. The drug is commercially available as ranitidine HCl. The chemical name for ranitidine is N- [2—[[[5-[(dimethylamino) methyl]-2-furanyl] methyl] thio] ethyl]—N-methyl-2-nitro-1, 1- ethane diamine². The empirical formula is C₁₃H₂₂N₄O₃S. HCl and its molecular weight is 350.869. A few HPLC methods³ have been reported for ranitidine HCl. Literature survey revealed that no visible and UV methods have been reported for estimation of RHCl. An attempt has been made to develop an accurate and reliable UV spectrophotometric method for estimation of RHCl in pure as well as in pharmaceutical dosage forms.

EXPERIMENTAL

All the chemicals used were of analytical grade. A Shimadzu UV-250 1PC double beam spectrophotometer was used for all absorbance measurements. The solubility study conducted revealed that RHCl has appreciable solubility in NaH₂PO₄ buffer; pH 6.7 and 0.1N methanolic hydrochloride.

* Author for correspondence; E-mail: amulmishra27@yahoo.com, Phone: 0294-2410406,09414738107

The stock solution of RHCl was made in 0.1N methanolic hydrochloride. 100 mg of RHCl was accurately weighed and dissolved in 100 mL of 0.1N methanolic hydrochloride. The stock solution was further diluted with NaH₂PO₄ buffer pH 6.7, to obtain a working standard of 100 µg/mL. All the further dilutions ranging from 10 to 70 µg/mL were made by dilution with NaH₂PO₄ buffer pH 6.7. Aliquots of solution ranging from 1 to 7 mL were transferred into series of volumetric flasks and the volume was made up to 10 mL with NaH₂PO₄ buffer pH 6.7. The individual samples were scanned from 200 to 400 nm and the maximum absorbance was observed at 313 nm.

RESULTS AND DISCUSSION

Thus, the absorbance was measured 313 nm against a blank reagent. The Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, regression equation and correlation coefficient were calculated and are shown in Table 1.

Table 1 : Optical characteristics of the proposed method

Parameters	RHCl
λ_{\max} (nm)	313 nm
Beers law limit (µg/mL)	10-90
Sandell's sensitivity (µg cm ⁻² /0.001 absorbance unit)	0.0257
Molar absorptivity (L mol ⁻¹ cm ⁻¹)	1.594 x 10 ⁴
Regression equation (Y = a + bc)	
Slope (b)	3.43 x 10 ⁻²
Intercept (a)	0.1238
Correlation coefficient (r)	0.9911
Relative standard deviation (%)*	0.276
* Average of eight determinations	

The results of analysis of pharmaceutical formulation of RHCl are presented in Table 2. An accurately weighed tablet powder of RHCl equivalent to 100 mg of pure drug was dissolved in 100 mL 0.1 N methanolic hydrochloride. This solution was filtered using Whatmann filter paper No. 41 and further diluted with NaH₂PO₄ buffer pH 6.7 to obtain

concentration of 50 µg/mL. Recovery studies were carried out to establish the validity and reproducibility of the developed method. Known amount of pure drug was added to previously analyzed tablet sample and mixtures were analyzed by proposed method.

Table 2 : Estimation of ranitidine hydrochloride in pharmaceutical formulation

Sample	Labeled amount (mg)	Amount found (mg) in proposed method	Recovery (%)
Ranitidine hydrochloride			
Tablet I	100	100.16	99.28
Tablet II	100	100.24	100.00

Thus, it could be concluded that the proposed method is simple, accurate and sensitive. Recovery studies revealed that the method is reproducible. It was observed that determination of RHCl was not interfered by the presence of excipients. Thus, the present method could be used for determination of RHCl both; in bulk and pharmaceutical formulations.

REFERENCES

1. J. G. Hardman and A. W. Petri, in Goodman and Gilman's, The Pharmacological Basis of Therapeutics, 9th Ed., McGraw-Hill, New York, (1996) pp. 1092-1094.
2. USAN List No. 298, Clin. Pharmacol. Ther., **44**, 363 (1988).
3. P. A. Bombart, K. S. Catheart, B. E. Bothwell and S. K. Closson, J. Liq. Chrom., **14(9)**, 1729 (1991).

Accepted : 29.05.2009