International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol.2, No.3, pp 2071-2074, July-Sept 2010

Simple Validated Spectroscopic Method for Estimation of Ranitidine From Tablet Formulation

Pallavi Salve*, Deepali Gharge, Rupali Kirtawade, Pandurang Dhabale, Kishor Burade

Government College of Pharmacy, Karad, Dist –Satara-415124, M.S., India.

Corres.author :plsalve2182@rediffmail.com

Abstract: Ranitidine Hydrochloride is H_2 – receptor antagonist indicated for duodenal ulcer. Various methods for analysis of the same are available but are time consuming and expensive. Here we have developed two new, precise and simple UV spectrophotometric methods for estimation of Ranitidine Hydrochloride from tablet formulation. The drug obeyed the Beer's law and showed good correlation. Absorption maxima of Ranitidine in distilled water was found to be at 313.5 nm. Beer's law was obeyed in concentration range 1– 13 mcg/ml. The results of analysis were validated by recovery studies. The recovery was more than 98%. The method was found to be simple, accurate, precise, economical and robust.

Key words: Ranitidine Hydrochloride, UV spectrophotometry, Recovery, Accuracy.

Introduction:

Ranitidine Hydrochloride, chemically 1,1 ethenediamine-N-[2-[[[5-[(dimethylamino) methyl]- 2 –furanyl] – methyl] thio] ethyl] -N'- methyl -2- nitro hydrochloride is H_2 – receptor antagonist indicated for duodenal ulcer.[1] Literature survey revels that for Ranitidine Hydrochloride HPLC[3, 4], spectrophotometric [5] and capillary electrophoresis [6,7] methods have been reported for its determination in human plasma and commercial formulation. However some of these methods are costlier and time consuming. To overcome these difficulties spectrophotometric analysis serves to be the quickest, promising and reliable method for routine analytical needs. The aim of the present study is to develop two new simple, rapid, reliable and precise UV spectrophotometric method for analysis of Ranitidine Hydrochloride from tablet formulation; first method is based on measurement of UV absorbance of Ranitidine at 313.5 nm in distilled water.

Second method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelength 310.5 nm and 316.5 nm. Area calculation processing item calculates the area bound by the curve and the horizontal axis (Fig.2)

Materials and Methods:

Apparatus:

Spectral runs were made on a Shimadzu UV-Visible spectrophotometer, model- 1700 (Japan) was employed with spectral bandwidth of 1 nm and wavelength accuracy of ± 0.3 nm with automatic wavelength corrections with a pair of 10 mm quartz cells. Glasswares used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven.

Reagents and Solution:

All the reagents used in this assay were of analytical grade and the reagent solutions were prepared using preanalysed distilled water. Ranitidine pure drug was obtained as a gift sample from Lupine Pharmaceutical Industries Ltd., Pune. Tablets of Ranitidine Hydrochloride were purchased from local market for analysis (Zintac) . Distilled water was used as a solvent for the spectrophotometric estimation.

Experimental:

Determination of λmax:

Weighed an accurate amount 10mg of Ranitidine Hydrochloride was dissolved in 100ml of distilled water to obtain a 100mcg/ml concentration of Ranitidine Hydrochloride in solution. This solution was subjected to scanning between 200 – 400 nm and absorption maxima at 313.5 nm was determined.

Standard Stock Solution:

A stock solution containing 100mcg/ml of pure drug was prepared by dissolving accurately weighed 10mg of Ranitidine Hydrochloride in distilled water and volume was adjusted to 100ml with the same in 100ml volumetric flask.

Working standard solution:

Stock solution is used as working standard solution.

Linearity and Calibration:

The aliquots working standard solution was diluted serially with distilled water to obtain the concentration range of 1 – 13 mcg/ml. A calibration curve for Ranitidine Hydrochloride was obtained by measuring the absorbance at the λmax of 313.5 nm (for method I) and by measuring area under curve between 310.5 to 316.5 (for method II). Statistical parameters like the slope, intercept, coefficient of correlation, standard deviation, relative standard deviation, and standard error were determined.

Analysis of Marketed Tablet Formulation:

Accurately weighed the 20 tablets and powdered. The powder equivalent to 150mg of Ranitidine was transferred to 100ml volumetric flask and 20ml double distilled water is added to dissolve the Ranitidine in it and made the volume to mark with the same. This mixture was sonicated for 15 minutes and filtered through Whatmann filter paper No. 41. Aliquots (0.1ml, six times) of the sample were removed and diluted to 10 ml with distilled water to obtain strengths as 15mcg/ml six time and determined the respective absorbance at 313.5 nm and area under curve between 310.5 nm to 316.5 nm against the distilled water as blank.

Recovery studies:

Recovery studies were performed to judge the accuracy of the method. 1ml of standard formulation (150mcg/ml) was taken in three 10ml volumetric flask and to it 80%, 100% and 120% (i.e. 0.8ml, 1.0ml, 1.2ml) of working standard solution (100mcg/ml) added respectively and made the volume upto the mark. The respective absorbance at 313.5 nm and area under curve between 310.5 nm to 316.5 nm was recorded against the blank. The amount of added concentration was determined from the obtained absorbance values and percent recovery was determined for the formulation.

Robustness:

The evaluation of robustness was performed for system suitability to ensure the validity of analytical procedure. This was done by varying the instrument, analyst, and time of study. The analysis was performed on Shimadzu UV-Visible spectrophotometer, model-1700 (Japan) and UV-Visible Spectrophotometer model -1800 (Japan). Interday and intraday analysis was performed by changing the analyst.

Table No. I: Optical characteristics and precision

Methode	I	II
Absorption maxima	313.5nm	310.5 -316.5 nm
Beer's law limit	1 -13mcg	1 -13mcg
Coefficient of Correlation	0.9994	0.9989
Regression equation	0.9989	0.9981
Slope	0.0498	0.299
y intercept	0.003411	0.03654
Molar absorptivity (lit/mole/cm)	15534.922735	17234.890
Sandell's sensitivity (mcg/Sq.cm/0.001)	0.020239	0.02965
LOD (µg/mL)	4.1667	4.09388
LOQ (µg/mL)	12.62	12.40

Results:

The UV scan of standard solution between 200 – 400 nm showed the absorption maxima at 313.5 nm, shown in fig. 1. The Beer's law was verified from the calibration curve by plotting graphs of concentration vs absorbance(method I) and concentration vs area under curve (method II). Regression analysis showed very good correlation. The calibration plots revealed zero intercept which is clear by the regression analysis equation Y = 0.0498X + C. (Where Y is absorbance, m is the slope and X is the concentration of Ranitidine Hydrochloride in mcg/ml) as obtained by the least square method. The results thus obtained are depicted in Table No. I. The results of analysis for assay and recovery studies for two different formulations were studied and are shown in Table No. II. No significant variations were observed on interday and intraday analysis. Also no significant variations were observed on changing the instrument make and model.

Fig. 1: Wavelength selected of Ranitidine for Zero order method in distilled water

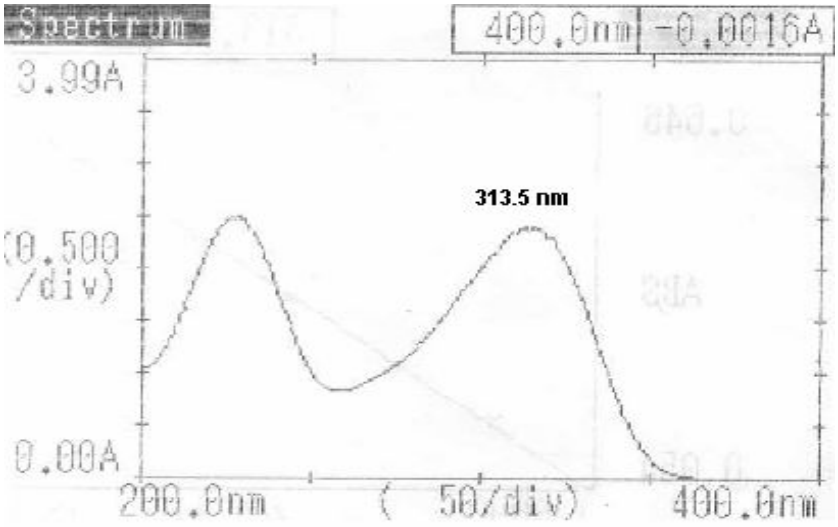

Fig. 2: Wavelength range selected for AUC method of Ranitidine

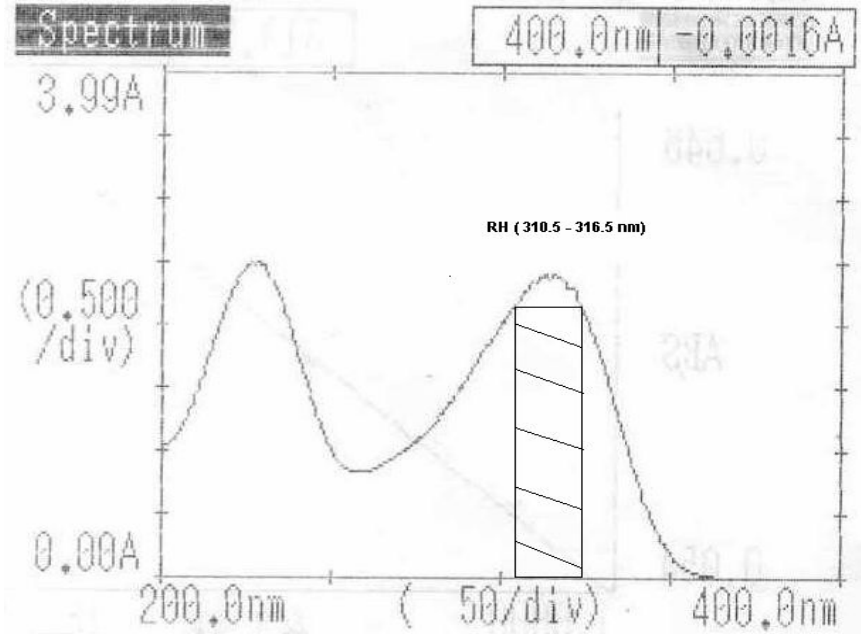

Table no. 2 : Results of analysis of tablet and recovery study:

Method	Formulation	Label Claim	% Label Claim found	Standard Deviation	Coefficient of Variation	% Recovery ± S.D
I	Zintac	150 mg	99.07667	0.6288	0.006599	100.34±0.1205
II	Zintac	150 mg	101.135	0.3709	0.005671	100.24±0.1727

Discussion:

The spectrum of Ranitidine Hydrochloride in double distilled water showed the absorption maxima at 313.5 nm. No effect of dilution was observed on the maxima, which confirmed the maxima at 313.5 nm. The statistical analysis of data obtained for the calibration curve of Ranitidine Hydrochloride in pure solution indicated a high level of precision for the proposed method, as evidenced by low value of coefficient of variation. The coefficient of correlation was highly significant. The linearity range was observed between 1 – 13 mcg/ml. The plot clearly showed a straight line passing through origin (Y = 0.0498X + 0.003411). The estimated method was validated by low values of % RSD and standard error, indicating accuracy and precision of the methods. Excellent recovery studies further proves the accuracy of the method. Robustness of the method was studied by varying the instrument, time of study and analyst. Reproducibility of the results confirmed the robustness of the method.

Conclusions:

From the results and discussion the method described in this paper for the determination of Ranitidine Hydrochloride from tablet formulation is simple, accurate, sensitive reproducible and economical. The proposed method utilizes inexpensive solvents. The proposed method could be applied for routine analysis in quality control laboratories.

Acknowledgements:

Authors are grateful to Lupin Pharmaceutical Industries Ltd., Mumbai for providing the gift sample of Ranitidine Hydrochloride. We are also thankful to the Principal and Head of Pharmaceutical Chemistry Department of Government College of Pharmacy, Karad for providing the necessary facilities to carry out this work.

References:

1] Keith GT, In; Gennaro, AR eds., Remington: The Science and practice of Pharmacy, 20th Ed., Vol-II, Maryland, USA: Lippincott Williams and Wilkins; 2000, p. 1225.

2] Keith GT, In; Gennaro, AR eds., Remington: The Science and practice of Pharmacy, 20th Ed., Vol-II, Maryland, USA: Lippincott Williams and Wilkins; 2000, p. 1236.

3] Ho c, Huang HM, Hus SY et al. Simultaneous HPLC analysis of famotidine ranitidine hydrochloride, cimetidine nizatidine in commercial products. Drug Develop. Ind Pharm 1999; 25:379-85.

4] Kanumula GV, Bhanu R. Simultaneous determination of ranitidine hydrochloride and domperidone in pharmaceutical dosage form by RP-HPLC. Indian Drugs 2000; 37: 375-78.

5] Walash M, Sharaf – E1 DM, Metwalli ME, et al. Spectrophotometric determination of nizatidine and ranitidine through charge transfer complex formation. Arch Pharm Res, 2004;27:720-6.

6] Wu SM, et al. Simultaneous determination of cimetidine famotidine nizatidine and ranitidine hydrochloride in tablets by capillary electrophoresis. Electrophoresis. 2001;22:2758-62.

7] Wu SM, et al. Head column field amplified sample stacking in capillary electrophoresis for determination of cimetidine famotidine nizatidine and ranitidine hydrochloride in plasma. Electrophoresis . 2001; 22;2717-22

*****