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A NEW AND SIMPLE SPECTROSCOPIC METHOD FOR RANITIDINE HYDROCHLORIDE FROM BULK AND FORMULATION

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Abstract

Ranitidine hydrochloride (RNH) is a H2-receptor antagonist, widely used in short term treatment of duodenal ulcer and in the management of hypersecretory conditions. Several methods have been reported for the determination of ranitidine in bulk, pharmaceutical dosage forms, and/or biological fluids. This method shows poor sensitivity and/or narrow range of linear response, time consuming. Here we have developed a new method by simple diazodisation, a Chromogenic agent reacts with NO2 group of ranitidine hydrochloride and gives spectrophotometric reaction that produce orange colour which gives absorption maxima at 504nm and validation shows a linear response from 100-500 mg/ml and correlation coefficient of 0.998.The method was accurate, robust, simple and economic.

INTRODUCTION

Ranitidine Hydrochloride, chemically 1, 1 ethenediamine-N-[2-[[[5-[(dimethylamino) methyl]- 2 –furanyl] – methyl] thio] ethyl] - N'- methyl -2- nitro hydrochloride is H2 – receptor antagonist indicated for duodenal ulcer[1,2].

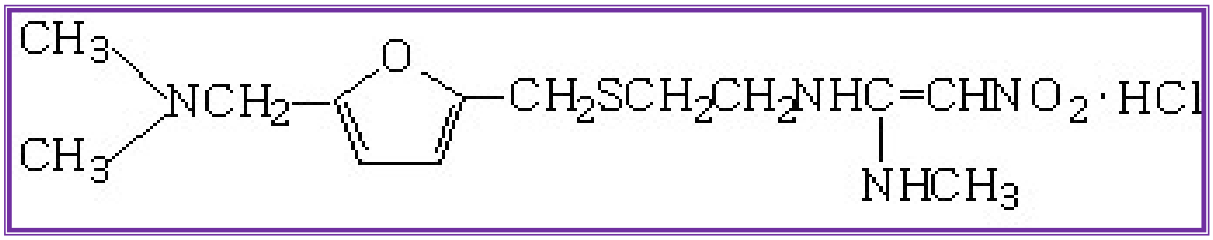

Figure 1 Structure of Ranitidine HCl.

Literature survey reveals that for Ranitidine Hydrochloride HPLC, spectrophotometric and capillary electrophoresis 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-VIS spectrophotometric methods for analysis of Ranitidine Hydrochloride from the bulk and tablet formulation.

The present work is based on the fact that both aromatic & aliphatic secondary amines will react with sodium nitrite by forming N-nitro amines as given below. These are in most cases yellow $R R_1 NH + NO_2 \longrightarrow RR_1 NNO+$. Purely aromatic or purely aliphatic tertiary amines & quaternary ammonium salts do not react with nitrous acid but mix aromatic aliphatic amines of the dimethylaniline type from green or yellow P- Nitrous derivatives when treated nitrous acid. This reaction has also been used for the determination of nitrites Primary Aromatic diamines cannot be diazotized but other reactions might occur. Thus O- phenyl die amine yields a trizole derivative & M-phenyl die amine yields an azodye by self coupling if submitted to the test conditions, & this reaction too has been used for the determination of nitrites. A false negative

reaction could be the result if the β napthol solution is not capable of creating an alkaline environment in the test solution since X nitrous β Napthol is formed under acidic condition instead of the intended azo dye.

MATERIALS & METHODS

Materials and apparatus: Alcohol (A R. Grade Conc.HCL (LR Grade) Sodium nitrite, (0.1% &0.3%) (AR .Grade) N-methylaniline (0.5% & 1%) (AR. Grade) Zinc dust (LR Grade) **Instrument Used** for study is UV Visible spectroscope, Jasco, V=530.

Colour reaction and Determination of λmax: Free Nitro group is present in ranitidine hydrochloride which undergoes diazotization. Ranitidine is soluble in alcohol therefore it dissolves in alcohol & acidifies by using dilute HCl in small quantity. For reduction zinc dust was added & it was kept for 1 hr. After that the solution was diluted by ethanol then appropriate quantity of solution was taken to that conc. HCl, sodium nitrite & N- methyl aniline were added the resulting solution is orange coloured. The coloured solution was scanned to obtain absorbance and λmax of colour complex & it was found to be 504nm.

Standard stock solution: 100mg drug was dissolved in 1ml HCL and 100ml alcohol which is then diluted to get different concentrations of range 100 µg/ml-500 µg/ml.1 gm of Zn dust was added to each solution. Then add conc. HCl and 0.3% sodium nitrite in aqueous solution was added to each diluted solution. The resulting solution was kept for 10min. Then 1% N-methyl aniline in alcoholic solution was added which yields orange coloured complex. The absorbance of each solution was observed by keeping reagent blank. The results are given in Table 1.

Recovery study: Accuracy is calculated as the percentage of recovery by the assay of the known added amount of analyte in the sample or as the difference between the mean and the results is reported in Table 2.

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.

RESULTS AND DISCUSSION

Ranitidine hydrochloride contains NO_2- groups reacts with $NaNO_2$ and form diazonium salt undergoes diazotization which yields orange colour complex can be determine by colorimetry. The developed method is valid for LOD, LOQ, linearity and precision. LOD of ranitidine hydrochloride was 100µg/ml. LOQ of ranitidine hydrochloride was 100µg/ml .Precision was carried out for low, medium and high conc. Ethanol(95%) is used to process because it is easily undergoes diazotization and drug having good solubility in ethanol, then calibration curve of ranitidine hydrochloride also drawn. Absorbance for that ranitidine hydrochloride of concentration 100µg/ml, 150µg/ml, 200µg/ml, 250µg/ml,300µg/ml, 350µg/ml, 400µg/ml, 450µg/ml, 500µg/ml, and 550µg/ml was found to be 0.2008, 0.3208, 0.4012, 0.5410, 0.6812, 0.7214, 0.9065, 1.1780, 1.2130 respectively. Hence we can use this method for routine analytical study of ranitidine.

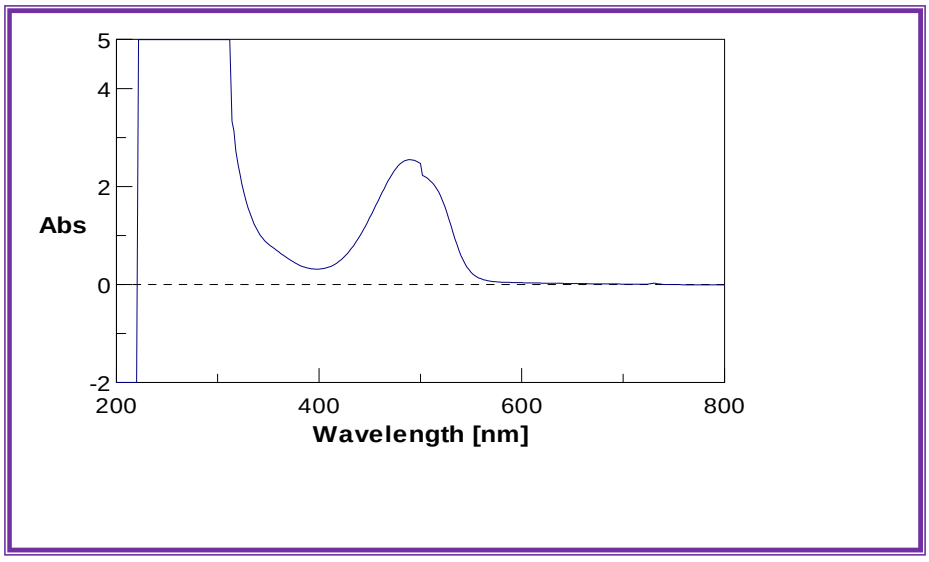

Figure 2 curve of ranitidine hydrochloride color complex

Table 1

Absorbance readings for Ranitidine hydrochloride colour at 504 nm

SR.NO	CONC.(µg/ml)	*AVERAGE ABSORBANCE*
1	100	0.2048
2	150	0.3208
3	200	0.4016
4	250	0.5415
5	300	0.6815
6	350	0.7215
7	400	0.9067
8	450	1.1768
9	500	1.2129

Table 2

Observation for recovery study of Ranitidine hydrochloride

Amount Of Sample Taken	Amount Of Std. drug Added	Total Drug Conc.	Absorbance	Calculated Total Conc.	Standard Recovery	% Recovery
100	10	110	0.2197	112.84	10.25	102.5
100	10	110	0.2201	113	11.3	113
100	10	110	0.2108	109.28	9.93	99.3
100	10	110	0.2190	112.56	10.23	102.3
100	10	110	0.2003	106.28	9.66	96.3
						Average =102.74

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