INTERNATIONAL RESEARCH JOURNAL OF MULTIDISCIPLINARY STUDIES &
SPPP's, Karmayogi Engineering College, Pandharpur Organize
National Conference Special Issue March 2016

Vol. 2, Special Issue 1, March, 2016 | ISSN (Online): 2454-8499 | Impact Factor: 1.3599(GIF), 0.679(IIFS)

COLOROMETRIC DETERMINATION OF RANTIDINE HYDROCHLORIDE

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Abstract- A simple, precise and cost effective colorometric method have been developed for the estimation of Rantidine hydrochloride in its pharmaceutical formulations. RNH shows λmax at 520.0 nm. The drug follows the Beer-Lambert's law. The method validated by following the analytical performance parameters suggested by the International Conference on Harmonization. All validation parameters were within the acceptable range. The developed methods were successfully applied to estimate the amount of RNH in pharmaceutical dosage forms.

Key words: - colorometric, rantidine hydrochloride, drug and pharmaceutical dosage.

1. Introduction:

Ranitidine,N-(2-{[(5-dimethylamino)-methyl]-2-furanyl)-2-methyl-thioethyl} - N′-methyl-2-nitro-1,1′-ethylenediamine (Fig. 1), is a histamine H2-blocker commonly used in clinical practice for the treatment of duodenal ulcers.

This RNH has been determined by high-performanc liquid chromatography, capillary electrophoresis, spectrofluorimetry, near infrared spectrophotometry, proton magnetic resonance spectroscopy, voltammetry, differential polarography, the techniques are tedious, time consuming, and involve expensive instrumental set-up.

In the present work, an effort has been made to develop simple, sensitive, selective and cost-effective methods utilizing the thio group of the molecule.

2 Experimental

2.1 Standard

Aliquots of standard reduced RNH solution (0.25-2.5 mL; 200 µg mL−1) were delivered into a series of10 mL calibrated flasks. The solution was acidified by adding 0.5 mL of 1 M HCl and the total volume was adjusted to 4 mL by adding water. Then, 1 mL each of 0.4% iodate and 6% sodium chloride solutions were added in succession, the contents were mixed well and the flasks were set aside for 20 min with occasional shaking. Finally, 2 mL each of 0.01% 2,4-dichlorofluorescein solution and monochloro acetic acid reagent (pH 4.35) were added to each flask and the volume was diluted to the mark with water. The absorbance of the coloured solution was measured at 520 nm against a reagent blank.

2.2 Sample

Twenty tablets were weighed accurately and ground into a fine powder. A portion of the powder equivalent to 200 mg of RNH was weighed accurately into a 100 mL

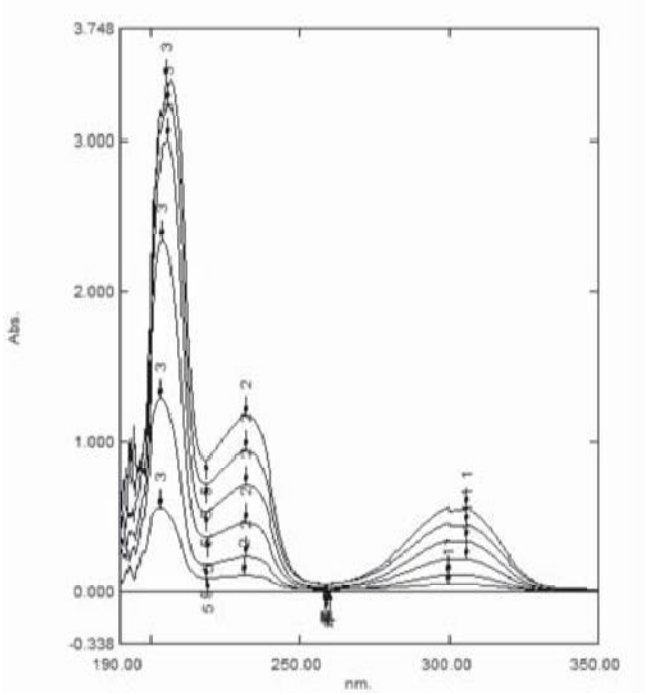
Vol. 2, Special Issue 1, March, 2016 | ISSN (Online): 2454-8499 | Impact Factor: 1.3599(GIF), 0.679(IIFS)

volumetric flask, 60 mL of water, 5 mL of 5 M HCl and 500 mg of zinc dust were added and shaken thoroughly for about 30 min. Then, the volume was made up to the mark with water, mixed well and filtered using Whatman No. 41 filter paper. A suitable aliquot was used for analysis by titrimetry. The solution was appropriately diluted with water to get 200 µg mL−1 solution and analysed spectrophotometrically using a convenient volume. In the case of injectable products, known volumes equivalent to 200 mg of RNH were measured accurately into a 100 mL beaker, 60 mL of water, 5mL of 5 M HCl and 500 mg of zinc dust were added and stirred for 30 min. The insoluble mass was filtered on a Whatman No. 41 filter paper, washedwith water and the filtrate plus washings were diluted to 100 mL with water in a calibrated flask.The solution (2 mg mL−1) was subjected to analysis by spectrophotometry as described above after appropriate dilution.

3. Result and discussion

In colorometry, the drug was treated with a large unmeasured excess of iodate and the iodine formed was determined by an auxiliary reaction with dichlorofluorescein. In both the methods, reduction of nitro group of the molecule with zinc/HCl was the first step. Unreduced RNH was found to give erratic results.

Absorption spectra of rantidine



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