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atadorno@iq.unesp.br
Universidade Estadual Paulista Júlio de Mesquita Filho
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Narayana, B.; Veena, K.; Ashwani, K.; Shetty, Divya. N.
NEW REAGENTS FOR THE SPECTROPHOTOMETRIC DETERMINATION OF RANITIDINE HYDROCHLORIDE
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Universidade Estadual Paulista Júlio de Mesquita Filho
Araraquara, Brasil

cal techniques, spectrophotometric techniques occupies a unique position, because of its simplicity, sensitivity, accuaracy and rapidity.

Literature survey revealed that the only titrimetric method [19] reported for RNH requires 300 mg of drug for each titration. There are few methods for the spectrophotometric determination of ranitidine. These are based on the reaction of ranitidine with some organic acidic dyes followed by extraction of the colored ion-pairs into organic solvents and absorbance measurements. Spectrophotometric determination of ranitidine in tablets has been also suggested through chromogenic reactions with 3-methylbenzothiozline-2--one hydrazone [20], 3,5-dichloro-pbenzoquinone chlorimine [20], Folin-Ciocalteu [21] reagents. These methods, however, are not adaptable for use in automated systems due to the long reaction time for color development (15- 30 min) , they require prior extraction of the colored reaction product and involve a high reaction temperature (-90°C).

In this communication, we demonstrate the use of spectrophotometric techniques for the determination of RNH. The present work involves sensitive, selective and cost effective methods for the determination of ranitidine hydrochloride. The method utilizes ceric ammonium sulphate and two dyes malachite green and crystal violet. Spectrophotometric techniques are in good agreement with the reported methods. In addition, it is not susceptible to interference from common tablet excipients. The developed method has been successfully applied to the determination of ranitidine hydrochloride in pure and dosage form.

Experimental

Aparatus

A SHIMADZU UV-2550 UV-VIS Spectrophotometer with 1 cm matched quartz cells were used for the absorbance measurements.

Reagents and Solutions

All reagents used were of analytical reagent grade and distilled water was used for the preparation of all solutions. A 1000 µg/ml standard drug solution of ranitidine hydrochloride was prepared in distilled water. The stock solution was diluted appropriately to get the working concentration.

Ceric ammonium sulphate (0.01 M) was prepared in 1M sulphuric acid and standardized. This was diluted stepwise to obtain the working concentrations containing 400 µg/ml (RNH--MAG system) and 900 µg/ml (RNH-CV system). Hydrochloric acid (1M), malachite green (0.05%), crystal violet (0.05%) were also used.

Procedure

Method A

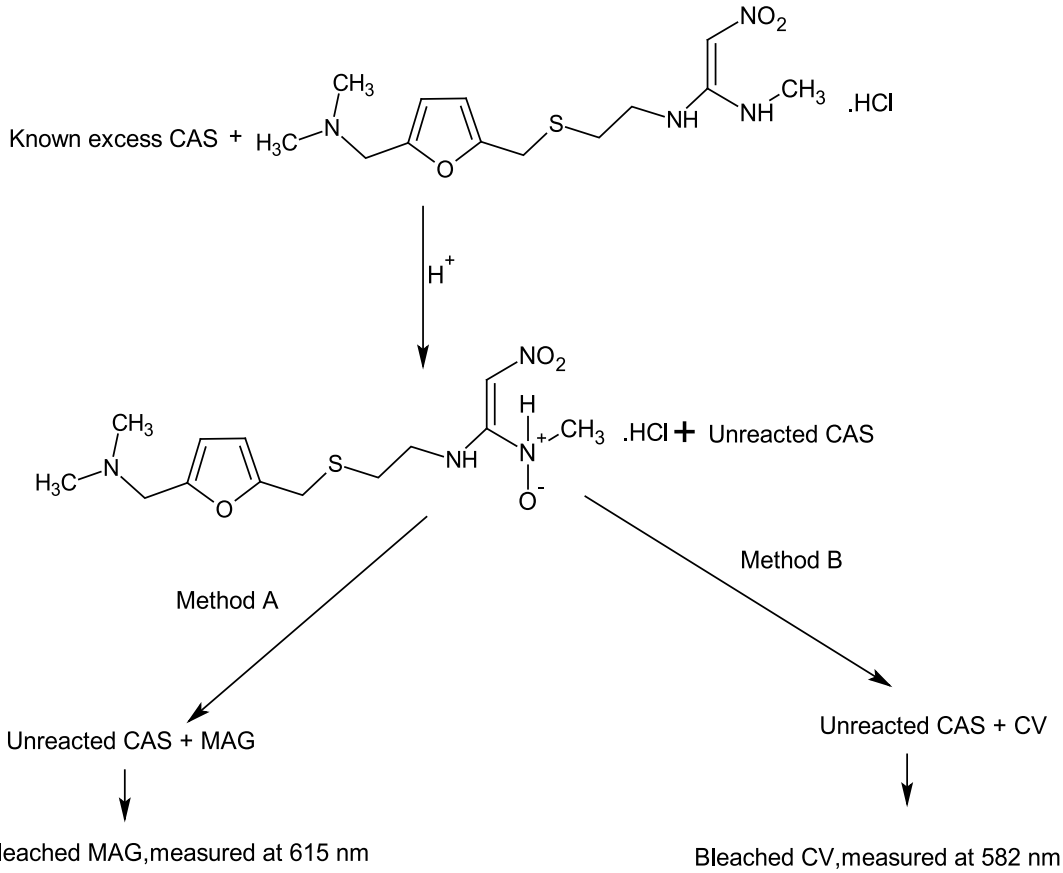
Different aliquots (0.4- 8.0µg/ml) of RNH were transferred in to a series of 10 ml calibrated flasks by means of a micro burette. Then, 1 ml of 5M HCl was added followed by 1ml of CAS solution. The contents were shaken well and were set aside for 15 minutes with occasional shaking. Then, 1.0 ml of malachite green was added to each flask, and the volume was adjusted up to the mark with distilled water and mixed well. The absorbance of each solution was measured at 615 nm against the corresponding reagent blank. The absorbance corresponds to the bleached color, which in turn corresponds to the drug solution, was obtained by subtracting the absorbance of the blank by that of the test solution.

Method B

Different aliquots (0.2-1.6 µg/ml) of RNH were transferred in to a series of 10 ml calibrated flasks by means of a micro burette. Then, 1 ml of 5M HCl was added followed by 1ml of CAS solution. The contents were shaken well and were

a method validation. The type of method and its respective use determine which parameters should be evaluated. It is the responsibility of the analyst to select the parameters considered relevant for each method [28]. The experimental conditions were chosen after testing the different parameters that influence the analysis. The methods involve the addition of a known excess CAS to ranitidine hydrochloride in acid medium, followed by determination of residual CAS by reacting with a fixed amount of either malachite green measuring the absorbance at 615 nm (RNH-MAG system), or crystal violet measuring the absorbance at 582 nm, (RNH-CV system). In the present method all parameters influencing the color development were investigated and are incorporated in the recommened procedure. When added in increasing concentrations to a fixed concentration of CAS, ranitidine consumes the latter proportionally and there is concomitant drop in the remaining concentration of CAS. When a fixed dye concentration is added to decreasing concentrations of CAS, a concomitant increase in the dye concentration results. The reaction mechanism are shown in scheme 1.

Scheme.1



Applications

A new method is described for the spectrophotometric determination of ranitidine hydrochloride. The proposed method is applied to the determination of ranitidine hydrochloride in pure and dosage forms. The comparisons of the reported methods with earlier methods are shown in table 1. The percent recovery of added pure drug which lies between 98.0 and 101.60 reveals that the procedures are free from interference from usual tablet excipients like talc, starch, calcium gluconate, sucrose, etc.

Table 1. Comparison of proposed method with earlier methods

Reagent	Remarks
F-C reagent [21]	Less sensitive
Bromothymol blue [22]	Involve extraction
Rose Bengal [23]	Involve extraction
$Hg(SCN)_2$-IRON(III) [24]	Less sensitive
KIO3-DCF [25]	Requires strict pH control and less sensitive.
$KMnO_4$/NBS azine dyes [26]	Involves extraction.
Proposed methods	Sensitive Selective, no interference from usual tablet excipients.

Conclusions

The method is sensitive, enabling the accurate and precise determination of the analytes over satisfactory concentration ranges without the need of special or laborious sample-pretreatment steps. The method, which is advantageously time- and cost-efficient, was successfully applied to the quantification of the analytes in commercial samples, with results being in good statistical agreement with the reported methods; therefore, it is considered useful for routine quality monitoring of pharmaceuticals.

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