

Short Communication

Spectrophotometric determination of famotidine in pharmaceutical preparations

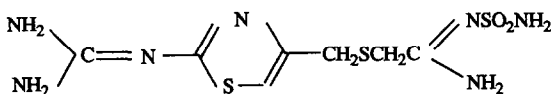
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Introduction

Famotidine (I) is a H₂ antagonist. It is official in the USP XXII which specifies a non-aqueous titration for assay of the raw material and a HPLC method for determination of the drug in tablets [1]. Other methods include colorimetry [2, 3] and HPLC [4–6]. In the present communication a simple, selective and sensitive method for the spectrophotometric determination of famotidine is described.



I

Experimental

Apparatus

All spectral measurements were made with a Shimadzu (UV 260) spectrophotometer using 1-cm matched glass cells.

Chemicals and reagents

All chemicals were of AnalaR grade (BDH) unless otherwise specified.

A 1% (w/v) solution of sodium nitroprusside was prepared in water. A standard solution (1 mg ml⁻¹) of famotidine was prepared in 0.1 M HCl; this solution was further diluted with 0.1 M HCl.

Procedure for calibration curve

An aliquot of standard solution of famotidine (50–500 µg 10 ml⁻¹) was transferred into a 10-ml volumetric flask. The volume of the aqueous phase was adjusted to 5 ml with 0.1 M HCl. A 1 ml volume of 1 N sodium hydroxide was added followed by 1 ml of sodium nitroprusside solution with shaking. After 3 min, 2 ml of 1 M HCl was added and the solution was diluted to 10 ml with distilled water. The absorbance was measured at 498 nm against a reagent blank. A calibration curve was prepared in the range 50–500 ppm of famotidine.

Analysis of tablets

The tablet powder equivalent to 40 mg of drug was transferred into a 100-ml beaker and 40 ml 0.1 M HCl was added; the mixture was shaken for 5 min and filtered; the beaker was washed with 5 × 2 ml of 0.1 M HCl and diluted to 100 ml with 0.1 M HCl. An aliquot of the solution was analysed for famotidine by the procedure described for the calibration curve.

Results and Discussion

Sodium nitroprusside reacts with famotidine in alkaline media to form a nitroso derivative of famotidine and, in addition, iron(III) in sodium nitroprusside is reduced to iron(II). The red complex formed with famotidine had a λ_{max} of 498 nm, a molar absorptivity of 5.9 × 10² l mol cm⁻¹ and a Sandell's sensitivity of

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Table 1
Effect of HCl molarity on the colour development of famotidine with sodium nitroprusside*

HCl molarity	Volume added (ml)	Absorbance	Molar absorptivity ($\times 10^2$) ($l\ mol^{-1}\ cm^{-1}$)
0.25	2	0.280	1.0
0.50	2	0.695	4.6
0.75	2	0.735	4.6
1.00	1	0.700	4.8
1.00	2	0.888	5.9
1.00	3	0.887	5.9
1.00	4	0.888	5.9

* Famotidine, 500 ppm; λ_{max} , 498 nm.

Table 2
Effect of sodium nitroprusside concentration on the colour development of famotidine*

Sodium nitroprusside (1%) (ml)	Absorbance	Molar absorptivity ($\times 10^2$) ($l\ mol^{-1}\ cm^{-1}$)
0.2	0.050	0.3
0.4	0.100	0.7
0.6	0.500	3.3
0.8	0.780	5.2
1.0	0.888	5.9
1.5	0.888	5.9
2.0	0.888	5.9

* Famotidine, 500 ppm; 1 M HCl, 2 ml; λ_{max} , 498.

$0.572\ \mu g\ cm^{-2}$. Beer's law was obeyed in the range 50–500 ppm of famotidine. The regression equation was: $conc. = 563.67 \times absorbance - 1.78$ (correlation coefficient = 0.999).

The effect of changes in the concentration of hydrochloric acid was studied for a fixed concentration of $500\ \mu g\ 10\ ml^{-1}$ of famotidine. A 2 ml volume of 1 M hydrochloric acid was adequate for maximum colour development (Table 1). Higher HCl concentrations did not adversely affect colour development. However, lower HCl concentrations decreased the absorbance value. Similarly an optimum volume of 1 ml of 1% sodium nitroprusside solution was required for the working concentration range (50–500 ppm) of famotidine (Table 2).

The order of addition of the reagents is first that sodium nitroprusside should be treated with famotidine in alkaline condition; 2 ml of 1 M HCl is then added to make the solution acidic. The colour is stable for more than 1 h.

The reproducibility of the method was found to be satisfactory with a relative standard deviation of 0.15% ($n = 6$). The mean recovery of added famotidine to a pre-analysed formulation was found to be 100.26% ($n = 6$). The tablet analyses given in Table 3 are

Table 3
Analysis* of famotidine tablets

Labelled amount (mg tablet ⁻¹)	Famotidine found (mg)		
	Present method		USP method
	Mean	SD†	
20	19.95	0.2	19.96
20	19.55	0.5	19.57
40	39.92	0.2	39.40
40	39.96	0.1	39.80
40	40.10	0.1	40.15

* Sodium nitroprusside, 1 ml 1%; 1 M HCl, 2 ml; λ_{max} , 498 nm.

† Seven determinations.

Table 4
Analysis* of famotidine in the presence of various excipients in synthetic mixtures

Excipients	Recovery† (%)
Talc	99.72
Propylene glycol	99.76
Magnesium stearate	99.54
Starch	100.35
Lactose	99.80
Acacia	100.5
Tragacanth	99.99
Glycerin	99.80

* Sodium nitroprusside, 1 ml (1%); 1 M HCl, 2 ml; λ_{max} , 498 nm.

† Mean of nine determinations.

comparable with those obtained by the USP method [1]. Common excipients did not interfere with this method (Table 4).

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