A New Spectrophotometric Determination of Famotidine from Tablets

N. RAMI REDDY[1], K. PRABHAVATHI[1], Y. V. BHASKAR REDDY[2] AND I. E. CHAKRAVARTHY*

Department of Chemistry, S. K. U. P. G. Centre, Kurnool-518 002, [1]Department of Chemistry, S. B. S. Y. M. Degree College, Kurnool-518 004, [2]Department of Pharmacology, Government Medical College, Kurnool-518 002, India.

A simple spectrophotometric method for determination of famotidine was described. The method was based on bromination of the drug with excess brominating mixture in acidic medium. The yellow colour developed was measured at 350 nm against distilled water blank. Beer's law was obeyed in the range of 40-200 µg/ml.

Famotidine, chemically 3-[[[(2-aminoiminomethyl)amino-]4-thiazolyl]methyl]thio]-N-(aminosulfonyl) propaninidamide, is used in the treatment of duodenal ulcer, gastric ulcer, stress ulcers and gastritis. Various methods have been reported for estimation of famotidine, which include spectrophotometric methods[1–3], spectrophotometric and spectrofluorimetric method[4] and flow-injection analysis[5].

In the present communication, a simple spectrophotometric method has been developed for the estimation of famotidine from pharmaceutical preparations. The proposed method was based on the bromination of the drug with excess brominating mixture in acidic medium. After bromination, the excess brominating mixture was treated with potassium iodide, which gave yellow colour. The maximum absorbance was measured at 350 nm. The

***For correspondence**

E-mail: ramireddy_m2000@yahoo.co.in

proposed method has not been studied earlier for estimation of famotidine in tablets.

All measurements were done on Milton Roy 1001 plus spectrophotometer by using 10 mm matched quartz cuvettes. All analytical grade chemicals were used, and all the solutions were freshly prepared with double-distilled water. Hydrochloric acid (4 N) was prepared and standardized using standard procedure. Potassium iodide (0.1 N) was prepared by dissolving 0.166 g in 100 ml distilled water. Brominating mixture solution (0.1 N) was prepared by dissolving 0.695 g of potassium bromate and 1.75 g of potassium bromide in distilled water and diluted to 100 ml with distilled water. Further dilution was done to obtain working concentration of 0.02 N brominating mixture solution.

One hundred milligrams of pure famotidine was dissolved in methanol and diluted to 100 ml with methanol. This stock solution was further diluted to get the desirable working concentration of 200 µg/ml.

The following procedure has been adopted for obtaining the standard curve. An aliquot each of 0.2, 0.4, 0.6, 0.8 and 1.0 ml of the drug solution was transferred into a series of 25 ml standard flasks. To each flask, 1 ml of 4 N hydrochloric acid and 1 ml of 0.02 N brominating mixture were added. The flasks were shaken well and kept aside for 5 min for complete bromination. Then, 1.0 ml of 0.1 N potassium iodide was added to each flask and diluted to 25 ml with distilled water. The yellow colour solution formed was measured at 350 nm against distilled water as blank. The calibration curve was obtained by plotting absorbance values against amount of standard drug in µg/ml. The amount of drug present in the sample was read from calibration curve. The calibration curve was found to be linear over the concentration range of 40-200 µg/ml.

Tablets were weighed, powdered and the contents well mixed; and powder equivalent to 50 mg of famotidine was dissolved in methanol, filtered, and the residue was washed with distilled water and the volume was adjusted to 50 ml with methanol. Further analysis was carried out as per the procedure described under calibration curve, and the amount of famotidine present in the sample was estimated from calibration graphs. The results are tabulated in Table 1.

In order to study the accuracy and suitability of the proposed method, known quantities of famotidine were added to the previously analyzed samples and the same mixtures were reanalyzed by the proposed method. The results are tabulated in Table 1.

TABLE 1: ESTIMATION OF FAMOTIDINE IN TABLETS

Sample	Labelled amount (mg)	Amount found in mg		% recovery*
		Proposed method*	Official method*	
Tablet 1[a]	20	20.10	20.05	99.70
Tablet 2[b]	40	40.02	40.00	99.60
Tablet 3[c]	20	19.98	19.96	100.2
Tablet 4[d]	40	40.02	40.06	99.90

*Average of five determinations based on label claim. [a]Famoti-20 marketed by USV Limited, [b]Famtac-40 marketed by Nicholas, [c]Topcid-20 marketed by Torrent and [d]Famowal-40 marketed by Wallace.

TABLE 2: STATISTICAL ANALYSIS OF ESTIMATION OF FAMOTIDINE

Sample	Labelled amount	S.D*	C.V**	[a]t_{cal}
Tablet 1[a]	20	0.1581	0.7865	1.414
Tablet 2[b]	40	0.2049	0.5119	0.2183
Tablet 3[c]	20	0.0836	0.4184	0.5361
Tablet 4[d]	40	0.1140	0.2852	0.7858

*Average of five determinations based on label claim. *Standard deviation, **Coefficient of variation, [a]Calculated 't' Value by proposed method, Theoretical values at 95% confidence limit, t' 2.57.

The present study was carried out to develop a simple, rapid, precise and reproducible spectrophotometric method for the estimation of famotidine in pharmaceutical formulations. Famotidine in slightly acidic conditions undergoes bromination with brominating mixture. After bromination was complete, the excess brominating mixture was treated with potassium iodide to form yellow-coloured complex. The colour obeyed Beer's law in the concentration range of 40-200 µg/ml. The experimental conditions were optimized by studying the effect of brominating mixture, hydrochloric acid, potassium iodide by sequence of addition. The recovery studies were conducted by addition of different amounts of pure drugs to a reanalyzed sample solution, and the data are tabulated in Table 1. The recovery values ranged from 99.6 to 100.2, indicating the accuracy of the method. The common excipients lactose, starch, calcium lactate and gum acacia did not interfere with the assays. The statistical analysis of various parameters was studied, and the results are summarized in Table 2. The values of standard deviation and coefficient of variation were satisfactorily low, indicating the reproducibility of the method. The data of assay values of commercial formulations is subjected to statistical evaluation for Student's 't' test to study the proposed method. The 't' values are less than 't' theoretical with 4 degrees of freedom at 5% level of significance,

indicating that there is no significant difference between the proposed method and reference method.

The proposed spectrophotometric method was found to be simple, precise, accurate and less time consuming. Hence the proposed method is a preferred method for routine analysis of estimation of famotidine in bulk drug samples and from pharmaceutical preparations.

ACKNOWLEDGEMENTS

One of the authors, Dr. N. Rami Reddy, is thankful to Dr. Balasiva Yogindra Maharaj, President and Correspondent, S. B. S. Y. M. Degree College, Kurnool, for granting permission to carry out research and for providing laboratory facilities during work.

REFERENCES

1. Abu Zuhri, A.Z., Shubietah, R.M. and Badah, G.M., **J. Pharm. Biomed. Anal.,** 1999, 21, 459.
2. Mohanmed, H.A., **Bull. Pharm. Sci., Assiut. Univ.,** 2000, 23, 157.
3. Sastry, C.S.P. and Ravi, C., **East. Pharm.,** 2000, 43, 159.
4. Abdel Kader, A.S., Kawy, A.M. and Nebsen, M., **Anal. Lett.,** 1999, 32, 1403.
5. Kamath, B.V., Shivram, K. and Shah, A.C., **J. Pharm. Biomed. Anal.,** 1994, 12, 343.

Accepted 5 October 2006
Revised 7 November 2005
Received 23 February 2004
Indian J. Pharm. Sci., 2006, 68 (5): 645-647