Asian Journal of Chemistry Vol. 20, No. 6 (2008), 4221-4224

Quantitative Spectrophotometric Estimation of Famotidine Using Hydrotropic Solubilization Technique

R.K. MAHESHWARI* and RAVI SHANKAR SHUKLA†
Department of Pharmacy, Shri G.S. Institute of Technology and Science
23, Park Road, Indore-452 003, India
Tel: (91)(731)2542213; E-mail: rkrkmaheshwari@yahoo.co.in

In the present investigation, 1.5 M metformin hydrochloride, (an economic drug) solution, was employed as hydrotropic solubilizing agent to solubilize poorly water-soluble drug, famotidine, for its UV analysis. Proposed method is new, simple, environmentally friendly, accurate and reproducible. Accuracy, reproducibility and precision of the proposed method was validated statistically.

Key Words: Metformin hydrochloride, Famotidine, Hydrotropy, Spectrophotometry.

INTRODUCTION

The term 'hydrotopy' has been used to designate the increase in solubility of various substances due to the presence of large amount of additives. Various hydrotropic agents have been used to enhance the aqueous solubility of a large number of drugs[1-13]. Maheshwari[1] has analyzed cefixime (a poorly water soluble drug) in tablet dosage forms using urea (8.0 M), sodium acetate (4.0 M) and sodium citrate (1.25 M) as hydrotropic solubilizing agents. Maheshwari[2] analyzed frusemide {a poorly water-soluble drug} by titrimetric analysis using hydrotropic solution of sodium benzoate (2.0 M). The same author[3] has developed titrimetric analysis methods to analyze ketoprofen and salicylic acid. Hydrotropic solutions of sodium benzoate (2.0 M), sodium salicylate (2.0 M) and sodium acetate (2.0 M) were employed for ketoprofen. Hydrotropic solution of urea (8.0 M), sodium citrate (1.25 M) and sodium benzoate (2.0 M) were employed in the estimation of salicylic acid. Maheshwari *et al.*[4] used hydrotropic solution of sodium benzoate (2.0 M) as solubilizing agent to analyze a poorly water soluble drug, ofloxacin, by spectrophotometric estimation. Maheshwari[5] has also developed a spectrophotometric method to analyze ketoprofen in tablet dosage form using hydrotropic solution of sodium acatete (4.0 M).

†Rishiraj College of Pharmacy, Sawer Road, Indore-453 331, India.

There was tremendous increase in the solubility of famotidine (a widely used anti ulcer) in 1.5 M metformin hydrochloride (a very economic antidiabitic drug; here used as hydrotropic agent) solution. Therefore, it was thought worthwhile to solubilize the drug with the help of metformin hydrochloride (1.5 M) to carryout the UV analysis. Chemically, famotidine is 3-[[2-(diaminomethylideneamino)-1,3-thiazol-4-yl]methylsulfanyl]-N'-sulfamoyl-propanimidamide.

EXPERIMENTAL

All chemicals and solvents used were of analytical grade. Metformin hydrochloride was obtained as gift sample from Anusandhan laboratories, Indore; and famotidine tablets were purchased from market.

Preliminary solubility studies of famotidine: Solubility of famotidine was determined in distilled water and 1.5 M metformin hydrochloride solution at 28 ± 1 ºC. There was more than 7 fold enhancement in the solubility of drug in 1.5 M metformin hydrochloride solution, as compared to the solubility in the distilled water.

Calibration curve: 50 mg famotidine bulk drug sample was accurately weighed and transferred a 50 mL volumetric flask. Then 10 mL, 1.5 M metformin hydrochloride was added and drug was solubilized by continuous shaking. Volume was adjusted to 50 mL with distilled water. From this solution (1000 µg/mL),the standard solutions containing 5, 10, 15, 20, 25, 30 and 35 µg/mL of drug were prepared by appropriate dilution with distilled water. The absorbances of these solutions were observed at wavelength 286 nm against respective reagent blanks to obtain the calibration curve.

Analysis of famotidine tablets by the proposed method: Tablet powder equivalent to 100 mg drug was shaken with 20 mL of 1.5 M metformin hydrochloride by continuous shaking for about 10 min and volume made up to 100 mL with distilled water. The resulting solution was filtered through Whatmann filter paper no. 41 and appropriate aliquot was prepared by diluting with distilled water. Absorbance of of this solution was observed at 286 nm against reagent blank.

Recovery studies: In preanalyzed tablet powder equivalent to 100 mg, bulk drug sample 20 and 40 mg were added as spiked concentrations and drug contents were determined by the proposed analytical method (used to analyze the tablets). The per cent recoveries estimated are presented in Table-2.

RESULTS AND DISCUSSION

As evident from Table-1, the mean per cent drug estimated in commercial tablet formulation I and II by proposed method were 99.84 and 99.43, respectively. The values are close to 100, indicating the accuracy of the

proposed method. Validation of the proposed method was further confirmed statistically by low values of standard deviation, per cent coefficient of variation and standard error (Table-1).

TABLE-1
ANALYSIS DATA OF FAMOTIDINE TABLET FORMULATION WITH STATISTICAL EVALUATION

Tablet formulation	Label claim (mg/tablet)	% Drug estimated (n = 3) (Mean ± SD)	% Coefficient of variation	Standard error
I	20	99.84 ± 1.414	1.416	0.816
II	40	99.43 ± 1.521	1.530	0.878

TABLE-2
RESULT OF RECOVERY STUDIES OF TABLET FORMULATIONS WITH STATISTICAL EVALUATION

Tablet formulation	Drug present in preanalyzed tablet powder (mg)	Spiked drug added (mg)	% Drug estimated (n = 3) (Mean ± SD)	% Coefficient of variation	Standard error
I	100	20	99.11 ± 1.032	1.041	0.596
	100	40	98.77 ± 0.992	1.004	0.573
II	100	20	99.34 ± 1.119	1.126	0.646
	100	40	98.25 ± 1.337	1.361	0.772

The per cent recoveries estimated ranged from 98.25 ± 1.337 to 99.34 ± 1.119. The values which are close to 100 indicated the accuracy of the proposed method. The values of standard deviation, per cent coefficient of variation and standard error are statistically low and thus validate the proposed method.

Conclusion

It may be concluded that the proposed method of analysis is new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. Definitely there is further scope of 1.5 M metformin hydrochloride as solubilizing agent for the UV analysis of other poorly water-soluble drugs (above 245 nm wavelength). The proposed method can be successfully employed in the routine analysis of famotidine in tablet formulations.

ACKNOWLEDGEMENT

The authors are thankful to Anusandhan laboratories, Indore for providing gift sample of metformin hydrochloride.

REFERENCES

1. R.K. Maheshwari, *Indian Pharmacist*, **4**, 63 (2005).
2. R.K. Maheshwari, *Indian Pharmacist*, **4**, 55 (2005).
3. R.K. Maheshwari, *Asian J. Chem.*, **18**, 393 (2006).
4. R.K. Maheshwari, S.C. Chaturvedi and N.K. Jain, *Indian Drugs*, **42**, 760 (2005).
5 R.K. Maheshwari, *The Pharma Rev.*, **3**, 123 (2005).
6. N.K. Jain, R.K. Agarwal and A.K. Singhai, *Pharmazie*, **45**, 221 (1990).
7. I.A. Darwish, A.T. Florence and A.M. Saleh, *J. Pharm. Sci.*, **78**, 577 (1989).
8. R.E. Coffman and D.O. Kildisq, *J. Pharm. Sci.*, **85**, 951 (1996).
9. G.K. Poochikian and J.C. Cradock, *J. Pharm. Sci.*, **68**, 728 (1979).
10. S. Ueda, *Chem. Pharm. Bull.*, **14**, 29 (1966).
11. M. Miyahara and T. Takahasi, *Chem. Pharm. Bull. (Tokyo)*, **30**, 288 (1982).
12. S. Agrawal, S.S. Pancholi, N.K. Jain and G.P. Agrawal, *Int. J. Pharm.*, **274**, 149 (2004).
13 P. Simamora, J.M. Alvarez and S.H. Yalkowsky, *Int. J. Pharm.*, **213**, 25 (2001).

(*Received*: 10 April 2007; *Accepted*: 25 February 2008) AJC-6373