Int. J. Chem. Sci.: 9(2), 2011, 949-952
ISSN 0972-768X
www.sadgurupublications.com

SIMPLE SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF QUETIAPINE FUMARATE IN TABLETS

G. SRIHARI[*] and I. E. CHAKRAVARTHI[a]

Department of Chemistry, S. B. S. Y. M. Degree College, KURNOOL – 518004 (A.P.) INDIA
[a]Department of Chemistry, Rayalaseema University, KURNOOL – 518002 (A.P.) INDIA

ABSTRACT

A simple, fast and reliable spectrophotometric method was developed for determination of quetiapine fumarate in pharmaceutical formulations.The methods is based on the reaction of quetiapine fumarate with wool fast blue, the formed ion pair complex extracted into chloroform at pH 1.5. The chloroform extractable layer is measured at 585 nm against reagent blank. The method is validated statistically.

Key words: Spectrophotometry, Wool fast blue, Quetiapine fumarate, Pharmaceutical, Dosage form.

INTRODUCTION

The chemical formula of quetiapine fumarate is 2-[2-(4-dibenzo[b,f][1,4] thiazepin-11-yl-1-piperazinyl)ethoxy] ethanol hemi fumarate. It is antipsychotic drug which is white or almost white powder, moderately soluble in water and soluble in methanol & 0.1 N HCl. It is used to treat psychosis associated with Parkinson's disease and chronicschizophrenia. The mode of action of quetiapine fumarate, as with other drugs used to treat schizophrenia is unknown. However, it is thought that the drug's therapeutic activity in schizophrenia is mediated through a combination of dopamine type 2 (D2) and serotonin type 2 (5HT2) receptor antagonisms.

Literature survey revealed that methods have been reported for the estimation of quetiapine fumarate in pharmaceutical preparation which includes high performance liquid chromatography method[1-4], spectrophotometric method[5,7], spectrophotometric method and acapillary zone electrophoretic (CZE) method[8], high performance liquid chromatochrophy-elecro spray mass spectrometry method[9]. The objective of the present work was to develop

[*]Author for correspondence

simple, rapid, accurate and specific spectrophotometric method for the estimation of quetiapine fumarate in pharmaceutical dosage forms. The developed method for the analysis of quetiapine fumarate was validated with respect to stability, linearity, sensitivity, precision and accuracy.

EXPERIMENTAL

Materials

All the reagents were of analytical grade. Double distilled water was used throughout the experiment. A Milton Roy spectrophotometer with 1 cm matched quartz cells were used for the estimation.

Standard preparation

An accurately weighed 50 mg of quetiapine fumarate was dissolved in 10 mL of methanol in a 50 mL volumetric flask and the volume was adjusted up to the mark with methanol to obtain a stock solution of 1 mg/mL. The stock solution is further diluted to obtain the working concentration of 100 μg/mL.

Buffer solution (pH 1.5)

Buffer solution is prepared by mixing 289 mL of glycine solution (37.52 gm of glycine and 29.24 gm of NaCl are dissolved in 500 mL of distilled water) with 711 mL of 0.1 M HCl.

Wool fast blue solution: (0.2% w/v)

Wool fast blue solution is prepared by dissolving 200 mg of wool fast blue (Flaka) in 100 mL of distilled water.

Assay procedure

Various aliquots of the standard quetiapine fumarate solution ranging from 0.5-2.5 mL are transferred into a series of separating funnel. To each flask, 1.0 mL of wool fast blue solution, 1.0 mL of buffer solution and 5 mL of chloroform are added. Reaction mixture in each funnel is shaken gently for 5 min. and allowed to stand for 5 min. so as to separate aqueous and chloroform layer. The chloroform layer is separated out and absorbance is measured at 585 nm, against the reagent blank prepared in similar manner omitting drug solution. Calibration graph is obtained by plotting absorbance values against the concentration of quetiapine fumarate solution. The calibration curve is found to be linear

over a concentration range of 50 to 250 μg/mL of quetiapine fumarate. The amount of quetiapine fumarate present in the sample is estimated from the calibration graph.

Pharmaceutical formulations

Twenty capsules of quetiapine fumarate were emptied and powder was weighed. Amount equivalent to 50 mg was transferred to 50 mL volumetric flask, dissolved in 20 mL of methanol and made up the volume with methanol, sonicate for 10 min. and filtered through Whatman filter paper No. 1. The filtrate is suitably diluted to get a final concentration of 100 μg/ mL of quetiapine fumarate. The absorbance of sample solution was measured as described in the calibration procedure and amount of quetiapine fumarate was determined by referring to the calibration curve.

Table 1: Assay of Quetiapine fumarate in tablets

Sample	Labelled amount (mg)	Amount found in mg		C.V.	$^{*}t_{cal}$
		Proposed method ± S.D*	Official method*		
Tablet 1	200	199.96 ± 0.25	199.94	0.1268	0.3527
Tablet 2	200	199.92 ± 0.34	199.7	0.1702	0.5259
Tablet 3	200	200.02 ± 0.37	199.9	0.1850	0.1208
Tablet 4	300	300.06 ± 0.18	300.02	0.0625	0.7159
Tablet 5	300	300.03 ± 0.17	299.8	0.0585	0.3816

*Average of five determinations based on label claim

RESULTS AND DISCUSSION

The proposed method has successfully estimated the amount of quetiapine fumarate in the range of 99.96 - 100.02% in all tested formulations. In this method the quetiapine fumarate treated with wool fast blue dye at 1.5 pH. The resultant solution is extracted with chloroform. The ion pair complex is form in extractable chloroform layer. The absorbance of the extractable ion pair complex is measured at 585 nm against the reagent blank prepared in a similar manner devoid of drug solution. The calibration curve is linear over the range of 50-250 μg/mL of quetiapine fumarate. The values of standard deviation and coefficient variation values are low, indicates high accuracy and reproducibility of the method. The ‘t’ calculated values are compared well with the theoretical value of 2.78 there by indicating that the there is no difference between proposed and official method. There is no effect of

additives and excipients such starch, calcium lactose and glucose in the concentrations those present in general pharmaceutical preparations.

CONCLUSION

Validation parameters consents, the applied spectrophotometric methods of analysis are simple, sensitive, accurate, precise and satisfactorily capable for determination of quetiapine fumarate in tablet formulation with reproducible specific results. In addition, the analyses by proposed methods are cheaper and economic too. Thus, proposed spectrophotometric method was applicable for the quality control and routine analysis and may also be proposed for determination from solid dosage form containing same drugs.

REFERENCES

1. C. Davis, J. Wong and O. Gefvert, J. Pharmaceut. Biomed. Analy, **20**, 271-282 (1999).
2. R. Mandrioli, S. Fanali, A. Ferranti and M. A. Raggi, J. Pharmaceut. Biomed. Analy., **30**, 969-977 (2002).
3. C. Frahnert, M. L. Rao and K. Grasmaeder, J. Chromatogr., **B 794**, 35-47 (2003).
4. R. H. Pullen, K. M. Palermo and M. A. Curtis, J. Chromatogr., **573**, 49 (1992).
5. R. Xavier Arulappa, M. Sundarapandian and Rithesh Singh, Asian J. Res. in Chem., **2(4)**, 452 (2009).
6. Borkar Bhaskar, Hiraman, Vidhate Sandip, R. T. Lohiya and M. Umekar, J. Inter. J. Chem. Tech. Res., **1(4)**, 1153-1161 (2009).
7. P. Baby Sudha Lakshmi, S. V. M. Vardhan, D. Ramachandran and C. Rambabu, UV, Asian J. Chem., **21(1)**, 811-813 (2009).
8. P. Vincenzo, M. Roberto, F. Anna, F. Sandra and A. R. Maria, J. Pharmaceut. Biomed. Analy., **32**, 1037-1044 (2003).
9. Li Z. Cheng, Z. Li, X. Bai X. Zhang, B. Wang and H. Li, Acta Pharmacol Sin, **1(25)**, 110-114 (2004).

Accepted : 09.03.2011