Spectrophotometric Estimation of Fexofenadine in Pharmaceutical Formulations by Using 3-Methyl Benzothiazolinone-2-Hydrazone

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Abstract- A simple, accurate, rapid and sensitive method has been developed for the estimation of fexofenadine in pharmaceutical dosage form. The method is processed based on oxidative coupling reaction of MBTH and Ferric chloride with fexofenadine to form greenish blue coloured chromogen showing maximum absorbance at 624nm. The method has been statistically examined and was proved to be high precise and accurate. The selective method is economical and sensitive for determination of fexofenadine in bulk drug and in formulation.

Keywords: Spectrophotometry, fexofenadine, MBTH (3-methyl benzothiozolinonehydrazone), Ferric chloride.

1. INTRODUCTION

Fexofenadine hydrochloride, chemically is (±)-4-[1-hydroxy-4-[4-(hydroxyldiphenylmethyl)-1-piperidinyl]-butyl]-α,α-dimethyl benzene acetic acid hydrochloride,has been known as important anti histaminic drug. In view of its pharmacological importance,considerable work has been done for its detection and quantification.Literature survey revealed various analytical techniques employed for the estimation of fexofenadine hydrochloride in serum,plasma,urine,pharmaceutical dosage, and so on,such as HPLC and colorimetric methods.The main objective of the present work is to developing the process and validate a suitable high precision and accurate analytical procedure for the estimation of Fexofenadine drug in pure and tablet dosage form by colorimetric method using MBTH as the reagent.

2. EXPERIMENTAL

Perkinelmer Lambda 25 UV/Vis double beam spectrophotometer equipped with 10 mm

matched quartz cells, Sartorius analytical balance were used for spectral measurements.

All the chemicals used were of analytical reagent grade.

2.1 Reagents:

Fexofenadine was used as standard, gifted by aurobindopharma Ltd, Hyderabad. Other reagents were of analytical reagent grade. Double distilled water was used in all experiments.

2.2 Standarad solution:

Stock standard solution of FXD was prepared by dissolving accurately weighed quantity of 100mg of drug in methanol to give a concentration of 1mg/ml. working standard solution of 10µg/ml of FXD was obtained by further dilution.

(1) 0.3% MBTH was prepared by dissolving 300 mg of MBTH using distilled water in a 100 ml volumetric flask and made to volume with the same.

(2) 0.3% Ferric chloride was prepared by dissolving 300 mg of Ferric chloride using distilled water in a 100 ml volumetric flask and made to volume with the same.

2.3 Procedure:

Standard stock solutionof Fexofenadine was synthesised by adding exact weight of 100 mg of drug in 100 ml of methanol to give a concentration of 1 mg/ml. The final concentration was brought to 500 mg/ml by further dilution.

2.4 Assay:

Aliquots of Fexofenadine solution ranging from 0.2 to 2.5 ml was transferred into 10 ml of series volumetric flasks. To each tube 2.5 ml of MBTH solution followed by 3 ml of ferric chloride was added and the contents were shaken vigorously for proper mixing and then make up to 10 ml with distilled water The observed absorbance value of the greenish blue coloured chromogen was measured at 624 nm. The amount of drug was computed from the corresponding calibration curve.

Table 1: Assay of FexofenedineTablets

Sample	Labelled amount	Amount obtained	% recovery of the proposed method
1.	500mg	498.34	99.75
2.	500mg	501.26	99.62

Optical and regression parameters for the determination of Fexofenedineby using MBTH

Parameter	Result
Beer's law range (µg/ml)	20-120
Molar extinction coefficient($L.mole^{-1}.cm^{-1}$)	2.583×10^{-2}
Sandells sensitivity ($\mu g/cm^2$)	1.54×10^{-2}
Regression equation (y=mx+c) Slope(m) Intercept(b)	y=0.0014x+0.07033 0.0014 0.0703
Correlation coefficient(r)	0.999514
Precision(%Relative Standard Deviation)	0.42

3. RESULTS AND DISCUSSION

The recommended method is accurate, sensitive and precise for the determination of Fexofenadine in different formulations. The method obeying Beer's law of absorption ranging from 20-120 µg/ml and the absorption maxima at 624 nm against the corresponding reagent blank. The regression parameters and recovery results presented in table 1 and 2 proved that this method is suitable for the determination of Fexofenedine in pharmaceutical preparations.

4. CONCLUSIONS

From the above studies the simple, sensitive, cost effective visible spectrophotometic method, developed for the estimation of Fexofenedinein both bulk and formulations was found to be suitable for routine determinations.

REFERENCES

[1].T.Radhakrishna and G.OmReddy,Simultaneous determination of fexofenadine and its related compounds by HPLC,J.Pharm.Biomed.Anal.,2002,pp.29,681-690.

[2]. M.Gergov, I.Ojanpera and E.Vuori, Simultaneous screening for 238 drugs in blood by liquid chromatography-ion spray tandem mass spectrometry with multiple reaction monitoring, J.Chromatogr.B,2003,pp.795,41-53.

[3]. A.A.Gazy, H.Mahgoub, F.A.E1-Yazbi, M.A.E1-Sayed and R.M.Youssef , Determination of some histamine H_{1-} receptor antagonists in dosage forms, J.Pharm.Biomed.Anal.,2002,pp.30,859-867.

[4]. S.S Zarpakar,n.p.Bhandari and U.P.Halkar,Simultaneous determination of Fexofenadine Hydrochloride and Pseudoephedrine Sulphate in pharmaceutical dosage by reverse phase high performance liquid chromatography, Indian drugs, 2000, pp.37,421-425

[5]. A.Golcu, B.Dogan and S.A.Ozkan, Anodic voltammetricbehavior and determination of anti histaminic agent: FexofenidineHCl, Anal. Lett., 2005,pp.38,1913-1931.