



New Visible Spectrophotometric Method for the Determination of Cefixime Trihydrate in Pharmaceutical Formulations

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ABSTRACT

A simple, sensitive and economical spectrophotometric method was developed for the determination of cefixime trihydrate in pharmaceutical formulations. This method is based on the formation of pink colored chromogen complex by the reaction of drug with ferric chloride and 2, 2 bipyridyl, which absorbs maximally at 520 nm. Beer's law is obeyed at a concentration range of 1-10 mcg/ml for method. This method has been successfully applied for the assay of the drug in pharmaceutical formulations.

Key words: cefixime trihydrate, ferric chloride, 2, 2 bipyridyl, Spectrophotometry.

INTRODUCTION

Suprax (cefixime) is a oral suspension, a semi synthetic cephalosporin antibiotic for oral administration.chemically , it is (6R,7R) 7- [2- (2-amino-4-thio-zolyl) glyoxylamido]- 8- oxo-3- vinyl 5-thia-1-azabicyclo[4.2.0] oct-2-ene-2carboxylic acid. cefixime is a broad spectrum antibiotic belongs to third generation cephalosporins. cefixime shows the antibiotic activity by disrupting the synthesis of the peptidoglycan layer of bacterial cell wall. It is effective against both gram positive and gram negative bacteria, so it widely used to treat infections caused by bacteria such as pneumonia, bronchitis, gonorrhoea and ear, lung, throat and urinary tract infections.

The drug has been determined by variety of analytical techniques such as high performance liquid chromatography assay with 1,2,4 triazole and mercury chloride[Jun Haginaka and Junko Wakai *Analyst*, 1985, 110, 1277-1281], spectrophotometric study catalyzed by metal ions[P. Gutiérrez Navarro, A. El Bekkouri and E. Rodriguez Reinoso *Analyst*, 1998, 123, 2263-2266], Determination in fermentation media by high-performance liquid chromatography using pre-column derivatisation with 1-hydroxybenzotriazole [Ajit J.Shah, Maxwell W. Adlard and Geoffrey Holt *Analyst*, 1988, 113, 1197-1200], Study of spectrophotometric and mercurimetric methods[B. Nowak and H. Wollmann *Pharmazie*, 1987, 42(12), 862-863], Determination of cefixime in the presence of cloxacillin[A. O. Akanni

and J. S. K. Ayim, Department of Pharmaceutical Chemistry, University of Ibadan, Ibadan, Nigeria], Simultaneous spectrophotometric and volumetric determinations [Qureshi SZ, Qayoom T, Helalet MI, Department of Chemistry, Analytical Research Laboratory, Aligarh Muslim University, India.]

The estimation of cefixime was carried out using different methods like spectrophotometric determination of cefixime [J. W. G. Smith, G. E. de Grey and V. J. Patel Analyst, 1967, 92, 247-252], quality control assay [L.A.Okoro E.N.Ejike], Copper(II) complexation with cefixime [S.V.Lapshin and V.G.Aleksee], determination of spectrophotometric method with pyrocatechol violet [Amin AS], department of Chemistry, Faculty of Science, Benha University, Benha, Egypt.], Spectrophotometric determination of some cephalosporins with ammonium vanadate. [Ibrahim el-SA, Beltagy YA, El-Khalek], Studies on ready mix suspension of cefixime trihydrate [Jafar m.*, Aejaz a. Vol 2, Suppl 2, 2010]. Different spectrophotometric have been recommended which include Reaction of hydrochloric acid and potassium iodate followed by Na_2SO_4 [analytical abstracts 1997], reaction of borate buffer with methanolic chloranil [analytical abstracts 1998], analytical investigation using paramolybdate anion [P.B.Issopoulos, J.Pharm, Biomed, analysis, 1998], spectrophotometric method by the reaction of Ce(III) ions complexed with arsenazo III [analytical abstracts 2001],

This paper describes simple and sensitive spectrophotometric method. it includes formation of pink colored complex by the reaction of drug with ferric chloride and 2, 2 bipyridyl, which absorbs maximally at 520 nm.

MATERIALS AND METHODS

Apparatus

Ultraviolet-Visible-Spectrometer

SHIMADZU-1700 with 1 cm matched quartz cells was used for all spectral measurements.

Reagents and standards

All the chemicals used were of analytical grade.
1). 2, 2 bipyridyl AR grade (2%W/V): 780mg of 2, 2

bipyridyl is dissolved in 100 ml of methanol AR grade.

2). Ferric chloride hexahydrate AR grade (0.2%W/V): 405mg of ferric chloride is dissolved in 100 ml of distilled water.

Procedure

Preparation of standard solution of cefixime trihydrate

Standard stock solution was prepared by dissolving 100mg of cefixime trihydrate in 100 ml of distilled water, sonicate for 15 min from these aliquots of standard solution taken to prepare 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 $\mu\text{g}/\text{ml}$ with dilution.

Method

Recommended procedure for the determination of cefixime trihydrate in bulk drug

Aliquots of working sample of drug containing (10-50 mcg/ml) is transferred into a series of 10ml graduated test tubes. To each test tube 2ml of 2%W/V (0.2560 M) solution of 2, 2 bipyridyl and 0.3 ml of 0.2% (0.012 M) solution of ferric chloride is added. These test tubes along with the blank were heated at a temperature of 70° c for 15 minutes. After heating these test tubes are cooled at room temperature and the volume is made up to 10ml using distilled water. The absorbance of the pink colored chromogen was measured at a maximal wavelength of 520nm against a reagent blank and the concentration was measured using calibration curve.

Procedure for the assay of cefixime trihydrate in pharmaceutical formulations

The methods was extended for the determination of cefixime Trihydrate from cefixime formulations. The total contents of 20 cefixime tablets were of powder and the powder equivalent to 10mg was dissolved in 50 ml of distilled water. and the volume if made to 100ml with distilled water. The above solution was further diluted and analyzed as described, in the above mentioned method for bulk drug. The procedure was repeated three times with cefixime formulations.

RESULTS AND DISCUSSION

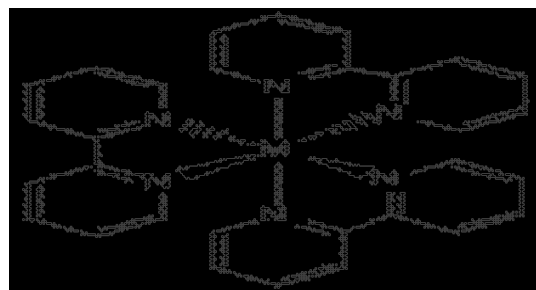
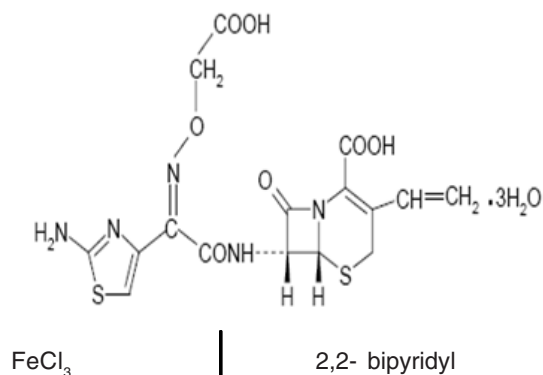
Iron(Fe) exhibits variable valency and exists as ferrous (FeII) and ferric (FeIII) salts.

Ferrous (Fe II) salts acts as a reductant and involved in complex formation with 2,2 bipyridyl which have a tendency to get oxidized.

Table 1: Optical characteristics & precision

Parameters	Method
λ_{\max} (nm)	520
Beer's law limits	1-10 mcg/ml
Molar absorptivity (l/mol.cm)	1.403×10^3
Sand ell's sensitivity (mcg/ml/cm ² /0.001 absorbance unit)	0.0241
Regression Equation* (Y)	
Slope (m)	0.0375
Intercept (c)	0.1744
Correlation Coefficient(r)	0.9966
Precision** (%Relative Standard Deviation)	0.356
Standard error of mean	0.256

Y= bC + a ; Where C is the concentration of cefixime trihydrate in mcg/ml and Y is the absorbance at the respective lambda max,**for eight measurements.



Pink coloured complex
here M= Fe

Table 2: Evaluation of cefixime trihydrate in pharmaceutical dosage forms

Formulation	Labeled Amount (mg/tab)	Amount obtained by Proposed Method	Percentage Recovery** +/-S.D
Cefixime	200	201	100.5+/-0.023
Cefixoral	200	199.2	99.6+/-0.013
Cefspan	200	202.6	101.3+/-0.037

**Average+/-S.D.of eight determinations.

Drug when reacted with known amount of iron (FeIII) undergoes oxidation to give reduced form of ferric (FeIII) i.e. ferrous (FeII) ion which has a tendency to give coloured complex with 2,2 bipyridyl.

Reaction mechanism

The ferrous (FeII) ion formed by the oxidation of drug undergoes reaction with 3 molecules of 2, 2 bipyridyl to form light pink coloured tris complex

CONCLUSION

A simple visible spectrophotometric method for the determination of cefixime trihydrate in pure and its dosage forms was developed. The absorbance of the chromogen was measured at maximum absorbance of 510nm against the corresponding reagent blank. The method is found to be simple, precise, economic, and less time consuming. The method has also been statistically evaluated and the results obtained are accurate,

precise and free from the interferences of other additives present in the formulation.

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