Biosciences, Biotechnology Research Asia Vol. **4**(2), 725-727 (2007)

Spectrophotometric methods for the determination of a Cephalosporin antibiotic in pharmaceutical formulations

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(Received: October 06, 2007; Accepted: November 19, 2007)

ABSTRACT

A simple, sensitive and reproducible visible spectrophotometric method is developed for the determination of Cefixime in pharmaceutical formulations**.** The Method is based on the formation of colored species on binding of Cefixime with Ferric chloride in 0.7 % HCl to produce a Yellowish green colored solution (λ_{max} at 430 nm). Results of analysis were validated statistically and by recovery studies. This method is successfully employed for the determination of Cefixime in various pharmaceutical preparations.

Key words : Cefixime, Visible Spectrophotometric determination, Sandell's sensitivity, Beer's Law.

INTRODUCTION

Cefixime designated chemically as (Z)-2-(tert-Methoxycarbonyl Methoxyimino)-2-(2-Aminothiazol-4-yl) Acetic Acid, is a broad-spectrum cephalosporin antibiotic involved in the management of urinary tract infections, children suffering from pharyngitis and/or tonsillitis were treated with either 8 mg cefixime/kg body weight once daily for 5 days .It is also effective in the treatment of Multiresistant shigella dysenteriae type 1. A few analytical methods based on HPLC[1-5], Spectrophotometry[6-12] and Polarography [13-14] have been reported so far in the literature for the assay of Cefixime in biological methods.

Keeping in view the structural configuration of cefixime and exploring the reactions of various functional groups the development of two simple, sensitive spectrophotometric methods for the routine quality control analysis of Pharmaceutical formulations containing Cefixime is described below explaining the reaction of Cefixime with ferric chloride in 0.5 N HCl to get a yellowish-green colored solution with λ_{max} at 430 nm.

EXPERIMENTAL

Instrumentation

Spectral and absorbance measurements are made with Systronics UV – Visible Double beam spectrophotometer model 2201.

Reagents

All the chemicals used were of analytical grade. All the solutions were freshly prepared with double distilled water. Freshly prepared solutions were always used. An aqueous solution of Ferric chloride (700 mg in 0.5N HCl) was used.

Standard and sample solution of cefixime

About 100 mg of Cefixime was accurately weighed and dissolved in 100 ml of Methanol in a volumetric flask to make a solution of 1 mg/ml

standard solution and further dilutions were made with the same solvent (100 µg/ml) for this method.

Assay procedure

Method

Aliquots 1.0 to 5.0 ml of standard cefixime solution (100 µg/ml) was transferred to a series of 10 ml graduated tubes. To each tube 2 ml of ferric chloride solution and the resulting solution is kept aside for 10 minutes. The volume was made upto 5 ml with distilled water and the absorbance of the Yellowish green colored chromogen was measured at 430 nm against the reagent blank. The amount of Cefixime was computed form the calibration curve.

RESULTS AND DISCUSSION

The proposed methods are based on oxidation of the drug followed by complex formation between the drug cefixime and ferric chloride in the presence of HCl. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and sandell's sensitivity for these methods are presented in Table 1. The regression analysis using the method of least squares was made for the slope (a), intercept (b) and correlation coefficient (r) obtained from different concentrations was summarized in Table 1. The precision and accuracy was found by analyzing six replicate samples containing known amounts of the drug and the results are summarized in Table 1.

Table 1:Optical characteristics, precision and accuracy of the proposed method

Parameters	Method
λ_{max} (nm)	430
Beer's law limit (µg/ml)	1 – 5
Sandell's Sensitivity (µg/cm^2/0.001 abs. unit)	0.039267
Molar absorptivity (litre.mole^{-1}.cm^{-1})	0.6595866 x 10^4
Correlation coefficient (r)	0.9942
Regression Equation (Y)*	
Slope (a)	0.1058
Intercept (b)	0.00206
% RSD**	0.58
% Range of errors (95% confidence limits)	
0.05 significance level	± 0.4849
0.01 significance level	± 0.7175

* Y= a + bx, where'Y'is the absorbance and x is the concentration of Cefixime in µg/ml

** For six replicates.

The accuracy of these methods were ascertained by comparing the results obtained with the proposed and reference methods in the case of formulations and are presented in Table 2. As an additional check on the accuracy of these methods, adding known amounts of pure drug to pre-analyzed formulations.

Performed recovery experiments and percent recovery values obtained is listed in Table 2. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

Table 2: Estimation of cefixime in pharmaceutical formulations

Formulations	Labeled amount mg/vial	% Recovery by Proposed Method
Capsule 1	200 mg	99.42
Capsule 1	200 mg	99.53
Capsule 1	200 mg	99.33
Capsule 1	200 mg	100.13
Capsule 1	200mg	100.2

Thus the proposed method is simple and sensitive with reasonable precision and accuracy. This can be used for the routine determination of Cefixime in routine quality control analysis.

ACKNOWLEDGEMENTS

The authors are grateful to management of Koneru Lakshmaiah College of Engineering, Vaddeswaram for their continuous support and encouragement and for providing the necessary facilities

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