International Journal of ChemTech Research
CODEN(USA): IJCRGG ISSN : 0974-4290
Vol. 3, No.3, pp 1025-1027, July-Sept 2011

Validated Spectrophotometric methods for the Determination of Cefditoren Pivoxil in Drug Formulations

Srinivasa Rao Narala[1]*, K.Saraswathi[2]

[1]Department of Chemistry, R.V.R. & J.C. College of Engineering, Guntur, A.P., India.

[2] Department of Chemistry, S.V. University, Tirupathi, A.P., India.

*Corres.author: srinunarala@gmail.com
Ph : +91-9392542747

Abstract: Two new, simple and sensitive spectrophotometric methods (A and B) have been developed for the determination of Cefditoren Pivoxil in bulk drug and pharmaceutical formulations. Method A is based on the formation of red colored chromogen obtained when Cefditoren Pivoxil was diazotized with nitrous acid followed by coupling with 1-naphthol, exhibiting λ_{max} at 500 nm. Method B is based on the reaction of Cefditoren Pivoxil with Folin-Ciocalteu phenol's reagent under alkaline conditions forming a blue colored chromogen exhibiting λ_{max} at 760 nm. The Beer's law is obeyed in the concentration range of 10-50 µg/ml for method A and 12-28 µg/ml for method B. The results of analysis have been validated statistically and by recovery methods.

Key Words: Spectrophotometry, 1-naphthol, Folin-Ciocalteu phenol's reagent.

Introduction:

Cefditoren Pivoxil is chemically (6R)-7-[[(2Z)-2-(2-amino -1,3-thiazool-4-yl)-2-methoxyiminoacetyl] amino]-3-[(Z)-2-(4-methyl-1,3-thiazol-5-yl)ethenyl]-8-oxo-5-thia-1-aza bicyclo [4.2.0]oct-2-ene-2-carboxylic acid. It is a third generation cephalosporin with antibacterial activity against gram-positive and gram-negative pathogens.

The literature survey reveals that few analytical methods for this drug are reported, which include chromatographic[1-3] and spectrophotometric[4-5] methods. The present investigation has been undertaken to develop two simple and accurate spectrophotometric methods for the determination of Cefditoren Pivoxil in bulk and pharmaceutical formulations using 1-naphthol and Folin-Ciocalteu phenol's reagent.

Experimental:

Apparatus: All spectral and absorbance measurements were made on a Techcomp UV – 2301 UV-Visible spectrophotometer with 1 cm matched quartz cells. The drug used for present investigation was obtained in highly pure form (pharmaceutical grade) from the local pharmaceutical laboratory, Hyderabad and its pharmaceutical formulations were procured from different commercial sources.

Reagents :

All the chemicals used were of analytical grade. Aqueous solutions of sodium nitrite (0.5% w/v), HCl (5N), ammonium sulphamate (0.5% w/v), sodium carbonate (10% w/v), Folin-Ciocalteu phenol's reagent (1: 2 ratio diluted solution with distilled water)

and alcoholic solution of l-naphthol (0.1% w/v) were prepared for these investigations.

Preparation of Standard Drug solution :

Accurately weighed 100 mg of Cefditoren Pivoxil was dissolved in 100 ml of methanol in a volumetric flask to obtain a concentration of 1mg /ml. From this suitable dilutions were made to obtain the working standard concentrations of 500 µg/ml for method A and 200 µg/ml for method B.

Preparation of sample solution:

Accurately weighed formulation powder equivalent to 100 mg of drug was transferred in to a 100 ml volumetric flask containing 50 ml of methanol, sonicated for 10 min. and diluted to 100 ml with methanol. The resulting solution was filtered through a whatmann filter paper. This solution was further diluted with methanol to obtain the working standard concentrations of 500 µg/ml for method A and 200 µg/ml for method B.

Method A

Aliquots of standard drug solution ranging from 0.5 to 5.0 ml (500 µg/ml) were transferred to a series of 25 ml volumetric flasks. To each flask 1.0 ml of HCl , 1.0 ml of sodium nitrite were added and kept for five min. at 0-5^{0}C. To which 1.0 ml of ammonium sulphamate, 1.0 ml of alcoholic 1- naphthol were added and kept for five min. Finally the volume is made up to the mark with distilled water. The absorbance of red colored chromogen was measured at 500 nm against a reagent blank. The amount of drug in the sample was computed from its calibration curve.

Method B

Aliquots of standard drug solution ranging from 0.5 to 5.0 ml (200 µg/ml) were transferred to a series of 25 ml volumetric flasks. To each flask 1.0 ml of Folin-Ciocalteu phenol's reagent and 1.0 ml of sodium carbonate were added, kept for 10 min. and the volume was made up to the mark with distilled water. The absorbance of blue colored chromogen was measured at 760 nm against a reagent blank. The amount of drug in the sample was computed from its calibration curve.

Assay Procedure:

Table-1 Optical characteristics of the proposed methods

Parameter	Method A	Method B
λ max	500	760
Beer's law limits (µg/ml)	10-50	12-28
Molar absorptivity (l mol^{-1} cm^{-1})	1.2936X10^3	1.8090X10^3
Sandell's sensitivity (µg cm^{-2})	0.4798	0.3431
Regression equation (Y= mX+b)		
Slope (m)	0.0210	0.0443
Intercept (b)	-0.0215	-0.3500
Correlation coefficient	0.9995	0.9997
R.S.D. (%)*	0.8598	0.9346
% Range of error (confidence limits)		
0.05 level	± 1.0674	± 1.1602
0.01 level	± 1.7702	± 1.9243

* Mean of five determinations

Table-2 Amount of Cefditoren Pivoxil found in formulations by proposed methods

Formulation	Labeled amount mg/tablet	Amount found *		% Recovery **	
		Method A	Method B	Method A	Method B
Tablet-1	200	199.89±0.062	199.88±0.059	98.93±0.160	99.82±0.089
Tablet-2	200	199.92±0.049	199.94±0.057	99.91±0.141	99.06±0.250

* Mean of five determinations

** Mean of three determinations

Results and Discussion:

The optical characteristics such as Beer's law limits, Molar absorptivity, Sandell's sensitivity and relative standard deviation were calculated and the results are summarized in Table 1. Regression characteristics like slope, intercept and correlation coefficient were calculated and are presented in Table 1.

Commercial formulations of Cefditoren Pivoxil were successfully analyzed by the proposed methods and the values are presented in Table 2. To evaluate validity and reproducibility of the methods recovery experiments were conducted and the results are summarized in Table 2.

Conclusion:

It could be concluded that the developed methods are simple, sensitive, precise, accurate and can be satisfactorily applied to the analysis of Cefditoren Pivoxil in bulk and Pharmaceutical formulations in the quality control.

Acknowledgements:

The authors express their gratitude to the Management R.V.R. & J.C. College of Engineering, Guntur for providing their continuous support throughout the work.

References:

1. Rieck W. and Platt D., Clin Lab., 2000, 46 (9-10), 477-482.
2. Masato O. and Graham B., International J. Pharmaceutics, 2004, 272 (1-2), 121-128.
3. Qi fice, Ji-Hong Yao, Cheng-Ye Su, Guo-zhu Han, Hui-Jun Sun, Kun Wang, Xu Han, Bin Qu and Ke-Xin Liu. Asian journal of pharmaco dynamics and pharmacokinetics, 2006, 6(3), 214 -218.
4. Appala Raju S., Karadi A.B. and Manjunath S., Asian J. Research Chem., 2009, 2 (3), 270.
5. Prema V., Niraimathi V., Aruna A. and Suresh A.J., Research J. Pharm. and Tech., 2010, 3 (2), 610.

*****