



## **SPECTROPHOTOMETRIC ESTIMATION OF CEFDITOREN PIVOXIL IN PHARMACEUTICAL ORAL SOLID DOSAGE FORM**

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### **ABSTRACT**

Two simple, sensitive, economical, accurate and precise spectrophotometric methods have been developed for the estimation of cefditoren pivoxil in pharmaceutical oral solid dosage form. Method A involves the determination of cefditoren pivoxil by diazotisation reaction. It is based on the reaction of cefditoren pivoxil with hydrochloric acid and sodium nitrite to form reddish brown colored chromogen, exhibiting maximum absorption at 450 nm. Method B is based on reaction of cefditoren pivoxil with ferric chloride and 1, 10-phenanthroline to form blood red coloured chromogen, exhibiting absorption maximum at 510 nm. The Beer's concentration was found to be between 50-500 µg/mL for Method A and 5-50 µg/mL for Method B. The methods have been statistically evaluated and were found to be precise and accurate. The proposed methods are economical and sensitive for the estimation of cefditoren pivoxil in bulk drug and formulations.

**Key words:** Cefditoren pivoxil (CP), Spectrophotometry, Ferric chloride, 1, 10-Phenanthroline.

### **INTRODUCTION**

Cefditoren pivoxil is (6R, 7R)[(2Z)-(2-amino-thiazolyl) (methoxy imino) acetyl amino]-3- [(1Z)-2- (4-methyl-5-thiazolyl) ethenyl ] 8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid. It is a third generation cephalosporin exhibiting bactericidal action by inhibiting cell wall synthesis. Cefditoren exerts its inhibitory effect via affinity for penicillin binding proteins of the pathogens. Literature survey revealed that few sophisticated analytical methods have been reported for the estimation of cefditoren pivoxil and no spectrophotometric /colorimetric methods have been reported for the determination of cefditoren pivoxil in pharmaceutical dosage forms.

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## **EXPERIMENTAL**

### **Instrumentation**

All spectral absorbance measurements were made on Shimadzu UV-VIS spectrophotometer - 1650.

### **Reagents**

1 M Hydrochloric acid, 3 % sodium nitrite in water, 1 M sodium hydroxide, 3 % ammonium sulphamate solution, 0.1 M ferric chloride and 0.03 M 1, 10-phenanthroline.

### **Preparation of standard stock solution**

It was prepared by dissolving an aliquot quantity of drug in 0.1 M HCl in a 100 mL standard flask and the volume was made up with the same to produce 1 mg/2 mL and 1 mg/4 mL for Method A and B, respectively.

### **Preparation of sample solution**

Twenty tablets were weighed and powdered. A quantity equivalent to standard concentration of cefditoren pivoxil was weighed, transferred to a 100 mL volumetric flask and shaken with 0.1 M HCl to dissolve the active ingredient and the volume was made up with the same. The solution was then filtered. First few mL of the filtrate was discarded and the filtrate was suitably diluted with water to give the required concentration.

### **Assay procedure**

#### **Method A – Diazotisation reaction<sup>1</sup>**

Aliquots of standard stock solution ranging from 50-500 µg/mL were transferred to a series of 25 mL volumetric flask. To each flask, 1 mL of 1 M hydrochloric acid and 2 mL of 3 % sodium nitrite in water were added and kept aside for 5 min; then 3 mL of 1 M sodium hydroxide was added to the solution. Excess nitrous acid was neutralized by addition of 2 mL of 3 % ammonium sulphate solution after addition of sodium nitrite. After five minutes, the volume was then made up with distilled water. These solutions were scanned between 400-800 nm (visible region) using reagent blank and the maximum absorption was observed at about 450 nm for reddish brown colored chromogen. The colored species were stable for more than an hour. The absorbance of the sample solution was also measured by repeating the same procedure.

### **Method B – using ferric chloride and 1, 10-phenanthroline<sup>2</sup>**

Aliquots of standard stock solution ranging from 5-50 µg/mL were transferred to a series of 25 mL volumetric flask. To each flask, 1 mL of 0.1 M ferric chloride and 1.5 mL of 0.03 M 1, 10-phenanthroline were added. The flasks were allowed to stand in water bath for 25 min. The flasks were then cooled to room temperature and the solutions were made upto the volume with water. The absorbance of the red coloured chromogen was measured at 510 nm against reagent blank. The colored species were stable for more than 3 hours. The absorbance of the sample solution was also measured by repeating the same procedure.

### **Recovery studies**

Recovery studies were done to ensure the accuracy and reproducibility of the results obtained. Known amounts of pure drug was added to the previously analysed samples and the spiked samples were reanalyzed by the proposed method. The percentage recoveries thus obtained are given in Table 2.

## **RESULTS AND DISCUSSION**

In the present study, the method A is based on the reaction of hydrochloric acid and sodium nitrite to form nitrous acid, which reacts with the primary aromatic amino group of cefditoren pivoxil to form a diazotized reddish brown colored chromogen. The colored chromogen was stable for more than an hour and exhibited maximum absorption at 450 nm. Method B is based on the reduction of ferric chloride to ferrous form by the drug, which forms complex with 1,10-phenanthroline to yield blood red colored chromogen. The colored chromogen was stable for more than 3 hours and exhibited maximum absorption at 510 nm. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are furnished in Table 1. The regression characteristics like slope (b), intercept (a), correlation coefficient (r), obtained from different concentrations were calculated and the results are summarised in Table 1. The assay results are presented in the Table 2. The conditions required for the formation of colored complexes were optimized. Statistical analysis was carried out and the results were found to be satisfactory.

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to preanalysed sample and the percentage recovery was calculated. The results are furnished in Table 2. The results indicate that there is no interference of other ingredients present in the formulations. Thus, the proposed methods are simple, sensitive, precise, accurate, reproducible and useful for the routine quality control.

**Table 1: Optical characteristics and statistical parameters**

Parameters	Method A	Method B
$\lambda_{\text{max}}$ (nm)	450	510
Beer's law limits ( $\mu\text{g/mL}$ )	50-500	5-50
Molar absorptivity ( $\text{L mol}^{-1} \text{cm}^{-1}$ )	1776.84	13498.34
Sandell's sensitivity ( $\mu\text{g cm}^{-2}$ /0.001 abs unit)	0.350038	0.046197
Slope (m)	0.002829	0.019679
Intercept(c)	0.009429	0.028
Regression equation *	$0.002829x + 0.009429$	$0.019679x + 0.028$
Correlation coefficient (r)	0.998609	0.9995
Standard deviation	0.020776	0.056
Relative standard deviation (%) **	0.010413	0.02805

\*( $y = mx + c$ ), \*\* Each value is the mean of 3 determinations

**Table-2: Assay and recovery of cefditoren pivoxil and its formulations**

Tablet	Label claim(mg)	Amount found by the proposed method (mg)*		% Recovery by the proposed method*	
		Method A	Method B	Method A	Method B
Cefditoren pivoxil	200	198.51	199.02	100.27	100.24
		199.96	199.62	99.25	99.02
		200.08	200.28	100.38	100.65

\*Each value is the mean of 3 determinations

## CONCLUSION

The percentage recovery of these two methods lies between 99-101%. The correlation coefficient for all the four methods is 0.999 and the recovery studies indicate that there is no interference of other ingredients present in the formulation. Thus, these two

methods are simple, precise, accurate, less time consuming and useful for the routine analysis.

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