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NEW SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF CEFDINIR IN PURE AND IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Two simple and sensitive visible spectrophotometric methods (A and B) have been developed for the estimation of Cefdinir (CFD) in pure as well as in pharmaceutical dosage forms. Method A is based on the oxidation followed by complexation between the CFD and 1, 10–phenanthroline (1, 10 PTL) in presence of ferric chloride to form a blood red colored chromogen with λ_{max} at 520 nm, whereas in method B, CFD reacts with Folin–Ciocalteu (FC) reagent in an alkaline media to form a blue colored chromogen with λ max at 710 nm. Beer's law is obeyed in the concentration range of 0.3–2.4 µg/mL and 1.5–7.5 µg/mL for method A and Method B, respectively. The results obtained are reproducible and are statistically validated and found to be suitable for the assay of CFD in bulk as well as in pharmaceutical dosage forms.

Key words: 1, 10–PTL, FC reagent, Cefdinir, Dosage forms

INTRODUCTION

Cefdinir[1] (CFD) is a third generation cephalosporin antibiotic. Chemically it is 7–[(2Z)–(2–(amino–4 thiazolyl)–(hydroxy imino) acetyl] amino] –3–ethenyl–8–oxo– (6R, 7R) 5–thia–1–azabicyclo [4. 2. 0] oct–2–ene–2–carboxylic acid. It mainly acts by the inhibition of the peptido–glycan synthesis at the enzymatic level causing the formation of spheroplasts and thereby, the destruction of the cell. Compared to the previous generation of drugs, these are much more effective in treatment of infections caused by gram –ve bacteria but equal to or slightly less in the treatment of gram +ve bacteria. They are much effective in the treatment of *Peudomonad* species and the *Klebsillae* species. Literature survey reveals that one HPLC[2] and two spectrophotometric[3–4] methods have been reported for the estimation of CFD. Hence, the authors were developed two simple and sensitive visible spectrophotometric methods have been developed for the estimation of CFD in bulk as well as in pharmaceutical dosage forms.

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EXPERIMENTAL

Instrumentation

Spectral and absorbance measurements were made on Systronics UV–Visible spectrophotometer–117 with 10 mm matched quartz cells.

Reagents

Aqueous solutions of ferric chloride (0.05%), 1, 10–phenanthroline (0.2%), Folin–Ciocalteu reagent (1N) and sodium carbonate (2N) were used. All these chemicals were of analytical reagent (AR) grade.

Preparation of standard and sample solutions

Accurately weighed 100 mg of CFD was dissolved in sufficient quantity of 0.5 N NaOH solution and made up to 100.0 mL with distilled water. This stock solution was further diluted with distilled water to get working standard solution of 10.0 µg/mL for method A and 30.0 µg/mL for method B. Sample (Capsule) solution of CFD was prepared same as above.

Assay procedures

Method A: Aliquots of working standard solution ranging from 0.3–2.4 mL (1.0 mL = 10 µg) were transferred in to a series of 10.0 mL graduated test tubes, 1.5 mL of ferric chloride and 2.0 mL of 1, 10–PTL were added to each of the test tubes and heated on boiling water bath for 15 min, cooled and add 1.0 mL of ortho–phosphoric acid was added and the solutions were made up to volume with distilled water. The absorbance of the blood–red colored species was measured at 520 nm. The color was stable up to three hours. The amount of drug in the sample was computed from the calibration curve.

Method B : Aliquots of working standard solution ranging from 0.5 – 2.5 mL (1mL = 30 µg) were transferred to a series of 10.0 mL graduated test tubes. To each of tube, 1.5 mL of FC reagent and 4.0 mL of sodium carbonate were added and made up to volume with distilled water. The absorbance of the colored species was measured at 710 nm against reagent blank. The color was stable up to 3 hours. The amount of drug in the sample was computed from the calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient and percent relative standard deviation, (calculated from the eight measurements containing $3/4^{th}$ of the amount of the upper Beer's law limits) were calculated and the results are summarized in Table 1. Regression characteristics like standard deviation of slope (S_b), standard deviation of intercept (S_a), standard error of estimation (S_c) and % ranges of error (0.05 and 0.01 confidence limits) were calculated and are shown in Table 1.

Table 1. Optical characteristics and precision of the proposed methods A and B

Parameter	Method A	Method B
λ_{max} (nm)	520	710
Beer's law limits (µg/mL)	0.3 – 2.4	1.5 – 7.5
Molar absorptivity (L mole^{-1} cm^{-1})	1.3 x 10^5	3.3 x 10^4
Sandell's sensitivity (µg cm^{-2} / 0.001 absorbance unit)	0.0285	0.0119
Regression equation (Y = a + bC)		
Slope (b)	–0.00099	–0.00004
Intercept (a)	0.0335	0.0083
Correlation coefficient (r)	0.9999	0.9999
Relative standard deviation (%)*	0.83	0.53
% Range of error (Confidence limits)*		
0.05 level	0.699	0.449
0.01 level	1.034	0.664

Y = a + bC, where C is the concentration in µg/mL and Y is absorbance unit.
* Eight replicate samples.

Pharmaceutical formulation of CFD was successfully analyzed by the proposed and reference methods. The results obtained by the proposed and reference methods are presented in Table 2. To evaluate validity and reproducibility of the method, known amounts of pure drug was added to previously analyzed samples and the mixtures were analyzed by the proposed method. There is no interference of other ingredients present in formulations. These results indicate that the methods and simple, rapid with reasonable precision accurate and are applicable to various formulations of CFD.

Table 2. Assay and recovery of CFD in dosage forms

Sample	Labeled Amount (mg)	Amount obtained (mg)			% Recovery proposed**	
		Proposed method		Reference^R method		
		A	B		A	B
1	300	300	297.6	297.9	100	99.2
2	300	299	302.4	296.9	99.6	100.8
3	300	299.4	292.8	298.6	99.8	97.6

R – Reference U.V. Method developed in our lab.
** Recovery amount is the average of three determinations.

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