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SPECTROPHOTOMETRIC ESTIMATION OF CEFPROZIL IN BULK DRUG AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

Two simple, accurate, rapid and sensitive spectrophotometric methods (A and B) have been developed for estimation of cefprozil in bulk drug and pharmaceutical formulations. The methods A and B were based on oxidation of Cefprozil with ferric chloride followed by complex formation with MBTH (3-methyl-2-benzothiazolinone hydrazone) and 1,10-phenanthroline, respectively. The complex shows maximum absorbance at 658 nm and 510 nm for method A and B respectively. The beers law concentration range is 100-500 mcg/ml and 2-10 mcg/ml for method A and B respectively. The results of all the methods were validated statistically and by recovery studies. The proposed methods are economical and sensitive for the estimation of Cefprozil in bulk drug and tablet dosage form.

Keywords: Ultraviolet-Visible Spectrophotometry, Cefprozil, MBTH, 1,10-Phenanthroline.

INTRODUCTION

Cefprozil is chemically (6R,7R)-7-(R)-2-amino-2-(p-hydroxy-phenyl)acetamido-8-oxo-3-propenyl-5- thia-1-azabicyclo (4.2.0) oct-2-ene-2-carboxylic acid and the structural formula is shown in (Fig: 1). The molecular formula is $C_{18}H_{19}N_3O_5S$ and molecular weight is 407.45 g/mol. It is a white to yellowish crystalline powder, stable at room temperature and freely soluble in water, soluble in methanol and very slightly soluble in alcohol. Cefprozil is a beta-lactam antibiotic. By binding to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, it inhibits the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that cefprozil interferes with an autolysin inhibitor. It is official drug in United States Pharmacopoeia [1-3]. From the literature survey, it was found that Cefprozil was estimated by analytical methods such as few UV-Visible methods [4-5], High-Performance Thin Layer Chromatography (HPTLC) method [6]. The present developed method was simple, precise, specific and accurate.

MATERIALS AND METHODS

Instrument

Shimadzu 1700 Ultraviolet-Visible double beam spectrophotometer with 1 cm matched quartz cells was used for all spectral measurements.

Reagents

All the chemicals used were of analytical reagent grade. All the solutions were freshly prepared.

1. MBTH (0.5%)
2. Ferric Chloride (1.2% and 0.3%)
3. 1,10-Phenanthroline
4. Distilled Water

Preparation of standard stock solution

100 mg Cefprozil powder was accurately weighed and dissolved in 40 ml of distilled water in a 100 ml volumetric flask and then the volume was made up to the mark with distilled water to obtain a final concentration of 1000 µg/ml (stock A solution).

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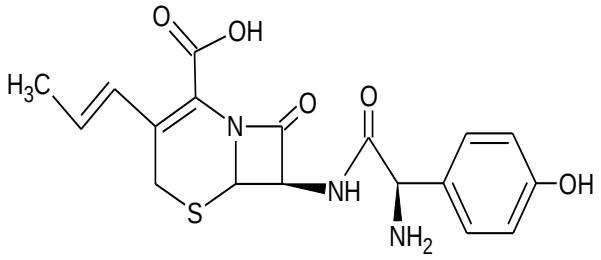
From the above stock 'A' solution, 10 ml of aliquot was pipetted out and transferred into a 100 ml volumetric flask and the volume was made up to the mark with distilled water to obtain a final concentration of 100 µg/ml (stock B solution).

Fig 1. Chemical Structure of Cefprozil



Method A [7-8]

Aliquots of standard solution of Cefprozil ranging from 1.0 to 5.0 ml (1 ml = 1000µg) were transferred into a series of 10 ml volumetric flasks. To each flask, 2.0 ml of MBTH (0.5% w/v) and 2.0 ml of ferric chloride (1.2% w/v) was added and kept aside for 10 min for complete color development. The volume in each flask was made upto 10 ml with distilled water. The absorbance of green colored chromogen was measured at 658 nm against the reagent blank. The colored chromogen was stable for 3 hrs. The amount of Cefprozil present in the sample was computed from calibration curve.

Method B [9]

Aliquots of standard solution of Cefprozil ranging from 0.2 to 1.0 ml (1 ml = 100 µg) were transferred into a series of 10 ml volumetric flasks. To each flask, 0.5 ml of Ferric Chloride (0.3% w/v) and 1.0 ml of 1, 10-Phenanthroline (0.3% w/v) was added and kept aside for 15 min for complete color development. The volume in each flask was made upto 10 ml with distilled water. The absorbance of red colored chromogen was measured at 510 nm against the reagent blank. The colored chromogen was stable for 2 hrs. The amount of Cefprozil present in the sample was computed from calibration curve.

Preparation of Sample Solution

Twenty tablets of Cefprozil each containing 250 mg were accurately weighed, average weight was determined and crushed into fine powder and a powder equivalent to 100 mg of Cefprozil was transferred into 100 ml volumetric flask and dissolved in 40 ml of distilled water and sonicated for 5 min. The solution was then filtered through Whatmann filter paper No.41. The residue was washed with 10 ml portions of distilled water three times and the total volume of the filtrate was made up to 100 ml with distilled water to obtain 1000 µg/ml (stock A' solution). From the above stock A' solution 10 ml of aliquot was pipetted out in a 100 ml volumetric flask and the volume was made up to the mark with distilled water to obtain the final concentration of 100 µg/ml (stock B' solution).

The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples and they are measured at 658 nm and 510 nm respectively for method A and B. The results are represented in Table 1.

Recovery Studies [10]

To ensure the accuracy and reproducibility of the obtained results, known amount of pure drugs were added to previously analyzed sample of formulation and these samples were analyzed by the proposed method and recovery experiments were performed. The percentage recoveries thus obtained were given in Table 1.

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work method A and B have been developed for the estimation of Cefprozil Hydrochloride from tablet formulation.

The developed methods A and B are based on formation of colored complexes with MBTH and 1,10-Phenanthroline respectively. The conditions required for the formation of colored complexes to form colored species were optimized. Statistical analysis was carried out and the results were found to be satisfactory. Relative standard deviation values were low that indicates reproducibility of the proposed methods. Recovery studies were close to 100 % that indicates accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptive and Sand ell's sensitivity are presented in Table 2.

Fig 2. Absorption Spectrum of Cefprozil with Ferric Chloride and MBTH

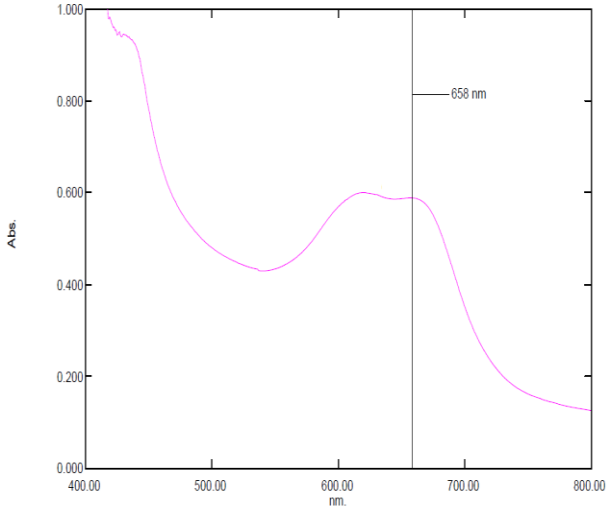


Fig 3. Calibration curve of Cefprozil at 658 nm by MBTH method

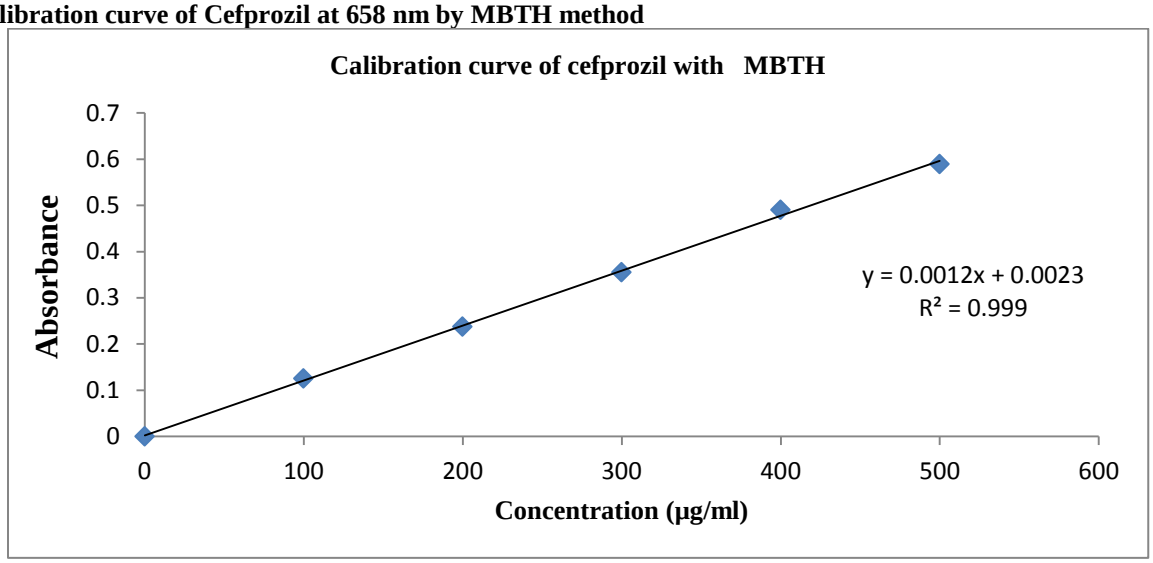


Fig 4. Absorption Spectrum of Cefprozil with 1,10 phenanthroline reagent

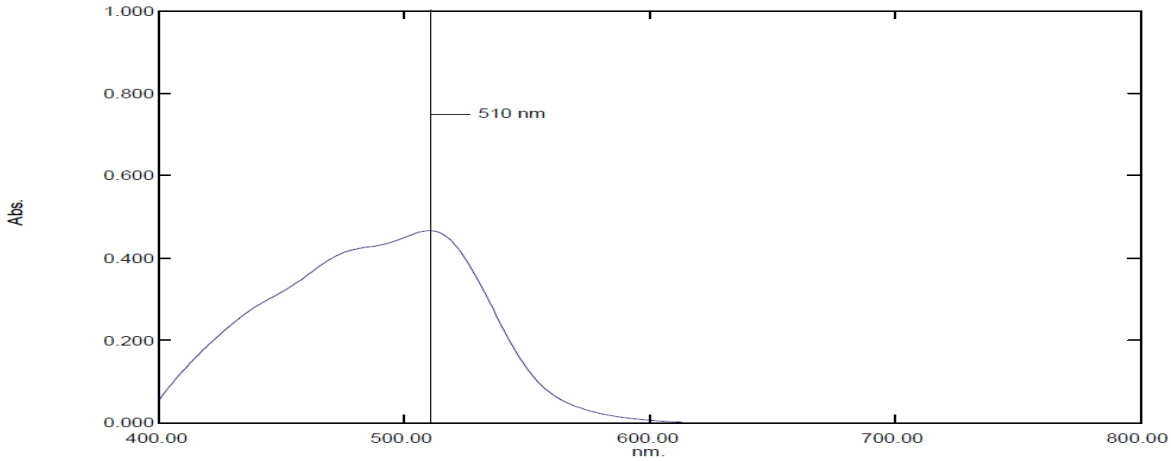


Fig 5. Calibration Curve of Cefprozil with 1, 10-Phenanthroline reagent

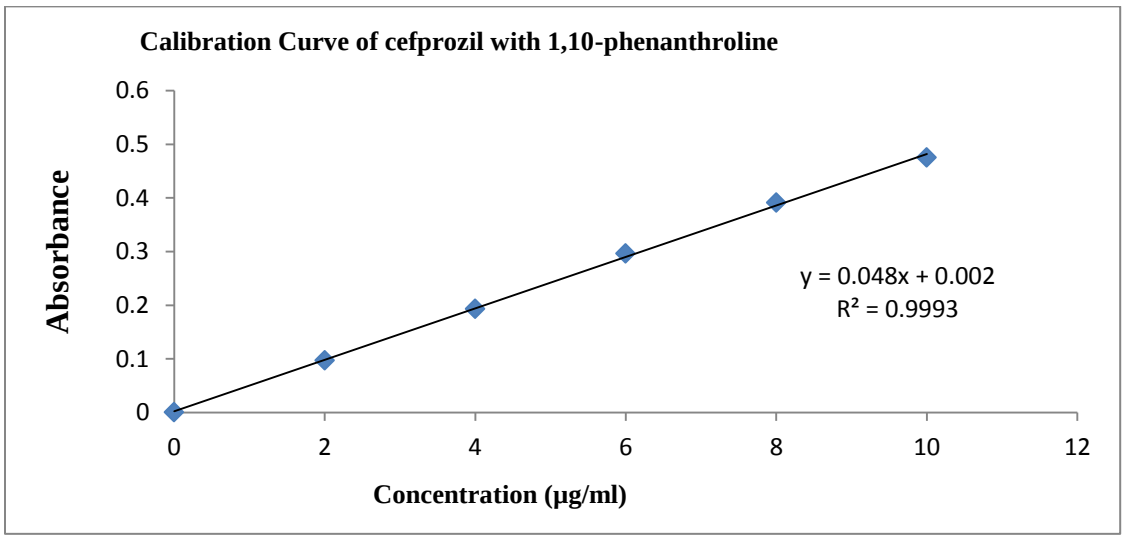


Table 1. Assay and recovery of Cefprozil in tablet dosage form

Formulation	Amount present (mg)	Amount obtained (mg)	% Assay*	Mean*	S.D*	% RSD*
REFZIL O	250	249.98	99.99	100.00	0.0333	0.0333
	250	250.1	100.04			
	250	249.94	99.97			

*Average of three determinations

Table 2. Optical characteristics and precision data Parameters Method A Method B

Parameters	Method A	Method B
λ_{max}(nm)	658	510
Linear range (µg/ml) (C)	100 - 500	2 - 10
Molar absorptivity (liter,mole^{-1} cm^{-1})	0.49 * 10^3	1.9757 * 10^4
Regression equation(Y*)		
Slope(b)	0.001	0.048
Intercept(a)	0.001	0.002
Correlation co-efficient (r^2)	0.999	0.999
% RSD	0.3755	0.9111
Standard errors**	0.000578	0.00162
LOD (µg/ml)	1.90	0.03
LOQ (µg/ml)	5.77	0.12
Standard deviation on slope (s_b)	0.0011	0.00115
Standard deviation on intercept (s_a)	0.00057	0.0005

CONCLUSION

Thus, it can be concluded that the method developed in the present investigation was economical, simple, accurate, rapid and precise. Hence, the above said method can be successfully applied for the estimation of Cefprozil in pharmaceutical dosage forms.

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