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METHOD DEVELOPMENT AND VALIDATION OF CEFPODOXIME PROXETIL BY UV- SPECTROPHOTOMETRIC METHOD IN BULK DRUG AND FORMULATION

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ABSTRACT

A new, simple, sensitive and reproducible spectrophotometric method has been developed for the estimation of Cefpodoxime Proxetil in pure form and formulations. Method involves the determination of Cefpodoxime Proxetil by dissolving in acetone and followed by measuring the absorbance at 330 nm. The linearity was obtained in the concentration range of 400-600 µg /ml. The suitability of method for quantitative analysis of Cefpodoxime Proxetil was proved by validation. This method was extended to formulation and there was no interference from excipients and diluents. This method has been statistically validated and is found to be precise and accurate.

Key words: Cefpodoxime Proxetil, spectrophotometry, Beer's law.

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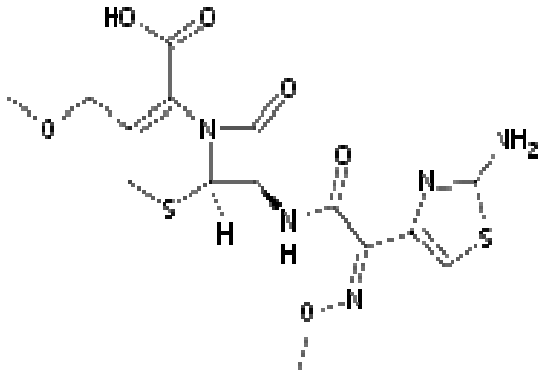
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INTRODUCTION

Cefpodoxime Proxetil^[1] is chemically (6R,7R) -7- { [(2Z)-2-(2-amino-1,3-thiazol-4-yl)-2-methoxyimino-acetyl] amino} -3- (methoxymethyl) - 8-oxo-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid which is an oral third generation cephalosporin antibiotic. It is used to treat infections caused by susceptible gram-positive bacteria. Cefpodoxime Proxetil is active against most of the gram negative

and gram positive organisms. It is used in the treatment of acute otitis media, pharyngitis and sinusitis. Literature reviews^[2-8] revealed very few method of estimation for Cefpodoxime Proxetil in bulk and formulation has been reported so far except HPLC^[9-10] in biological fluids.



Cefpodoxime Proxetil

MATERIALS AND METHODS

All the measurements were made using Shimadzu UV-visible double beam spectrophotometer with

1mm matched quartz cells. All the solutions were freshly prepared using Acetone AR grade.

Preparation of standard stock solution

It was prepared by dissolving 100mg of Cefpodoxime Proxetil in 100ml in 100 ml volumetric flask to produce 1000 µg/ml.

Absorption maximum

The stock solution was suitably diluted with actone so as to contain 100 µg /ml of Cefpodoxime Proxetil (CPX). This solution was subjected to scanning in UV region of 200 – 400 nm and found that Cefpodoxime Proxetil exhibited maximum absorbance at about 330 nm. The spectrum is recorded and shown in Figure.1.

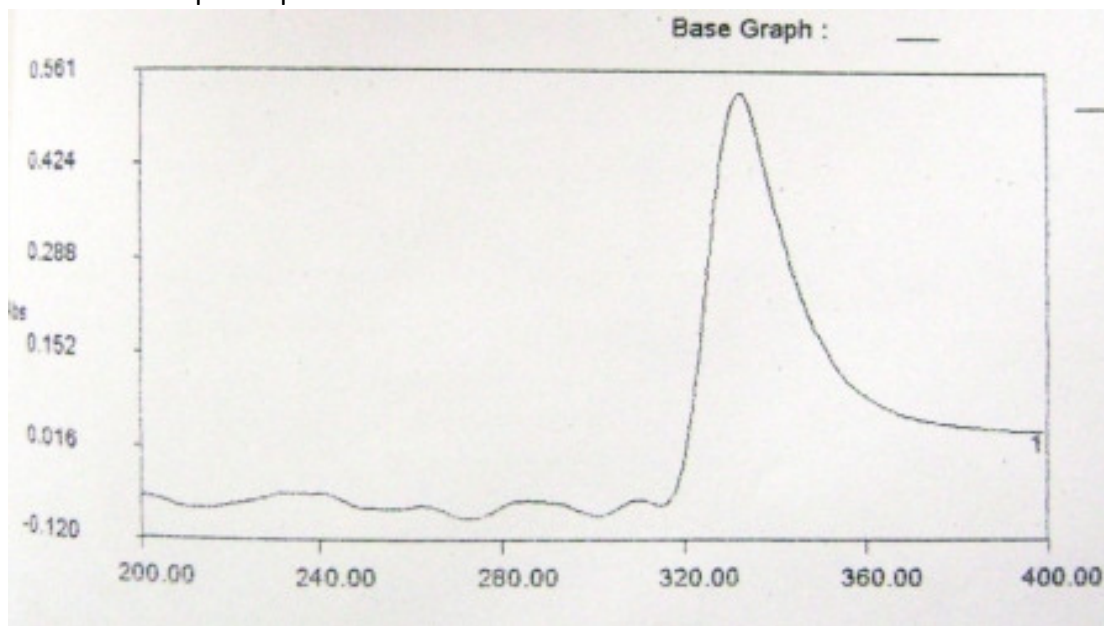


Figure.1 Spectrum of Cefpodoxime Proxetil

Linearity (calibration curve)

Adequate dilutions were made from the stock solution to get concentrations ranging from 400-600 µg /ml of Cefpodoxime Proxetil using acetone. The absorbances were measured at 330 nm using

acetone as blank and the calibration curve was constructed by plotting absorbance vs. concentration. It was found that the above concentration range obey Beer's law (Fig.2).

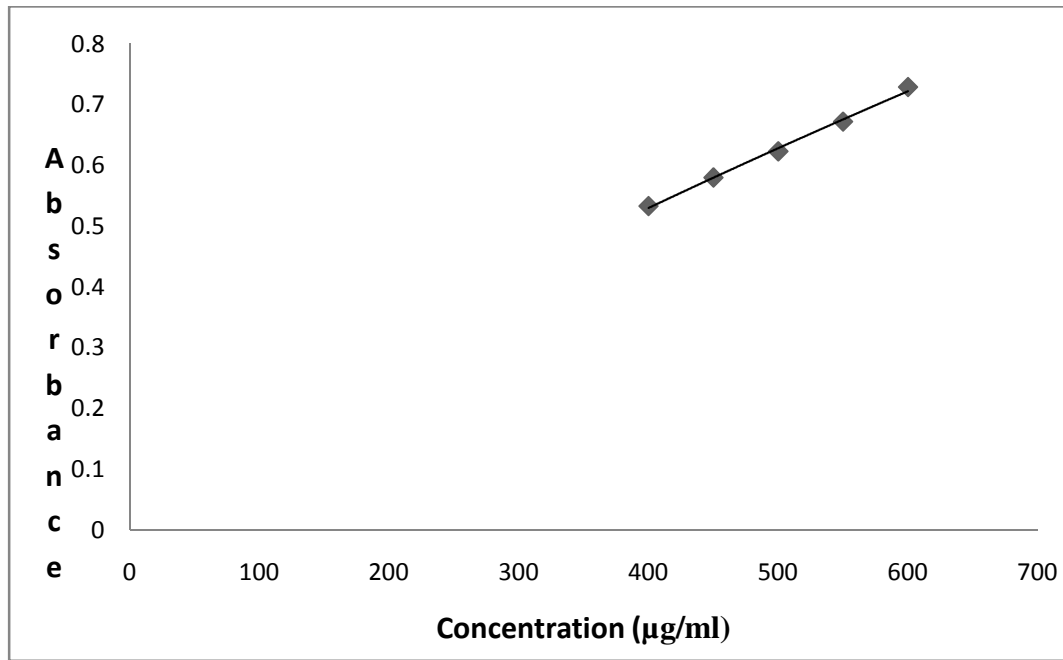
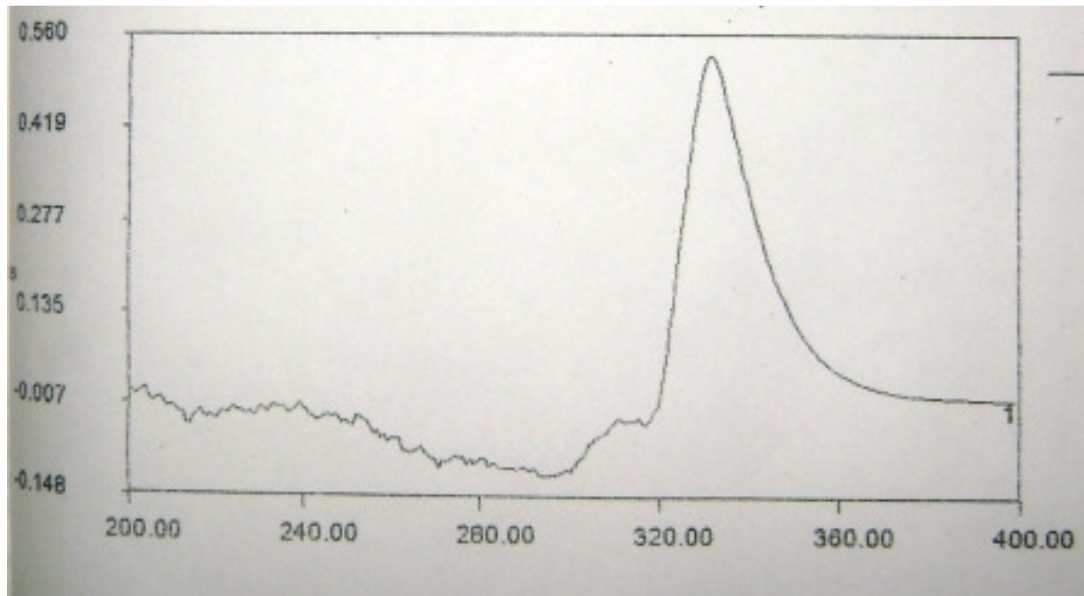


Figure.2 Calibration graph of Cefpodoxime Proxetil

Analysis of formulation

20 tablets of Cefpodoxime Proxetil were powdered and weighed an amount of powder equivalent to 100 mg of Cefpodoxime Proxetil. The volume is made up to 100 ml using acetone in a 100 ml volumetric flask and filtered. The above solution

was further diluted to get concentrations ranging from 400 µg / ml. Absorbance of this solution was measured at 330 nm and the amount was calculated (table.1).



Spectrum of Cefpodoxime formulation

RESULT AND DISCUSSION:

Estimation of Cefpodoxime Proxetil (CPX) by UV spectrophotometry is done using acetone as solvent. The wavelength 330 nm was fixed for the estimation of Cefpodoxime Proxetil. Different concentrations of Cefpodoxime Proxetil were

prepared from the stock solution and their absorbances were measured at selected wavelength. The calibration curves were obtained in the range of 400- 600 µg /ml with the correlation coefficient of 0.998645. The sample solution was prepared by dissolving the amount equivalent to

100mg of cefpodoxime proxetil and made up the volume to 100 ml with acetone and filtered. The above solution was diluted to get a concentration ranging from 400 – 600 µg /ml, spectrum was recorded and the absorbances were measured at the selected wavelength. The concentration of the drug in formulation was determined. To study the validity ^[11-16] of the method, Accuracy, Linearity, Repeatability, Intra and Inter day precision were carried out using same optimum conditions. Accuracy of the method was carried out by recovery studies by adding known amount of standard drug to the pre-analyzed formulation and analyzed as per the formulation procedure (table.2). Precision studies were carried out as repeatability, Intraday and Interday assays (table.3). The Limit of detection (LOD) and Limit of quantification (LOQ) were found to be 20 µg/ml and 100 µg /ml respectively. The proposed method

was found to be accurate, simple, sensitive and rapid. The low standard deviation value and good percentage recovery indicate the reproducibility and accuracy of the newly developed method.

CONCLUSION

The developed method is found to be simple, sensitive, accurate and precise. The proposed method can be used for routine analysis of Cefpodoxime Proxetil formulation. The developed method was validated and the results proved that the method is reproducible and selective for the analysis of Cefpodoxime Proxetil as single drug in bulk as well as in pharmaceutical formulations.

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Table 1: result of analysis of formulation

Drug	Amount (mg/ tab)		% label claim ± S.D*
	Labelled	Found*	
CPX	100	98.71	98.71 ±0.015

Table 2: Recovery data

Drug	Label claim (mg/ tab)	Amount found (mg/ tab)	% recovery ±S.D* 100%
CPX	100	98.71	102.2 ± 0.35

*Each average of 3 determinations.

Table 3: Optical characteristics for Cefpodoxime Proxetil

Parameters	CPX
λ _{max} (nm)	330 nm
Linearity range (µg/ml)	400-600 µg/ml
Correlation coefficient	0.998645
LOD	20 µg/ml
LOQ	400 µg/ml
<u>Accuracy*</u>	102.2 ± 0.35
<u>Precision*</u>	
Intraday (n=3) (%RSD)	0.161
Interday (n=3) (% RSD)	2.14
Repeatability (% RSD)	1.59
Slope	0.000968

*Each average of 3 determinations.

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