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Research Article

Novel UV Spectrophotometric Method for the Quantitative Analysis of Cefpodoxime Proxetil in Pharmaceutical Formulations by First Derivative Technique

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ABSTRACT

The spectrophotometric method for estimation of Cefpodoxime Proxetil employed first derivative amplitude UV spectrophotometric method for analysis using methanol as solvent for the drug. Cefpodoxime Proxetil has absorbance maxima at 235nm and obeys Beer's law in concentration range 10-50µg/ml with good linearity i.e. r^2 about 0.999. The recovery studies established accuracy of the proposed method; result validated according to ICH guideline. Results were found satisfactory and reproducible. The method was successfully for evaluation of Cefpodoxime Proxetil in tablet dosage form without interference of common excipients.

Keywords: Cefpodoxime Proxetil, First derivative, UV spectrophotometric, Cefpodoxime Estimation.

INTRODUCTION

Cefpodoxime Proxetil is an oral third generation cephalosporin antibiotics. It is active against most Gram positive and Gram negative organisms. The antibacterial action of Cefpodoxime Proxetil is through inhibition of bacterial cell wall synthesis probably by acylation of membrane bound trans peptidase enzymes; this prevents cross linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity. It is commonly used to treat acute otitis media, pharyngitis, and sinusitis[1]. So far, thirteen methods are reported for the determination of Cefpodoxime Proxetil in dosage forms. Of these methods, eight methods are by HPLC determination[2-6] four UV-Spectrophotometric methods by zero order method[7-8] and one method by Hydrotropic Solubilization method[9]. No First derivative UV Spectrophotometric method for routine determination of this drug was reported and there for; aim of the present study was to develop an accurate, simple, economical First derivative UV spectrophotometric method for the rapid determination of Cefpodoxime Proxetil in individual bulk drugs and single component tablet formulations.

MATERIALS AND METHODS

Materials

Shimadzu 1800 spectronic UV spectrophotometer Instrument, a pair of 1cm path length quartz cells and Methanol (95%) as the solvent were used for the study. Tablet brands for the assay studies were obtained from the local market.

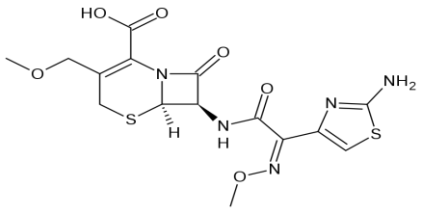
Methodology

Determination of amplitude at zero crossing point for the selection of wavelength

Standard stock solution of Cefpodoxime Proxetil was prepared by dissolving accurately weighed quantities (25 mg) in 25ml of methanol and transferred it to 25ml volumetric flask. Volume was adjusted with methanol to obtain stock solution 1000µg/ml concentration. For obtaining clear solution was ultra-sonicated. Dilutions were done to get concentration of 10µg/ml. The standard solution of Cefpodoxime Proxetil (10µg/ml) was scanned at wavelength range of 220nm to 280nm keeping N=5 and the amplitude were found to be 0.005 with zero crossing point at 235nm. (Figure 1). There for, 235nm was selected analytical wavelength for the determination of Cefpodoxime Proxetil in bulk drugs and pharmaceutical formulations.

Linearity

Standard stock solution of Cefpodoxime Proxetil, relevant amount of solution was pipette out into 25ml volumetric flasks and dilutions were made with methanol to be working standard solutions of concentrations 10, 20, 30, 40, 50µg/ml. The difference in amplitude of Cefpodoxime Proxetil were measured in the first



Cefpodoxime Proxetil

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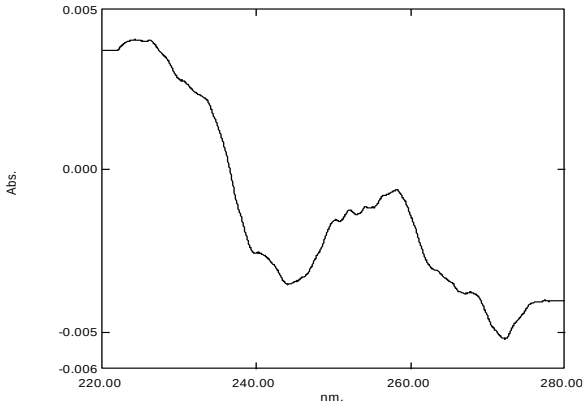

Figure 1: First derivative spectrum of Cefpodoxime Proxetil 10µg/ml.

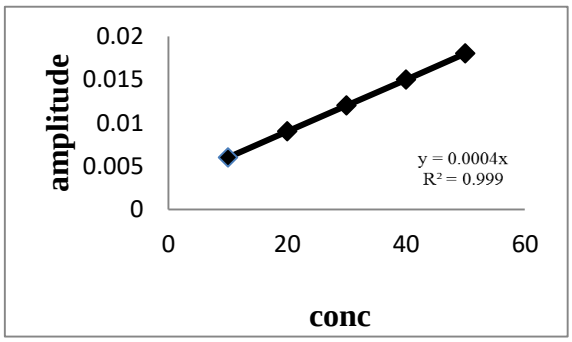

Figure 2: First order derivative calibration plot for Cefpodoxime Proxetil.

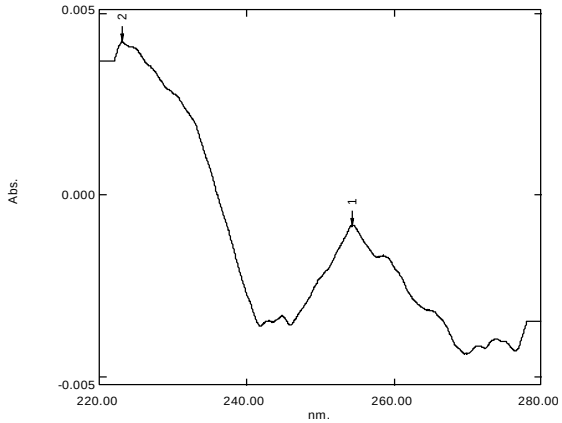

Figure 3: First derivative spectrum of Cefpodoxime Proxetil 10µg/ml.

derivative mode with N=5 of instrument at 235nm. The calibration curve of drugs was plotted. The concentration range over which the drugs followed linearity was chosen as an analytical concentration range i.e.10-50µg/ml for Cefpodoxime Proxetil. (Table 1 and Figures 2 to 7)

Validation of the proposed method

Evaluation of drug from dosage form (Tablet assay study)

Standard

Standard stock solutions having 1000µg/ml of Cefpodoxime Proxetil was prepared by dissolving 2.5mg

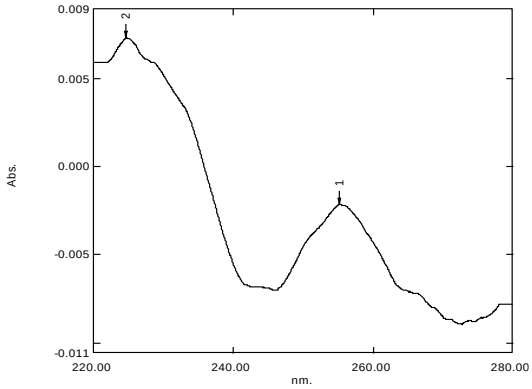

Figure 4: First derivative spectrum of Cefpodoxime Proxetil 20µg/ml.

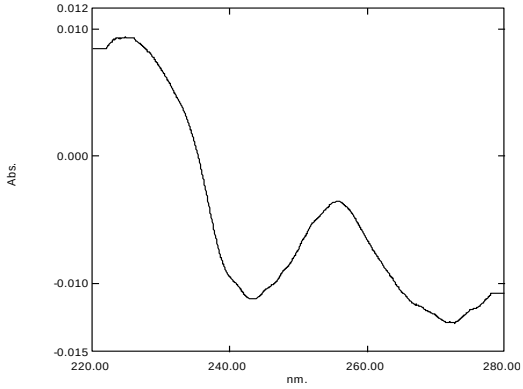

Figure 5: First derivative spectrum of Cefpodoxime Proxetil conc. 30µg/ml.

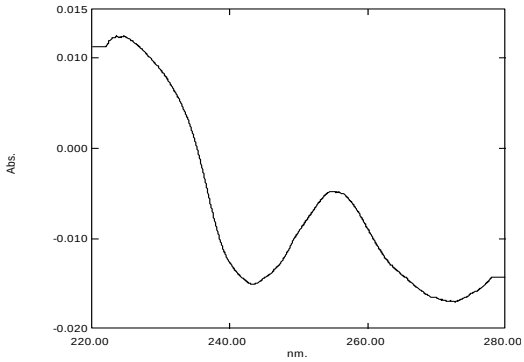

Figure 6: First derivative spectrum of Cefpodoxime Proxetil 40µg/ml.

of drug in 25ml methanol to get the final concentration of 20µg/ml. Dilutions of standard stock solution were made using methanol. This were scanned at 235nm and with derivative mode N=5.

Table 1: Calibration Data for Cefpodoxime Proxetil.

Sr. No	Conc. (µg/ml)	Amplitude
1.	10	0.005
2.	20	0.009
3.	30	0.012
4.	40	0.015
5.	50	0.019

Table 2: Assay of Cefpodoxime Proxetil in tablet formulation Gudcef 200 and Cefpodem 200.

Brand Name	Label Claim (mg/tab)	Amount Found (mg/tab)	% Or Label Claim	Mean	SD	CV
	200	198.75	99.37			
	200	198.01	99.00			
Brand 1	200	199.80	99.90	99.59	0.411	0.1693
	200	200.00	100.00			
	200	199.45	99.72			
	200	198.80	99.40			
	200	199.06	99.53			
Brand 2	200	199.80	99.90	99.61	0.322	0.1040
	200	198.50	99.25			
	200	200.00	100.00			

*mean of three determinations

Table 3: Accuracy parameter of Cefpodoxime Proxetil for Brand 1.

Level of % Recovery	*Amount Present (mg)	Amount Of Stand. Added (mg)	Total Amount Recovered (mg)	% Recovery	%mean Recovery	SD	CV
80	200	160	159.36	99.60			
80	200	160	160.16	100.10	99.626	0.460	0.212
80	200	160	158.68	99.18			
100	200	200	500.10	100.05			
100	200	200	199.64	99.82	99.590	0.608	0.370
100	200	200	197.80	98.90			
120	200	240	238.32	99.30			
120	200	240	238.72	99.47	99.663	0.489	0.239
120	200	240	240.52	100.22			

Table 4: Accuracy parameter of Cefpodoxime Proxetil for Brand 2.

Level of % Recovery	*Amount Present (mg/ml)	Amount Of Stand. Added (mg/ml)	Total Amount Recovered (mg/ml)	% Recovery	%mean Recovery	SD	CV
80	200	160	158.84	99.28			
80	200	160	159.76	99.85	99.700	0.455	0.207
80	200	160	160.28	100.18			
100	200	200	198.22	99.11			
100	200	200	196.00	98.00	98.706	0.614	0.377
100	200	200	198.02	99.01			
120	200	240	240.16	100.07			
120	200	240	238.72	99.47	99.630	0.385	0.148
120	200	240	238.44	99.35			

Sample

Twenty tablets of brand Gudcef 200 and Cefpodem 200 containing 200mg of Cefpodoxime Proxetil weighed; powered respectively. Amount of powder sample equivalent to 100mg Gudcef 200 brand and 100mg Cefpodem 200 brand of Cefpodoxime Proxetil was taken and dissolved in methanolusing volumetric flask respectively. Dilutions were done to get concentration 20µg/ml of Cefpodoxime Proxetil. These concentration was scanned at 235nm and with derivative mode N=5. (Table 2)

Accuracy (Recovery Study)

Accuracy was analysed by recovery experiments. By adding known amounts of powdered tablet in pure drug then experiments of recovery were performed. The recovery was carrying out at three levels, 80%, 100% and 120% of Cefpodoxime Proxetil standard concentration.

By using above procedure three accuracy samples were prepared for each accuracy level. Solution were analysed; the % recoveries were calculated by using formula

$$\%\ Rcovery = \frac{Observedamountofcompoundinsample}{Amountofallcompuntpresentinsample} \times 100$$

Table 5: Precision data of Cefpodoxime Proxetil.

Sample Number	Assay of Cefpodoxime Proxetil %of labelled amount (Inter-day precision)			
	Analyst I	Analyst II	Analyst III	Analyst IV
1	99.67	98.97	99.44	100.08
2	98.25	99.02	100..17	98.99
3	100.05	99.74	99.79	99.09
4	99.40	100.26	99.20	100.00
Mean	99.34	99.49	99.65	99.54
S.D.	0.775	0.618	0.422	0.579
CV	0.601	0.382	0.178	0.336

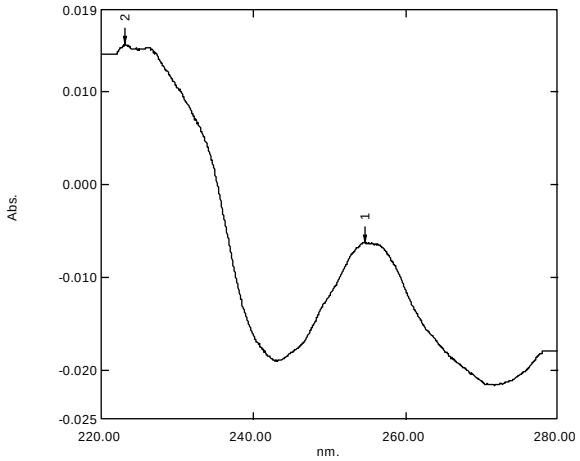

Figure 7: First derivative spectrum of Cefpodoxime Proxetil 50µg/ml.

The recovery values are summarized in following tables 3 and 4.

Precision

The precision (inter-day) was evaluated by carrying four independent samples of Cefpodoxime Proxetil with four different analysts in the same laboratory.The precision values obtained by four analysts were summarized in table.5.

RESULTS AND DISCUSSION

The standard solutions of Cefpodoxime Proxetil in Methanol (10µg/ml each) subjected to a scan at the series of wave-lengths of 220nm to 280nm at First order derivative spectra were taken at N=5 using Shimadzu 1800 spectronic UV-Visible spectrophotometer. And amplitude found to be 0.005 The calibration curve of Cefpodoxime Proxetil was found to be linear at conc. Range 10µg/ml to 50µg/ml at 235nm. There for, it was clear that Cefpodoxime Proxetil can be determined in presence of methanol with no intervention of any irrelevant substance in pharmaceutical products.

With the intention of determining the practicability of the developed technique for the assessment of commercially available commercial brands of medicinal formulations, the technique was initially tried on bulk drugs in their synthetic mixture sample as well as concentrations were estimated. Then the technique was subjected to the assay of in marketed dosage forms and satisfactory conclusions were attained within the acceptable limits as per the content of the label claim for Cefpodoxime Proxetil.

The newly developed method was validated as per the international guidelines and parameters. The novel method for the quantitative investigation of Cefpodoxime Proxetil was subjected to different validation parameters like selectivity and specificity in presence of formulation additives and excipients, studied for Linearity and range at different levels of concentrations and calibration standards where the determination range was optimized, accuracy was proved by recovery studies at different concentration levels, precision was established through inter day precision studies, where the samples were subjected to changed conditions other than optimized parameters.

CONCLUSION

It can be concluded that the proposed newly developed First derivative method is a rapid, economical, reproducible, accurate and precise method for the routine determination of Cefpodoxime Proxetil in its single component synthetic bulk drug form as well as commercial tablet formulations; economically alternative to HPLC and better than UV-spectrophotometric methods zero crossing methods.

CONFLICT OF INTEREST

None

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