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AREA UNDER CURVE UV SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF CEFPODOXIME PROXETIL IN SINGLE COMPONENT TABLETS

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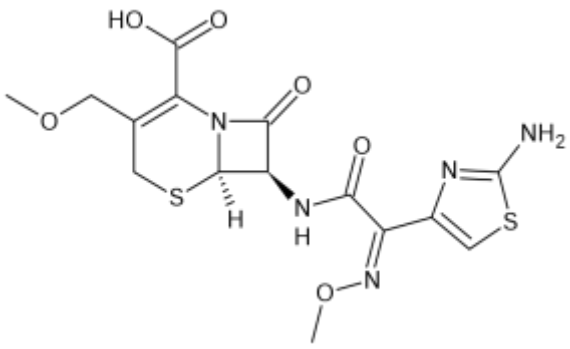
Keywords:

Cefpodoxime Proxetil; Estimation; Area under curve; UV spectrophotometri; single component; tablets.

Abstract

An UVspectrophotometric area under curve method is developed for the estimation of Cefpodoxime Proxetil in its single component tablets. The new method is area under curve method for the analysis of Cefpodoxime Proxetil using methanol as solvent for the drug. Cefpodoxime Proxetil has absorbance maxima at 235nm at area under curve wavelength range of 230nm-240nm. Cefpodoxime Proxetil obeys Beer's law in concentration range 10-50µg/ml. The recovery studies ascertained accuracy of the proposed method; results 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.

Introduction



Cefpodoxime

Cefpodoxime Proxetil is an oral third generation cephalosporin antibiotic. 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, ten 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 and 8] and one method by Hydrotropic Solubilization method [9].

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No Area Under Curve UV Spectrophotometric method for routine determination of Cefpodoxime Proxetil was reported and there for; aim of the present study was to develop an accurate, simple, economical Area Under Curve UV spectrophotometric method each for the rapid determination of Cefpodoxime Proxetil in individual bulk drug and tablet formulations.

Materials and Methods

Shimadzu 1800 spectronic UV spectrophotometer Instrument and Methanol (95%) as the solvent were used for the study. 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) searched separately in the wavelength range of 220nm-280nm and the AUC was found to be 3.116 in area between 230nm-240nm. (Figure 1)

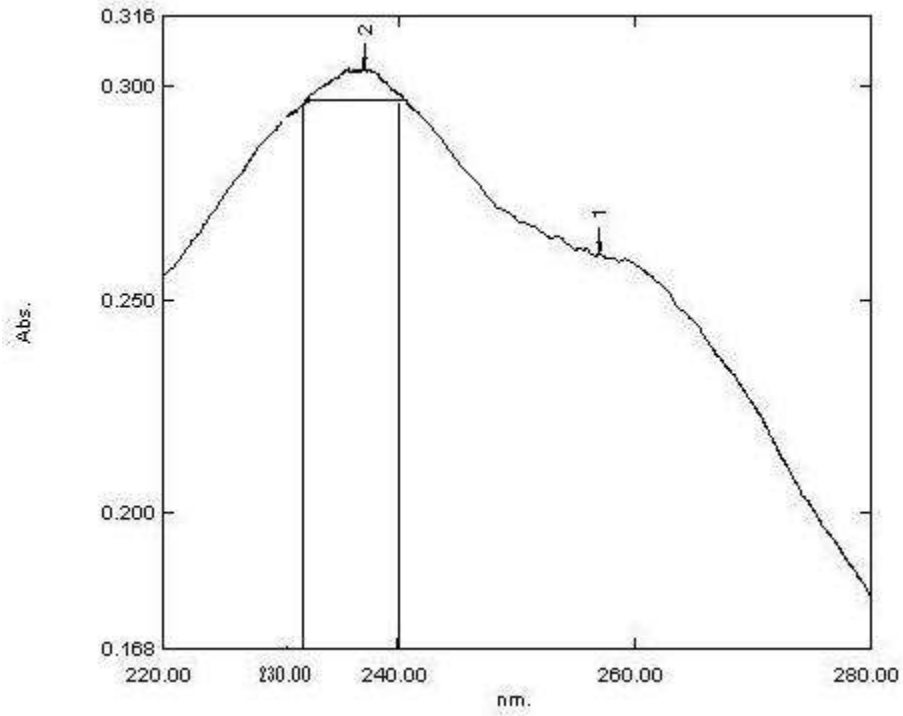

Figure 1: Area under curve of Cefpodoxime Proxetil

Linearity:

Standard stock solution of Cefpodoxime Proxetil, relevant amount of solution were 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 differences in AUC of Cefpodoxime Proxetil were measured area between 230nm-240nm. 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 1and Figure 2-5)

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Table 1: Standard Calibration DataTable for Cefpodoxime Proxetil

Sr. No	Conc. (µg/ml)	AUC
1.	10	3.250
2.	20	6.115
3.	30	8.990
4.	40	12.081
5.	50	15.100

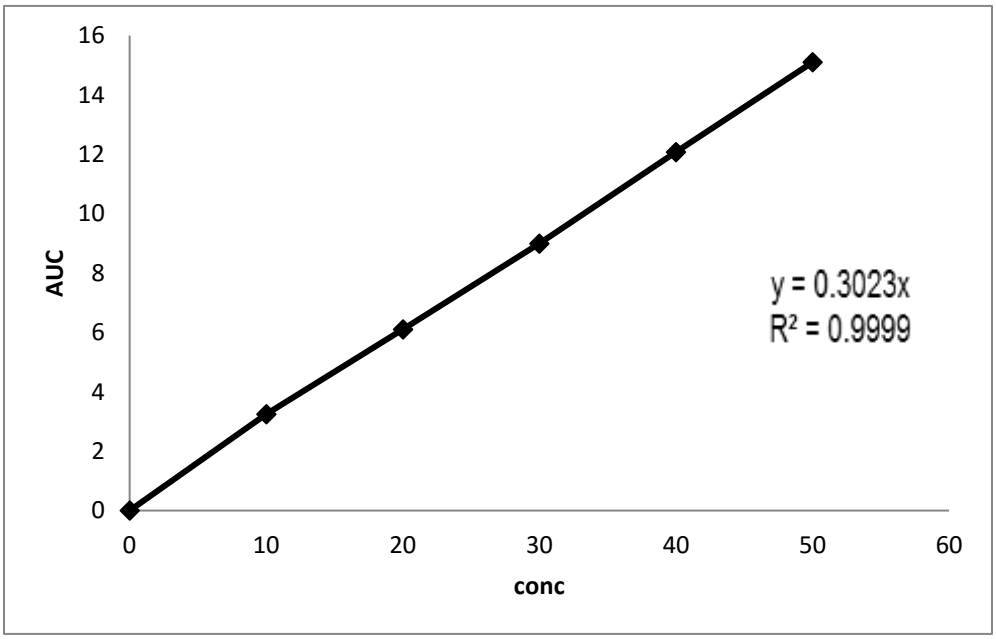

Figure 2: Area under curve Calibration Plot for Cefpodoxime Proxetil

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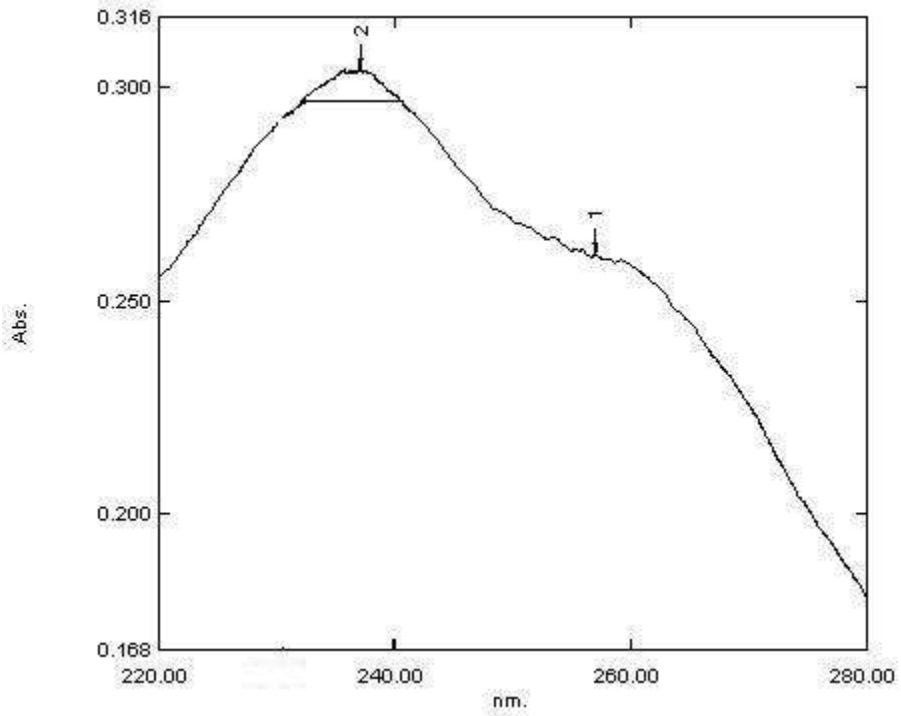

Figure 3: Area under curve of Cefpodoxime Proxetil concentration 10µg/ml

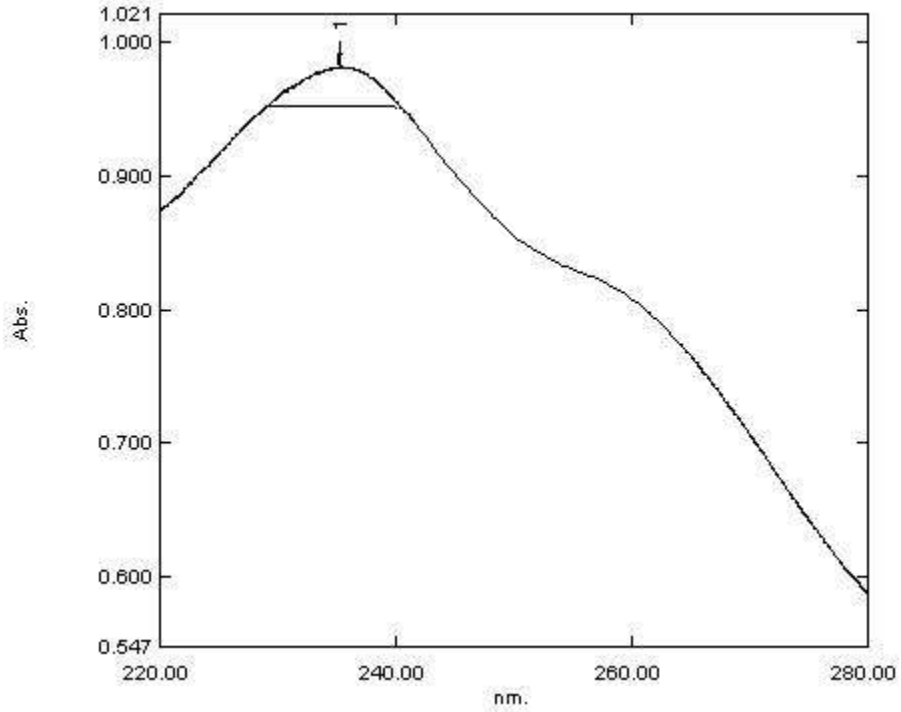

Figure 4: Area under curve of Cefpodoxime Proxetil concentration 30µg/ml

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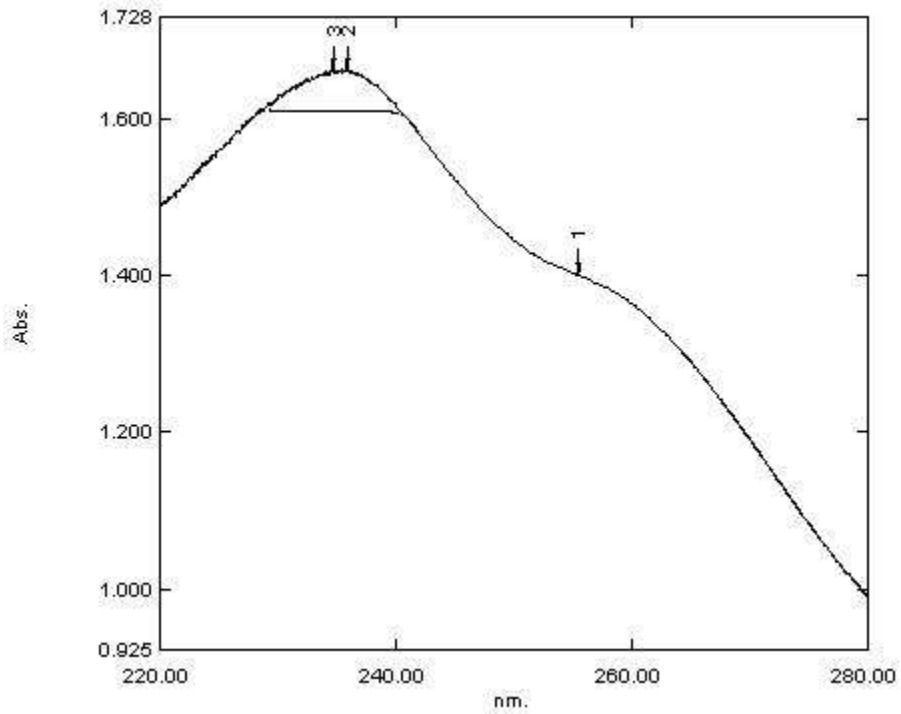

Figure 5: Area under curve of Cefpodoxime Proxetil concentration 50µg/ml

Validation:

Assay:

Applicability of the new method was tested by carrying out assay of commercial branded tablet formulations using pure drug reference standard.

Standard:

Standard stock solutions having 1000µg/ml of Cefpodoxime Proxetil was prepared by dissolving in 2.5mg of drug in 25ml methanol. To gate the final conc. (20µg/ml) dilutions of standard stock solution were made using methanol. The AUC measured in area between 230nm-240nm.

Sample:

Twenty tablets of brand Gudcef and Cefpodem containing 200mg of Cefpodoxime Proxetil weighed and powdered respectively. Amount of powder sample equal to 77.7mg [Gudcef 200] and 57.5mg [Cefpodem 200] containing 100mg of Cefpodoxime Proxetil was taken and dissolved in methanolusing volumetric flask respectively. Dilutions were made to get concengration of 20µg/ml Cefpodoxime Proxetil. These concentrations were scanned in area between 230nm-240nm. Results are given in table 2.

Table 2: Assay of Cefpodoxime Proxetil in commercial tablet formulation

Brand Name	Label Claim (mg/tab)	Amount Found (mg/tab)	% Or Label Claim	Mean	SD	CV
GUDCF 200	200	200.01	100.00	**99.59**	**0.411**	**0.1693**
	200	199.45	99.72			
	200	199.80	99.90			
	200	198.75	99.37			
	200	198.01	99.00			
	200	200.00	100.00			
	200	199.06	99.53			

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CEFPODEM 200	200	198.50	99.25	**99.61**	**0.322**	**0.1040**
	200	199.80	99.90			
	200	198.80	99.40			

Accuracy by 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 and results are given in table 3.

$$\%Recovery = \frac{Observed\ amount of compound\ in\ sample}{Amount of all compound\ present in sample} \times 100$$

Table 3: Recovery data of Cefpodoxime Proxetil

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	158.68	99.18	**99.626**	**0.460**	**0.212**
80	200	160	160.16	100.10			
80	200	160	159.36	99.60			
100	200	200	199.64	99.82	**99.590**	**0.608**	**0.370**
100	200	200	500.10	100.05			
100	200	200	197.80	98.90			
120	200	240	238.32	99.30	**99.663**	**0.489**	**0.239**
120	200	240	240.52	100.22			
120	200	240	238.72	99.47			

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 4.

Table 4: Determination of precision of Cefpodoxime Proxetil

Sample Number	Assay of Cefpodoxime Proxetil as %of labelled amount (Inter-day precision)			
	Analyst I	**Analyst II**	**Analyst III**	**Analyst IV**
1	99.40	100.26	99.20	100.00
2	100.05	99.74	99.79	99.09
3	98.25	99.02	100..17	98.99
4	99.67	98.97	99.44	100.08
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

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Results

The standard solutions of Cefpodoxime Proxetil in Methanol (10µg/ml each) subjected to scanning under area between 230nm to 240nmand the area was found to be 3.116 for area under curve method using Shimadzu 1800 spectronic UV-Visible spectrophotometer. The calibration curve of Cefpodoxime Proxetil was found to be linear at conc. Range 10 to 50 µg/ml at area between 230nm to 240nm. With the intention of determining the practicability of the developed technique for the assessment of commercially available brands (Gudcef-200 and Cefpodem-200) of medicinal formulations, the technique was initially attempted 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.

Discussion

The described method offer precise and accurate results for the quantitization of Cefpodoxime Proxetil individually in the synthetic mixture of bulk drugs and commercial tablet formulations exclusive of separation and applied without any difficulty for the regular determinations. The method is also simple, rapid and economical method which gives reproducible results on the instrument used. The reported method is an economical method in which only Methanol is used as the solvent and does not require the use of costly reagents. This proposed method is competent of being used for the quantification of Cefpodoxime Proxetil in bulk and tablet dose forms devoid of the interfering of additives with a significant and comparative correctness and exactness with the reported methods. This newly developed method has the advantages over the previously reported methods because, present methods is economical.

The percentage standard deviation values show that the proposed method provides acceptable variation of Cefpodoxime Proxetil. The standard deviation percentages of proposed technique is within the acceptable limits for Cefpodoxime Proxetil shows the competence of the technique to stay unchanged by minute and purposeful changes in the system restraints and assures its consistency in regular routine application.

Conclusion

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

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