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Simultaneous UV Spectroscopic Estimation of Cefpodoxime Proxetil and Clavulanic Acid In Tablet

S. Malathi*
PSG college of Pharmacy, Department of Pharmaceutical analysis, Coimbatore-641004

ABSTRACT

Simple, rapid, accurate and economical method has been developed for the simultaneous Estimation of cefpodoxime proxetil and Clavulanic acid in a synthetic mixture. The linearity was observed in the concentration range of 35 to 63 µg/ml for cefpodoxime proxetil and 10 to 18 µg/ml for Clavulanic acid. The method is based on the simultaneous equations, absorbance of both the drugs were determined at 232 nm (λ max of cefpodoxime proxetil), and at 269 nm (λ max of Clavulanic acid). The method was validated in terms of accuracy and precision. The Proposed method was found accurate, reproducible and economical for the routine analysis of both the drugs in synthetic mixture.

Keywords: Cefpodoxime Proxetil, Clavulanic acid, UV spectroscopic analysis, Simultaneous Equation.

*Corresponding Author Email: malathisanju@gmail.com
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INTRODUCTION

Cefpodoxime Proxetil (CEF) is a beta lactamase class of bactericidal drug, (Figure.1A) chemically is iso propoxy carbonyl oxy ethyl (f)-(6R, 7R)-7(2 amino 4 thiadyl)-2-2(z) methyl 1 amino)Acetonide)-3 methoxy methyl – 8 – oxo 5 thia -1-azabicyco oct2- one 2-0- carboxyl ate).It is a third generation cephalosporin antibiotic having activity against gram positive and gram negative microorganisms. Clavulanic acid (CLA)is an antibacterial drug, (Figure.1B)chemically is (2-R-(2α-3Z,5α)-3-(2-Hydroxyethylidine)-7-oxo-azabicylo(3.2.0) heptanes-2-carboxylic acid (Figure.1 B).It is used as a beta lactamase inhibitor, enhances the activity of penicillin and cephalosporin antibacterial against many resistant strains of bacteria.(1-2) Many methods have been described in the literature for the determination of cefpodoxime proxetil and Clavulanic acid individually and in combination with other drugs (3-8). However, the present work aims to develop the simultaneous estimation of these drugs in combined dosage form by UV spectroscopic method.

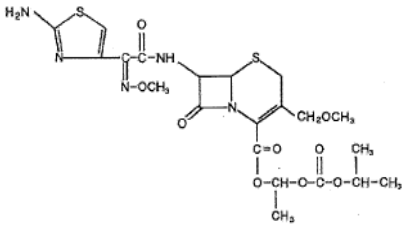

Figure 1(A): Structure of Cefpodoxime Proxetil

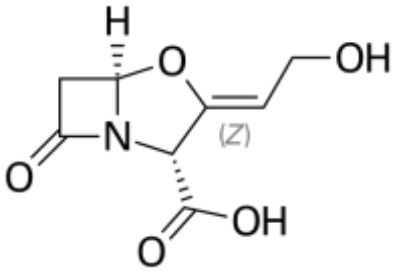

Figure 1(B): Structure of Clavulanic acid

MATERIALS AND METHODS

Procurement of drug samples and formulation

Cefpodoxime proxetil was obtained from aurobindo pharm. Ltd, Hyderabad. Clavulanic acid was obtained from Cadila pharmaceutical ltd, Ahmedabad.

Reagents and chemicals used

Doubled distilled water used throughout the study. Chemicals were purchased from S.D fine chemicals Mumbai.

Instruments used

Elico model SL-164 double beam UV/VIS spectrophotometer with a pair of 10mm matched quartz cells was used to measure absorbance of the resulting solutions.

EXPERIMENTAL

Selection of solvent and wavelength

Standard CLA and CEF stock solution of 10 µg and 35 µg /ml concentration was prepared in ethanol respectively. The standard stock solution of CLA and CEF were scanned in the range of 200 nm to 400 nm against ethanol as a blank. Maximum absorbance was obtained at 232 nm and 269 nm for CEF and CLA respectively. The overlain spectra of CEF and CLA were shown in Figure.2. Absorbance of each solution was measured at both the wavelength 232 nm and 269 nm.

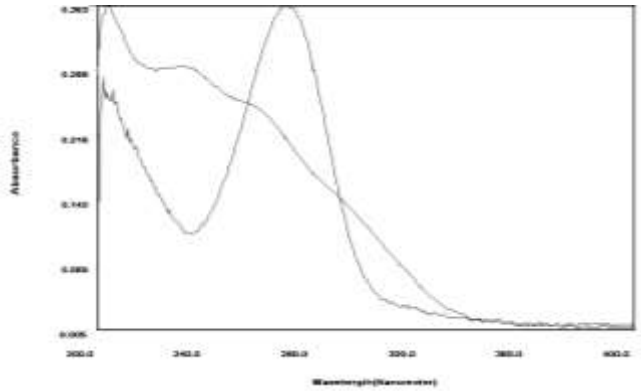

Figure 2: Overlain spectra of Cefpodoxime Proxetil and Clavulanic acid

Analysis of formulation

Calibration curves were constructed for CEF and CLA by plotting absorbance verses concentration at both the wavelengths. A calibration curve was plotted over a concentration range of 35 to 63 µg /ml for cefpodoxime proxetil and 10 to18 µg/ml for Clavulanic acid. The synthetic mixture of CLA and CEF was prepared in the ratio of 1:3.5.CEF and CLA tablet (100 mg and 28.5 mg each) were weighed and quantity equivalent to 10 mg of Clavulanic acid and 35 mg of cefpodoxime proxetil were dissolved in ethanol. Shake it for 20 minutes and make up to the mark by using same. The solution was filtered and further diluted to get concentration 10 µg /ml and 35 µg /ml of Clavulanic acid and cefpodoxime proxetil respectively. The absorbance of final sample solution was measured against ethanol as a blank at 232 nm and 269 nm. In the simultaneous equation method concentration of CEF and CLA in the synthetic mixture found out by using simultaneous equations method.

$$C\ x = A_2ay_1 - A_1ay_2 \,/\, ax_2ay_1 - ax_1ay_2$$

$$C\ y = A_1ax_2\text{-}A_2ax_1 / ax_2ay_1\text{-}ax_1ay_2$$

Where Cx, C_Y = concentration of CLA and CEF in the sample solution.A_1, A_2 = Absorbance of the Sample solution at 232 nm and 269 nm respectively. ax_1, ax_2 = absorptivities of CLA at 232,269 nm respectively.ay_1, ay_2= absorptivities of CEF at 232,269 nm respectively. The proposed validated method was successfully applied to determine CLA and CEF in the synthetic mixture. (Table.1).The % recoveries for CEF and CLA obtained were 99.70, 101.59 by simultaneous Equation method. No interference of the excipients with the absorbance appeared. Hence the Proposed method is applicable for the quantitative determination of CEF and CLA in synthetic mixture.

RESULTS AND DISCUSSION

The analytical method was validated with respect to parameter according to ICH guidelines (9, 10) such as Linearity, Precision, accuracy and stability.

Linearity and range

Preparation of calibration curve and linearity studies

CEF was found to be linear at the concentration range of 35-63 µg/ml. Individual standard solutions were scanned using ethanol as blank. The absorbance of this solution was noted at the wavelength 232 nm and 269 nm and calibration curve were plotted using concentration Vs absorbance, the calibration graph was shown in Figure.3, 4. CLA was found to be linear at the concentration range of 10-18 µg/ml. The absorbance of this solution was noted at the wavelength 232 nm and 269 nm and calibration curve were plotted using concentration Vs absorbance, the calibration graph was shown in Figure.5, 6. The values are shown in Table 1 and 2.

Table 1: Absorbance of cefpodoxime Proxetil at selected wavelength

S. No	Concentration 269nm(µg/ml)	Absorbance at 232nm	Absorbance at
1	35	1.248	0.927
2	42	1.489	1.098
3	49	1.744	1.286
4	56	2.011	1.457
5	63	2.282	1.684

Table 2: Absorbance of Clavulanic acid at selected wavelength

S. No	Concentration (µg/ml)	Absorbance at 232nm	Absorbance at 269nm
1	10	0.135	0.272
2	12	0.165	0.383
3	14	0.214	0.525
4	16	0.249	0.638

5	18	0.296	0.748

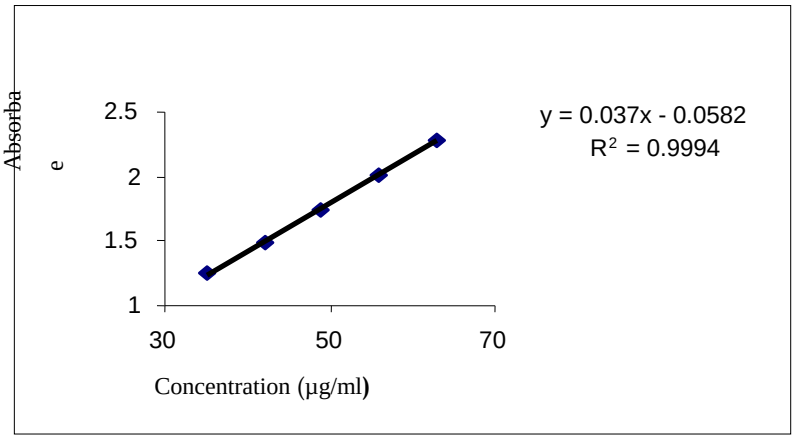

Figure 3: Calibration graph of Cefpodoxime Proxetil at 232nm

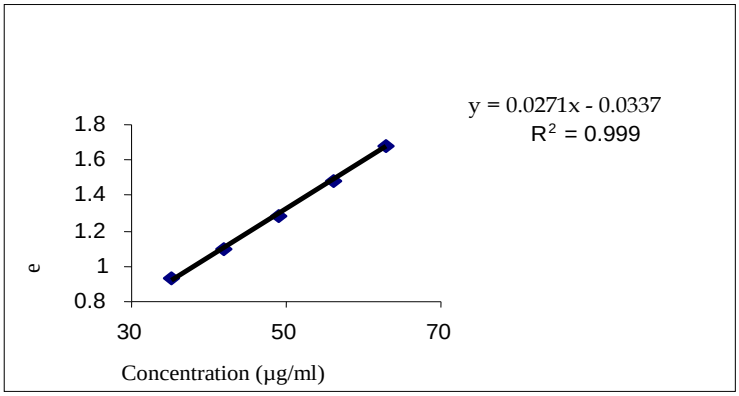

Figure 4: Calibration graph of Cefpodoxime Proxetil 269nm

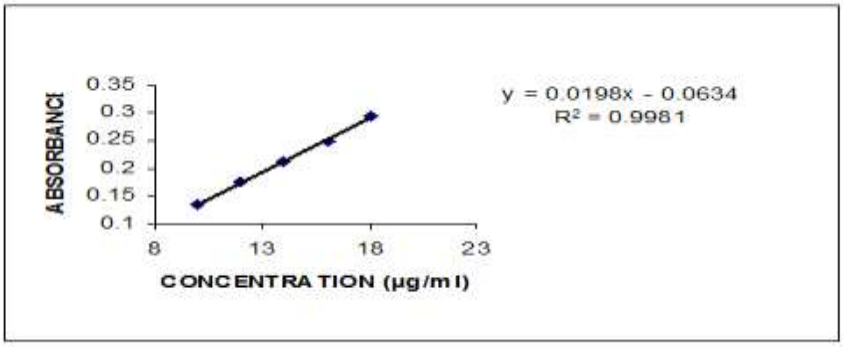

Figure 5: Calibration graph of Clavulanic acid at 232nm

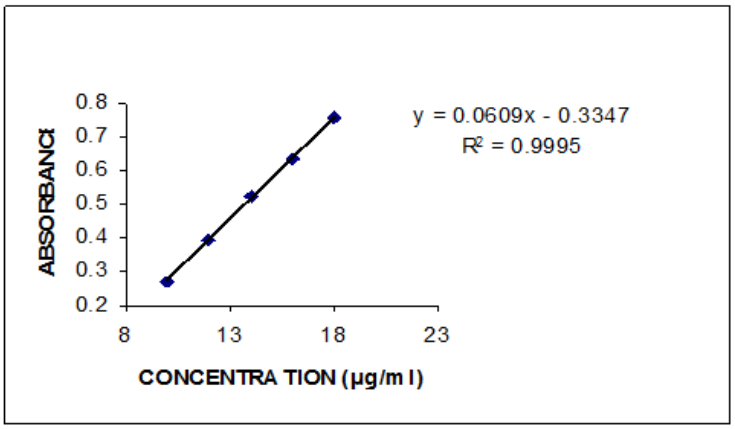

Figure 6: Calibration graph of Clavulanic acid 269nm

PRECISION

Precision of the method was demonstrated by, 1.Intraday precision 2.Interday precision

Intraday precision

Intraday precision was found out by carrying out analysis of standard drug solution at three different concentrations in the linearity range for three times on the same day and % RSD was calculated.

Interday precision

Interday precision was found out by carrying out analysis of standard drug solution at three different concentrations in the linearity range for three day over a period of one week and % RSD was calculated.

Accuracy

The results of recovery studies at various levels shows that the recovery is between 99.0 to 102.0 % (Ideally should be between 98-102 %). It indicates that there is no interference in the analysis of the drug from the excipients in the tablet formulation. The results of recovery studies of the marketed formulation are shown in the following Table 3.

Table 3: Recovery studies

S.No	Level	%Recovery		%RSD	
		CEF	CLA	CEF	CLA
1	50	98.85	99.70	0.109	0.170
2	100	99.70	101.59	0.103	0.424

***RSD of five observations**

Stability

The sample solution was subjected to stability studies under room condition. Stability was studied looking for any change in absorbance and peak shape when compared to UV spectra of

freshly prepared solution. The solution store under room temperature was stable upto 3 hours.

Assay

The tablets were analysed and the results were obtained in the range of 96-99.6 % compared to the label claim. The results of analysis of marketed formulation are shown in Table 4.

Table 4: Analysis of formulation

S.No	Drug	Amount(mg)	%Label claim		%RSD
			Labelled	Found	
1	CEF	100	98.8	98.8	0.212
2	CLA	28.5	29.0	101.11	0.918

RSD of five observation

CONCLUSION

Thus the method developed in the present investigation is simple, sensitive and not time consuming. This method is novel and can be employed for routine analysis in quality control analysis. The described method is giving accurate and precise results for the determination of CEF and CLA in mixture in marketed formulation.

ACKNOWLEDGEMENT

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