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Validated AUC Method for the Spectrophotometric Estimation of Cefadroxil in Bulk and Tablet Dosage Form

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ABSTRACT

A new and simple Area under curve spectroscopic method was developed and validated for the estimation of Cefadroxil in bulk and pharmaceutical dosage form and Area under curve was measured at 257-267nm in 0.1N Hydrochloric acid. The linearity was found to be in the concentration range of 2-10 µg/ml and the correlation coefficient was found to be 0.9997 and it has showed good linearity, reproducibility, precision in this concentration range. The regression equation was found to be Y=0.0342X +0.0008. The % recovery values were found to be within the 99.79-100.9% and showed that the method was accurate. The LOD and LOQ were found to be 0.085 and 0.255 µg/ml, respectively. The % RSD values were less than 2. The present method is to accomplish the validation parameters according to ICH guidelines. The developed method was successfully applied for the quantitative estimation of Cefadroxil in bulk and pharmaceutical dosage forms.

Key words: Cefadroxil, Area under curve Spectroscopy, validation, pharmaceutical formulations.

INTRODUCTION

Cefadroxil is a semi-synthetic first generation oral cephalosporin drug effective against gram-positive and gram-negative bacterial infections and similar to cephalexin and cephradine in structure and spectrum of antibacterial activity. [1] It is used in the treatment of mild to moderate infections of the respiratory and urinary tracts, skin and soft tissue infections. It has been used in the prophylaxis of recurrent urinary tract infections in children. The chemical name of Cefadroxil is (6R,7R)-7-[(2R)-2-(4-hydrophenyl) acetamido]-3-methyl-8-OXO-5-thia-1-[4.2.0] oct-2-ene-2-carboxylic acid hydrate. It has a molecular formula $C_{16}H_{17}N_3O_5S$ and molecular weight of 363.38g/mol. Cefadroxil is freely soluble in water and methanol. [2]

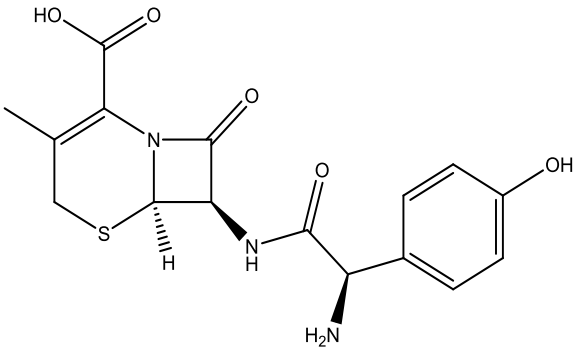

Fig.1: Chemical structure of Cefadroxil

Literature survey revealed that there were some analytical methods have been reported for the estimation of Cefadroxil in pure drug and pharmaceutical dosage forms by using UV spectrophotometric, [3-8] HPLC, [9-14] and HPTLC [15-16] so far

The aim of present work is to develop and validate a novel, simple, rapid, precise and specific Area under curve spectrophotometric method for the estimation of Cefadroxil in bulk and tablet dosage form.

MATERIALS AND METHOD

Instrument:

UV-Visible double beam spectrophotometer, SHIMADZU (model UV -1800) with UV probe software. All weights were taken on analytical balance.

Chemicals:

Cefadroxil pure form was obtained as a gifted sample from Microlabs pharma industry located at Bommasandra, jigani link road, Bangalore and its pharmaceutical dosage form Cefadrox 10 Tablets labelled claim 500mg. Manufactured by Aristo Pharmaceuticals Pvt Ltd, Baddi at Mumbai. Batch no: B712K117procure from local pharmacy Mandya.

0.1N Hydrochloric acid available in the laboratory of Bharathi College of pharmacy, bharathinagara.

Solvent:

0.1N Hydrochloric acid (prepared by dissolving 8.2gm in 1000ml of distilled water).

Selection of Analytical Wavelength:

Appropriate dilutions were prepared for Cefadroxil from the standard stock solution and the solution was scanned in the wavelength range of 200-400nm. The absorption spectra thus obtained were derivatised from Area under curve method.The absorbance was taken in the range of 257 nm-267 nm at 262 nm. (Fig-2).

Preparation of standard stock solution:

100mg of Cefadroxil was accurately weighed and transferred into 100ml volumetric flask and diluted with 0.1N Hydrochloric acid up to the mark. From this solution pipette out 10ml into 100ml volumetric flask and diluted with 0.1N Hydrochloric acid up to the mark, from this solution pipette out 0.2,0.4,0.6,0.8, and 1.0ml into 10ml individual volumetric flask and add 0.1N Hydrochloric acid up to the mark, this gives 2,4,6,8 and 10µg/ml concentrations.

Preparation of sample solution:

20 tablets of Cefadroxil marketed formulations were weighed and powdered. The tablet powder is equivalent to 100mg of Cefadroxil was transferred into 100ml volumetric flask then it was diluted with 0.1N Hydrochloric acid and made up to mark.From this solution pipette out 10ml into a 100ml volumetric flask and make up to the mark with 0.1N Hydrochloric acid.

Method and validation:

The method was validated according to the various parameters of ICH guidelines. [17]

RESULTS AND DISCUSSION

Method: Area under curve (AUC) method.

Linearity:

The linearity of an analytical method is its capacity to show the test results that are directly proportional to the concentration of the analyte in the sample within the range. The linearity was established in the concentration range of 2-10µg/ml was measured between 257-267nm and absorbance values are shown in table-1. The calibration curve was prepared by plotting graph against the concentration and absorbance and the graph shown in Fig-3. Statistical parameters like slope, intercept, regression equation, correlation coefficient and Sandell's sensitivity were determined. (Table-2).

Precision:

The precision of an analytical method expresses the closeness of a series of individual analyte measurements obtained from multiple sampling of the sample. Precision was determined by intra-day and inter-day study. Intra-day precision was determined by analysing the2,4,6,8 and 10µg/ml concentration for three times in a same day. Inter-day precision was determined by analysing the same concentration daily for three different days. (Table-3).

Accuracy:

The accuracy of an analytical method describes that closeness of test results obtained by that method to the true value. To assess the accuracy of the developed method, recovery studies were carried out at three different levels as 80%, 100% and 120%. In which the formulation concentration was kept constant and varied pure drug concentration. (Table-4).

Ruggedness:

It is defined as the reproducibility of the results when the method is performed under the variant conditions. This includes different analysts, laboratories, instruments, temperature etc. Ruggedness was determined between two different analysts. The value of %RSD was found to be less than 2 were shown in (Table-5).

Limit of Detection and Limit of Quantification:

Limit of detection is an individual analytical method in which the smallest amount of analyte in a sample can be reliably detected by the analytical method. Limit of quantification is an individual analytical procedure in which the smallest amount of analyte in a sample can be quantitatively determined. The LOD and LOQ were calculated by using the following formula.

LOD = 3.3(SD)/S and LOQ = 3(LOD)

LOD and LOQ value of Cefadroxil were found to be 0.085 and 0.255 µg/ml

Tables:

Table 1: Results of calibration curve at 257-267nm by Area under curve.

SL NO	Concentration (µg/ml)	Absorbance ±Standard deviation**
1	0	0
2	2	0.072 ±0.0021
3	4	0.137±0.0044
4	6	0.204±0.0036
5	8	0.272±0.0030
6	10	0.345±0.0046

**Average of six determination

Table.2: Regression parameters for Cefadroxil by Area under curve method.

Regression Parameters	Cefadroxil
Range	2-10
AUC wave lengths	257-267
Regression Equation	Y=0.0342x+0.0008
Slope(b)	0.0342
Intercept(a)	0.0008
Correlation Coeffcient$(R)^2$	0.9997
Sandell's Sensitivity	0.029
Limit of detection(µg/ml)	0.085
Limit of quantitation(µg/ml)	0.255

Table.3: Determination of precision results for Cefadroxil at 257-267nm by Area under curve.

C Concentration (µg/ml)	In Intra-day Absorbance ±Standard deviation	%RSD**	Intra-day Absorbance ±Standard Deviation	%RSD**
2	0.068±0.0011	1.644	0.073±0.0011	1.521
4	0.129±0.0019	1.488	0.139±0.0025	1.860
6	0.197±0.0025	1.312	0.207±0.0014	0.714
8	0.266±0.0030	1.139	0.274±0.0022	0.816
10	0.336±0.0039	1.171	0.348±0.0022	0.658

**Average of three determinations **percentage relative standard deviation.

Table.4: Determination of Accuracy results for Cefadroxil at 257-267nm by Area under curve.

Spiked Levels	Amount of Sample(mg	Amount of Standard (µg/ml)	Amount Recovered	%Recovery ±Standard Deviation*	%RSD*
80	5	4	9.02	100.3 ±0.555	0.553
100	5	5	9.97	99.79 ±0.604	0.605
120	5	6	11.1	100.9 ±0.341	0.337

*Average of three determinations, **percentage relative standard deviation.

Table 5: Determination of Ruggedness results for Cefadroxil at 257-267nm by Area under curve.

Analysts	Analyst-1	Analyst-2
Mean Absorbance	0.203	0.207
±Standard deviation*	0.001247	0.001247
%RSD**	0.612	0.601

*Average of three determinations, **percentage relative standard deviation.

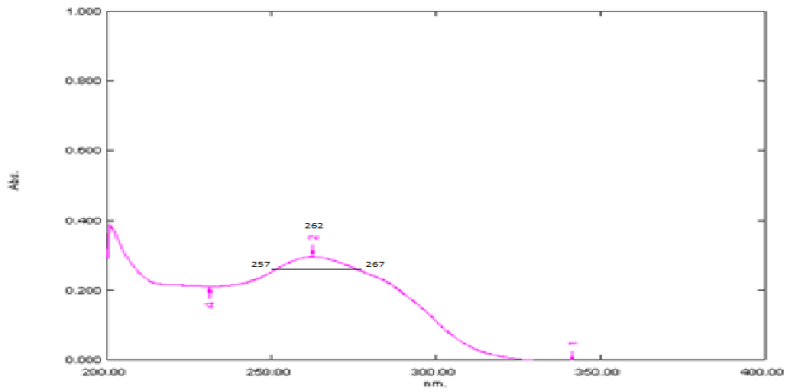

Fig 2: Typical Zero order spectra of Cefadroxil showing Area under curve (AUC) from 257nm to 267nm.

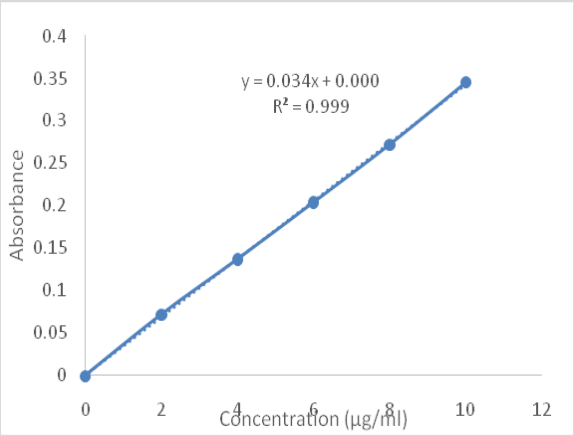

Fig 3: Calibration curve of Cefadroxil by Area under curve method

CONCLUSION

The present analytical method was validated as per the ICH guidelines and met the acceptance criteria. It was concluded that the developed analytical method was simple, accurate, economical, specific and sensitive and can be applied for the routine analysis of Cefadroxil in bulk drug and its pharmaceutical dosage forms.

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