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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CEFADROXIL IN PHARMACEUTICAL DOSAGE FORM BY USING UV-SPECTROSCOPY

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ABSTRACT

The aim of the present work is to develop a simple accurate, precise and cost effective UV- spectrophotometric method for the estimation of cefadroxil, a first generation cephalosporin an anti-biotic drug in bulk and pharmaceutical dosage form. The solvent used were aqueous solution of sodium bicarbonate (0.75M) and the λ max or the absorption maxima of the drug was found to be 263nm. The method obeys Beers law in the concentration range of 10-50µg/ml respectively. The accuracy of the method was assessed by recovery studies and was found between 99.28 % - 100.05 %. The method was successfully applied for routine analysis of this drug in formulations.

Key Words:- Cefadroxil, Sodium bicarbonate, Beers law.

INTRODUCTION

Cefadroxil is a first generation semi synthetic cephalosporin antibiotic. Cephalosphorin are derivatives of 7-aminocephalosphoric acid and are closely related to penicillin in structure. Cephalosporins have six membered sulfur containing ring adjoining a lactam ring. Cefadroxil is very active against gram positive cocci. Antibiotics require constant drug level in body for therapeutic effect. This is achieved by taking the medication at regular interval of time throughout the day and night as prescribed. Cefadroxil is important to take the drug for the full time period as prescribed. If you discontinue the therapy, it may result in ineffective treatment (Anonymous1). According to literature survey, it revealed that cefadroxil was quantitatively assayed by using liquid chromatography, UV-Visible spectroscopy however no UV-Spectrophotometry method was proposed for the estimation of cefadroxil by using of Sodium bicarbonate (0.75M) as a solvent in Tablet dosage forms. In the present study to develop a simple, accurate and precise UV spectroscopic method for estimation of cefadroxil in tablet dosage form. The validation carried out as per ICH guidelines (Patel Satish A *et al*., 2011; Sharif S *et al*., 2010; Patel C *et al*., 2010; Espinosa Boscha M *et al*., 2008; Ravi SS *et al*., 2008; Kareti Srinivasa R *et al*., 2012; Chilukuri SPS *et al*., 2010; Suddhasattya D *et al*., 2012)

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MATERIALS AND METHODS

Apparatus

A Systronics double beam UV visible spectrophotometer model 2202, band width of 2nm wavelength accuracy ±0.5nm and two matched quartz cells with 1cm path length was used for all spectral measurements.

Materials

All the chemicals used were of analytical grade. A gift sample of cefadroxil obtained from Merit Organics Ltd, Mumbai, was used as working standard. The formulation of cefadroxil tablet was purchased from retail shop.

Solubility test

Solubility test for the drug Cefadroxil was performed by using various solvents. The solvents include Water, Methanol, Ethanol, Acetonitrile, Hydrochloric Acid (HCl), Sodium Hydroxide (NaOH), Sodium bicarbonate and Chloroform.

DETERMINATION OF λ MAX

Preparation of stock solution

Standard stock solution of Cefadroxil was prepared by dissolving 100mg of Cefadroxil in 100ml aqueous solution of Sodium bicarbonate (0.75M) which gives 1000µg/ml. One ml of this stock solution was taken and was diluted up to 10ml by using Sodium bicarbonate (0.75M) to produce a concentration of 100 µg/ml solution.

Preparation of working solution

From the above stock solution 2ml was transferred into 10ml volumetric flask and volume was made up to the mark with aqueous solution of sodium bicarbonate (0.75M) to make 20µg/ml. Then the sample was scanned with UV-Vis Spectrophotometer in the range 200-400nm against Sodium bicarbonate (0.75M) as blank and the wavelength corresponding to maximum absorbance was noted which is its λ-max i.e. at 263nm.

Preparation of calibration curve

One ml of this 100µg/ml solution was further diluted and the volume was made up to 10ml by using method to produce 10µg/ml solution. 2ml, 3ml, 4ml and 5ml of 100µg/ml solution were diluted and the volume was made up to 10ml using Sodium bicarbonate (0.75M) to produce 20µg/ml, 30µg/ml, 40µg/ml, 50µg/ml solutions respectively. Then the construction of calibration curve was done by taking the above prepared solutions of different concentration ranging from 10- 50µg/ml. Then taking the absorbance, calibration curve was plotted taking concentration on x-axis and absorbance on y-axis which showed a straight line. This straight line obeyed linearity in the concentration range of 10-50µg/ml. The correlation coefficient was found to be 0.9999.

Assay of Cefadroxil tablet (ODOXIL500mg)

A quantity of powder equivalent to 50mg of cefadroxil was taken in a 50ml volumetric flask and it was dissolved and diluted up to the mark with Sodium bicarbonate (0.75M). The resultant solution was ultrasonicated for 5 minutes. The solution was then filtered using Whatmann filter paper No. 40. From the filtrate, appropriate dilutions were made in Sodium bicarbonate (0.75M) to obtain the desired concentration (50 µg/ml). This solution was then analyzed in UV and the result was indicated by % recovery given in table 1.

Method validation

Validation is a process of establishing documented evidence, which provides a high degree of assurance that a specific activity will consistently produce a desired result or product meeting its predetermined specifications and quality characteristics. The validation for UV method development was performed using parameters like Linearity, Accuracy, Precision, Robustness, and Ruggedness.

Linearity

Various aliquots were prepared from the secondary stock solution (100µg/ml) ranging from 10-50 µg/ml. The samples were scanned in UV-Vis Spectrophotometer against Sodium bicarbonate (0.75M) as blank. It was found that the selected drug shows linearity between the ranges of 10-50 µg/ml (table 1 & 2).

Accuracy

Solutions were prepared in triplicate at levels 80%, 100% and 120% of test concentration using cefadroxil working Standard as per the test method and taken absorbance of each solution in triplicate. The recovery results showed that the proposed method has an acceptable level of accuracy for cefadroxil which is from 80% - 120% of test concentration is form 99.28 % - 100.05 % (table 1).

Precision

Precision of the method was demonstrated by six different solutions of same concentration 20µg/ml were analyzed. From the absorbance result mean, standard deviation and %RSD was calculated and given in table 1.

Specificity

Got spectrum in the range of 200nm to 400nm for appropriate concentration of sample, blank, placebo.

Ruggedness

Ruggedness of the method was determined by carrying out the analysis by different analyst and the respective absorbance of 20µg/ml was noted. The result was indicated as %RSD and given in (table 3).

Table 1. Summary of validation

Parameter	Results
Linearity indicated by correlation coefficient	0.9999
Precision indicated by % RSD	0.26%
Accuracy indicated by % recovery	99.9044%
Specificity	No interferences of impurity
Range	10µg-50µg/ml
Linear regression equation	0.0338x-0.0069
Assay indicated by % recovery	99.98%

Table 2. Optical characteristics

Beer's law limit(µg/ml)	10-50µg/ml
Correlation coefficient	0.9999
Regression equation(Y*)	0.0338x-0.0069
Slope	0.338
Intercept	0.0069

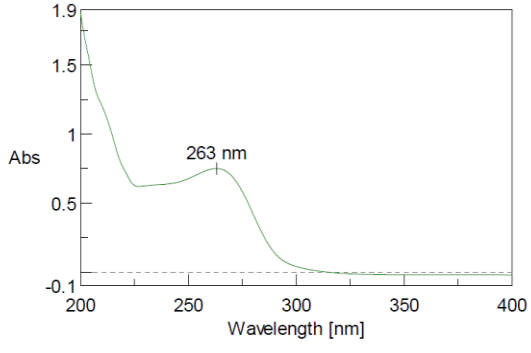
Table 3. Ruggedness

Analyst 1			Analyst 2		
Concentration (µg/ml)	**Absorbance**	**Statistical analysis**	**Concentration (µg/ml)**	**Absorbance**	**Statistical analysis**
20	0.661	Mean=0.661	20	0.661	Mean=0.6617
20	0.661		20	0.661	
20	0.660	SD=0.0011	20	0.662	SD=0.0008
20	0.663		20	0.662	
20	0.660	%RSD=0.16	20	0.663	%RSD=0.12
20	0.661		20	0.661	

Table 4. Robustness

λ-max 261nm			λ-max 265nm		
Concentration (µg/ml)	**Absorbance**	**Statistical analysis**	**Concentration (µg/ml)**	**Absorbance**	**Statistical analysis**
20	0.661	Mean=0.6598	20	0.661	Mean=0.6608
20	0.661		20	0.663	
20	0.660	SD=0.0012	20	0.661	SD=0.0013
20	0.658		20	0.659	
20	0.659	%RSD=0.17	20	0.661	%RSD=0.20
20	0.660		20	0.660	

Fig 1. λmax of cefadroxil



Robustness

Robustness of the method was determined by carrying out the analysis under different λ-max i.e. at 261nm and 265nm. The respective absorbance of 20µg/ml was noted and the result was indicated as %RSD and given in (table 4).

RESULTS AND DISCUSSION

The drug was analyzed at 263nm in sodium bicarbonate (0.75M) using UV-Visible spectrophotometer. Optical characteristics such as Beer's law limits, intercept and slope has been calculated using regression equation, which has been presented in Table 2.

To ensure the accuracy method, recovery studies were performed by standard addition Method at 80%, 100% and 120% levels of drug concentration, to the pre-analyzed samples and percent recovery values were calculated. Recovery experiment indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

The linearity studies were performed by plotting different concentration of standard solution against their respective absorbances. Cefadroxil were found to be linear in the concentration range of 10- 50µg/ml. Correlation co-efficient value were found to be 0.999, calibration curve shows that it obeys Beer's law limit within the concentration range.

The proposed method was found to be simple, accurate, precise, simple, sensitive, robust and cost effective. The results of the validation tests were found to be satisfactory and therefore this method can be applied successfully for the estimation of Cefadroxil in Tablet dosage form.

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