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ESTIMATION AND DEGRADTION MONITORING 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 in the combination of water and methanol in the ratio of 75:25 and the λ max of the absorption maxima of the drug was found to be 224nm. The method obeys Beers law in the concentration range of 10-50µg/ml respectively. The developed method was subjected to stress degradation under different conditions as per ICH guidelines.

KEYWORDS

UV- spectrophotometric method, Cefadroxil, Water and Methanol.

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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. Cephalosporin's 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[1]. 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 Distilled water and Methanol (75:25) 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 aim of this work was to perform the stress degradation studies on the Cefadroxil using the proposed method [2-9].

EXPERIMENTAL WORK

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 Intra labs India Ltd, Bangalore, 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 10mg of Cefadroxil in 10ml of Distilled water and Methanol (75:25) which gives 1000 µg/ml. One ml of this stock solution was taken and was diluted up to 10ml by using Distilled water and Methanol (75:25) 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 methanol to make 20µg/ml. Then the sample was scanned with UV-Vis Spectrophotometer in the range 200-400nm against Distilled water and Methanol (75:25) as blank and the wavelength corresponding to maximum absorbance was noted which is its λ-max i.e. at 224nm (Figure No.1).

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 methanol 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 (Figure No.2).

Assay of Cefadroxil tablet (CAREDROX 500mg)

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 Distilled water and Methanol (75:25). 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 Distilled water and Methanol (75:25) to obtain the desired concentration (50µg/ml). This solution was then analyzed in UV and the result was indicated by % recovery given in Table No.1.

Degradation studies

The International Conference on Harmonization (ICH) guideline entitled stability testing of new drug substances and products requires that stress testing be carried out to elucidate the inherent stability characteristics of the active substance.

Hydrolytic degradation under acidic condition

To 2 ml of stock solution (1000 µg/ml) of Cefadroxil, 1 ml of 3 N HCl was added in 10 ml of volumetric flask and the volume was made up to the mark with Distilled water and Methanol (75:25). Then, the volumetric flask was kept at normal condition for 90 minutes. After 90 min. time interval, 1 ml of solution was pipetted out from this flask, neutralized and diluted with Distilled water and Methanol (75:25) in order to make the volume up to 10 ml and the dilution was carried out to achieve the appropriate concentration (20 µg/ml). This solution was taken in cuvette. For the blank, 0.5 ml solution of 3N HCl and 0.5 ml solution of 3N NaOH were diluted with methanol in 10 ml of volumetric flask was repeated (Table No.3 and Figure No.3).

Hydrolytic degradation under alkaline condition

To 2 ml of stock solution of Cefadroxil 1 ml of 0.1 N NaOH was added in 10 ml of volumetric flask and made up the volume to the mark with Distilled water and Methanol (75:25). Volumetric flask was kept at normal condition for 90 min. After 90 min time interval, 1 ml of solution was pipetted out from this flask, neutralized and diluted with Distilled water and Methanol (75:25) in order to make the volume up to 10 ml and the dilutions were carried out to achieve the appropriate concentration (20 µg/ml). The solution was then taken in cuvette. For the blank, 0.5 ml solution of 0.1N HCl and 0.5 ml solution of 0.1N NaOH diluted with methanol in 10 ml of volumetric flask (Table No.3 and Figure No.4).

Dry heat induced degradation

Cefadroxil sample was taken in a petriplate and exposed to a temperature of 70°c for 48 hours in an oven. After 48 hours, 10 mg of the sample was diluted with Distilled water and Methanol (75:25) in order to make the volume up to 10 ml. From this solution, dilutions were carried out to achieve the appropriate concentration (20µg/ml) and the solution was taken in cuvette for the UV-Vis Analysis (Table No.3 and Figure No.5).

Oxidative degradation

To 1.5 ml of the stock solution of Cefadroxil (1000 µg/ml), 1 ml of 30 % w/v of hydrogen peroxide added in 10 ml of volumetric flask and the volume was made up to the mark with Distilled water and Methanol (75:25). The volumetric flask was then kept at room temperature for 15 min. For the blank, 1 ml of the 30 % w/v of hydrogen peroxide was kept at normal condition for overnight in 10 ml of volumetric flask. Both solutions were heated on boiling water bath to remove the excess of hydrogen peroxide. Finally after 15 minutes dilutions were made from the stock solution to achieve the required concentration (30µg/ml). The solution was then taken in a cuvette and analyzed (Table No.3 and Figure No.6).

RESULTS AND DISCUSSION

The drug was analyzed at 224nm in Distilled water and Methanol (75:25) 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 No.2.

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 stress degradation studies showed that Cefadroxil undergoes degradation in acidic, oxidation and alkaline conditions whereas it is relatively stable when exposed to acidic conditions. Summary of the results of stress degradation studies of Cefadroxil are shown in the Table No.3.

Table No.1: Summary of Results

S.No	Parameter	Result
1	Linearity indicated by correlation coefficient	0.9999
2	Range	10µg-50µg/ml
3	Linear regression equation	y = 0.010x + 0.429
4	Assay indicated by % recovery	99.98%

Table No.2: Optical characteristics

S.No	Beer's law limit(µg/ml)	10-50µg/ml
1	Correlation coefficient	0.9999
2	Regression equation(Y*)	y = 0.010x + 0.429
3	Slope	0.010
4	Intercept	0.429

Table No.3: Degradation study by UV-Spectroscopy

S.No	Degradation Type	Duration	Report (% Degradation)
1	Acidic degradation	90-mins	6.25%
2	Alkali degradation	90-mins	λ Max shifted
3	Dry heat induced	48-hours	λ Max shifted
4	Oxidative degradation	15-mins	λ Max shifted

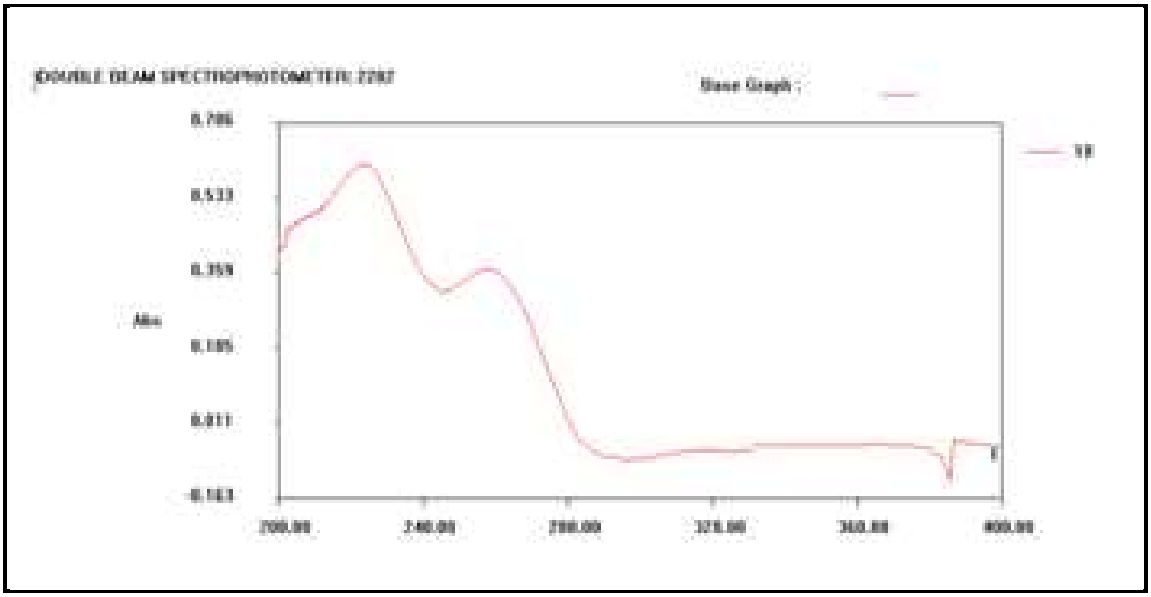

Figure No.1: 1-λmax of Cefadroxil

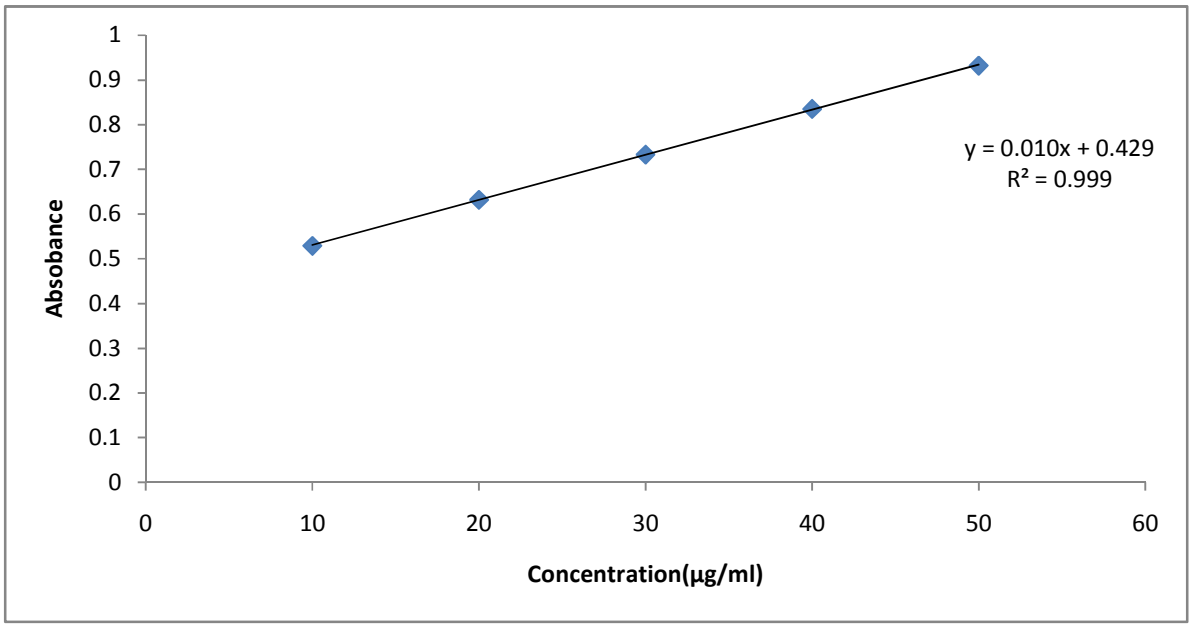

Figure No.2: Calibration graph of Cefadroxil

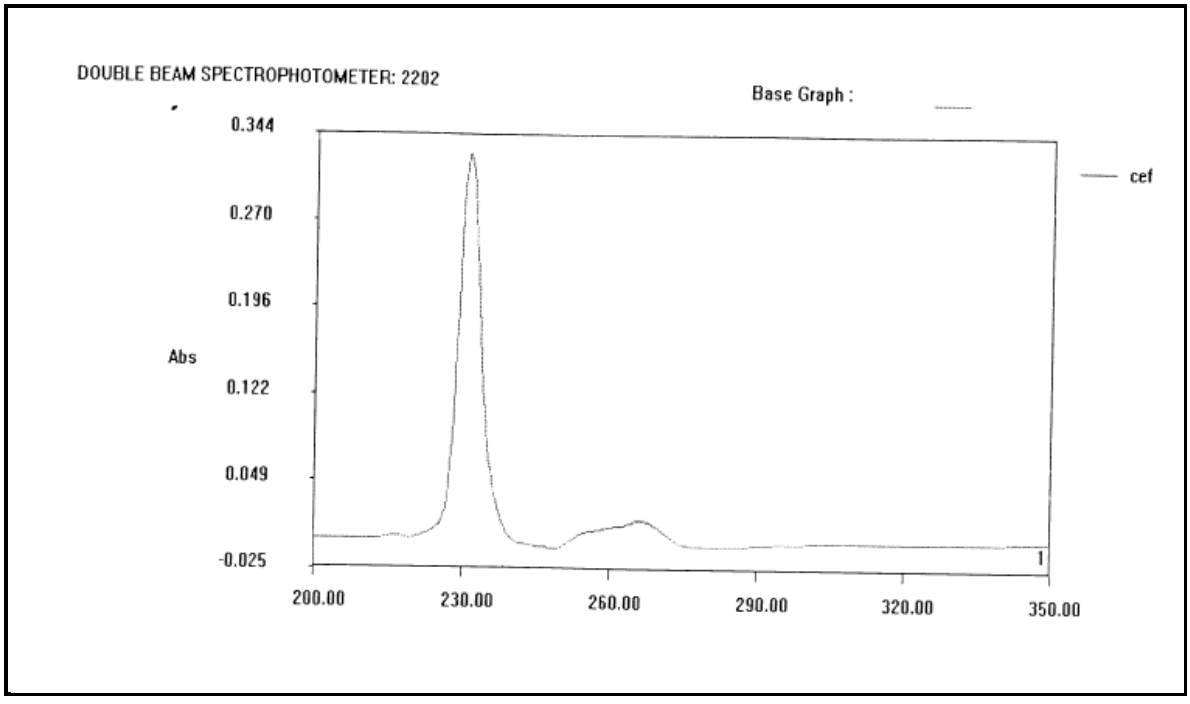

Figure No.3: Acid degradation of Cefadroxil

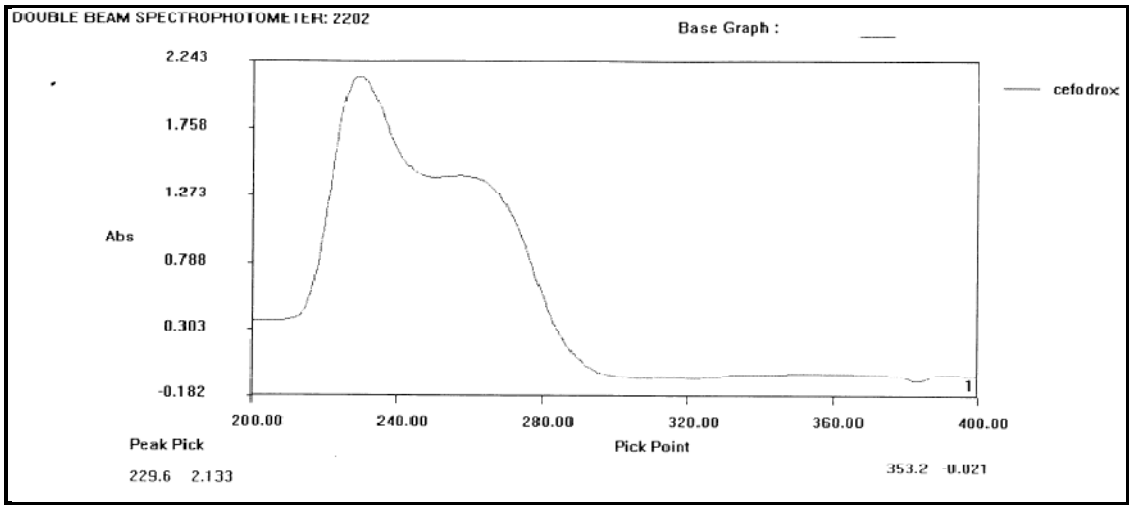

Figure No.4: Alkali degradation of Cefadroxil

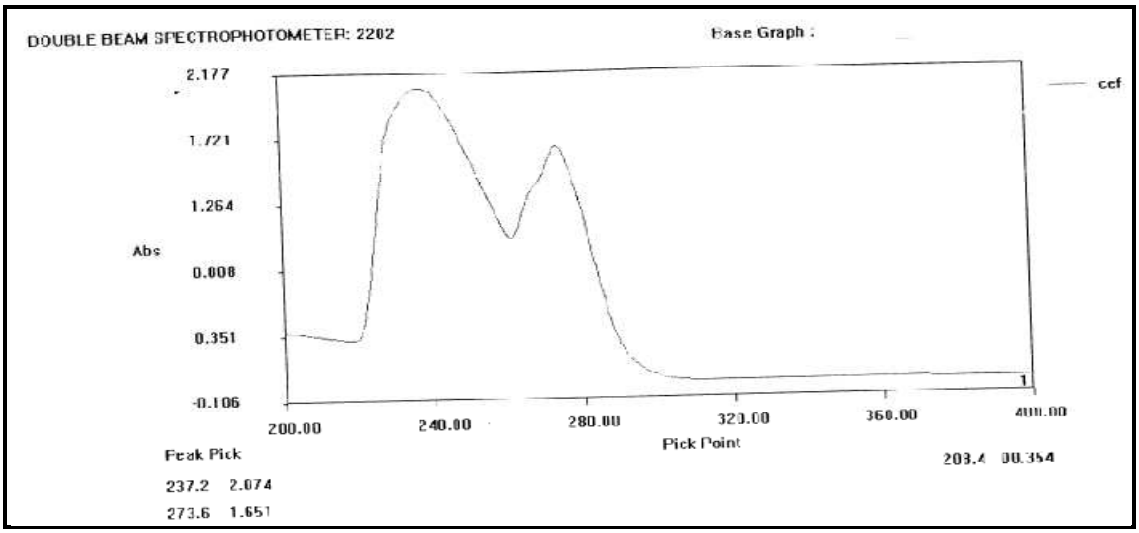

Figure No.5: Dry heat degradation of Cefadroxil

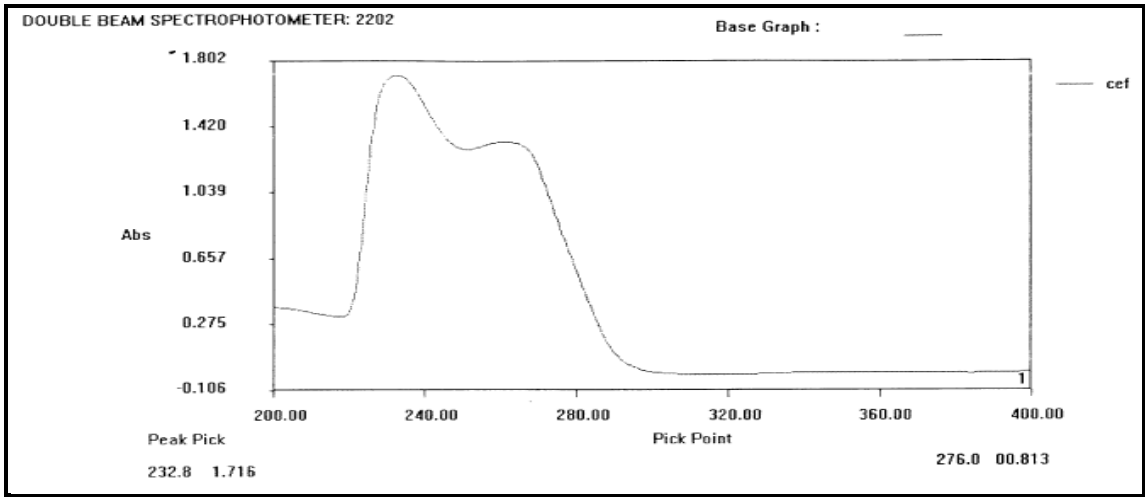

Figure No.6: Oxidative degradation of Cefadroxil

CONCLUSION

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. The proposed method is also useful for determination of cefadroxil stability in Sample of pharmaceutical dosage forms.

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