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New Analytical Method Development and Validation for the Estimation of Cefuroxime Axetil in Bulk and Pharmaceutical Tablet Dosage Forms by UV Spectrophotometry

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ABSTRACT

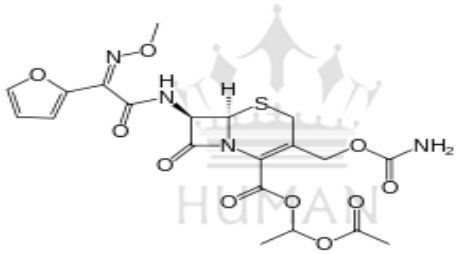
Objective: There is no analytical method yet reported for estimation of cefuroxime axetil using ethanol for the preparation of stock solution as a solvent and for further dilutions distilled water used as a solvent in single dosage form by UV spectroscopy. So, the present work is aimed to develop a simple, precise, accurate, and new spectrophotometric method in the UV- region for the estimation of Cefuroxime axetil in its tablet dosage form. Cefuroxime axetil exhibited maximum absorbance at 269.7 nm in ethanol-water. It obeys Beer's law in the concentration range of 9-50 µg/ml. **Method**: This can be analyzed by the single component analytical method by UV Spectrophotometer. Take 10 tablets of Cefuroxime axetil and weigh. An accurately weighed quantity of powder equivalent an about 100 mg of Cefuroxime axetil was transferred to a 100ml standard flask. The content of the flask was mixed with a little amount of Ethanol and shaken to dissolve the active ingredient and then made up to the volume 100 ml of ethanol to prepare the stock solution and further dilution was made with distilled water to give the concentration range from 9-50 µg/ml. Absorbance values of sample solution were recorded at 269.7nm **Results**: The relative standard deviations were ≤0.055%, with repeatability Values of 100.2% -102.0 % and recovery study values of 109.0 to 131.0% and these results were validated for its repeatability, recovery studies and validated statistically. **Conclusion**: The proposed method of analysis is novel, simple, accurate, and reproducible. This method can be routinely employed in the analysis of Cefuroxime axetil in tablet formulations precluding using ethanol and distilled water as a solvent.

INTRODUCTION:

Cefuroxime axetil is chemically (6R, 7R) – 3 – carbamoyloxymethyl – 7 - [(Z)-2-(2-furyl) – 2 - (methoxyimino) acetamido] – ceph – 3 - em-4- carboxylic acid. Cefuroxime is official in Indian pharmacopeia and the United States of Pharmacopoeia. It is the first of the series of alpha methoxyiminoacyl substituted cephalosporins that constitute most of the third generation agents available for clinical use. It is active against some *beta-lactamase* strains that are resistant to cefamandole[1,2]. The literature survey revealed that various methods of analysis for cefuroxime alone or in combination with other drugs have been reported, which included, HPLC[3–6], electrokinetic[7], HPTLC[8], and spectrophotometric methods.[9,11]

Accordingly, The objective of the present study is to develop an inexpensive, simple, precise, accurate, and new spectrometric method for estimation of Cefuroxime axetil in tablet dosage forms by ethanol and distilled water.

Figure no 1: It shows the structure of Cefuroxime axetil



MATERIALS AND METHODS:

Single pan electronic balance-Sartorius GE412, UV visible spectrophotometer, UV visible double beam spectrophotometer, Systronics2203 (smart), Matched quartz cells corresponding to 1 cm path length. Pure samples of Cefuroxime axetil were obtained from Alkem Pharmaceuticals Pvt Ltd., Mumbai, India. The solvent ethanol of analytical grade was purchased from Arun Pharmaceuticals Pvt Ltd., Kadapa, India.

Reagents: Ethanol and distilled water, Reference standard.

Procedure:

Preparation of standard stock solution:

A standard stock solution of Cefuroxime axetil was prepared by dissolving 100mg of the drug is dissolved in Ethanol and makeup with the same solvent and further diluted with Distilled water. Then the solution was further diluted to get the concentration of 9,10,20,30,40,50,60 µg/ml. The solutions were scanned in the UV region between 200-400nm. The absorbance values of the above sample solutions were recorded at 269.7 nm.

Beer's law concentration range

A standard stock solution of Cefuroxime axetil was prepared by dissolving 100mg of the drug is dissolved inethanol and makeup with the same solvent and further diluted with distilled water to get a concentration range from 1 to 1000 µg/ml. The solutions were scanned in the UV region between 200-400nm and their absorbance was measured at 269.7. Using the absorbance values against concentrations calibration curve was plotted and shown in Fig.6.From the graph, it was found that Cefuroxime axetil obeys Beer's law between 9-50 µg/ml. The data was given in Figures 2 and 3.

Analysis of formulation

Procedure

Weigh and powder 10 tablets. An accurately weighed quantity of powder equivalent to about 100 mg of Cefuroxime axetil was transferred to a 100ml standard flask. The content of the flask was mixed with a little amount of Ethanol and shaken to dissolve the active ingredient and then made up to the volume with solvent Ethanol and further dilution with Distilled water to give the concentration ranging from 9-50 µg/ml. Absorbance values of the sample solution were recorded at 269.7nm.

Validation of the method

The proposed method is validated for the following parameters.

Repeatability

Recovery

Repeatability testing:

Repeatability expresses the precision under the same operating conditions. It is also termed as intra assay precision. It is assessed by using a maximum of 9 determinations for each tablet containing the specified range for procedures (three concentrations/ three replicates each).

Recovery test: The accuracy, precision, suitability, and validity of the proposed method were satisfied by conducting recovery studies. They were carried out by adding a known quantity of the standard drug to the pre-analyzed sample and the contents reanalyzed by the proposed method.

Percentage recovery was calculated by the following formula:

$$\text{percentage recovery} = \frac{\text{Amount of drug found after the addition of standard drug} - \text{Amount of drug found before the addition of stand}}{\text{Amount of standard drug added}} \times 100$$

RESULTS AND DISCUSSION:

The UV spectra of Cefuroxime axetil were presented. The absorption maxima were obtained at 269.7 nm. and its obeyance to beer's law range was confirmed by the linearity of the calibration curve of the Cefuroxime axetil. Cefuroxime axetil showed a concentration range of 40-60 µg/ml.

Beer's law range

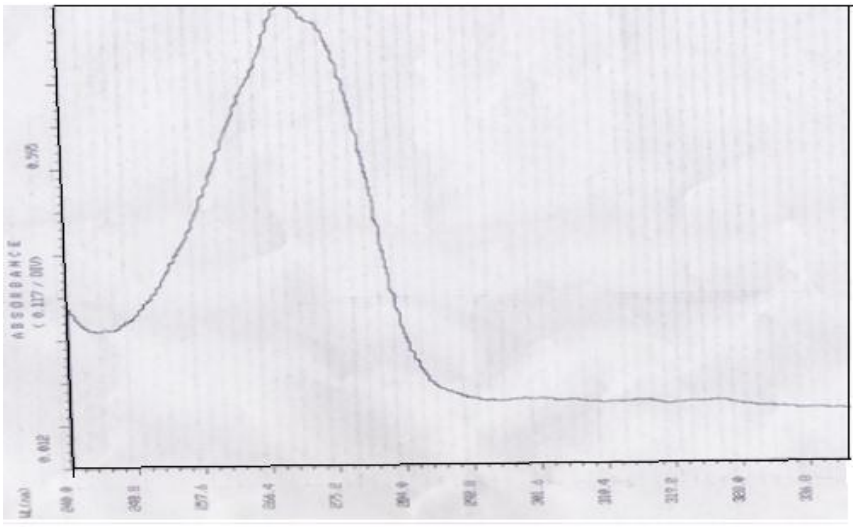


Figure No 2: It shows the Spectrum of cefuroxime axetil

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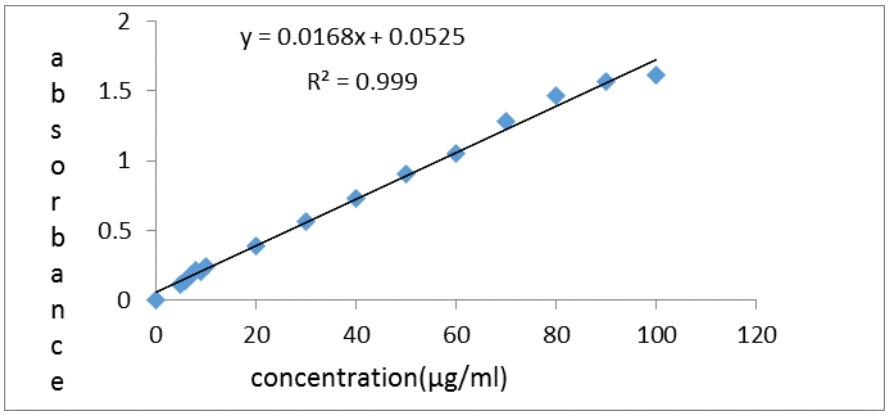

Figure No 3: It shows Absorbance Vs Concentration

❖ **Quantitative estimation of Cerom 500 mg tablets**

The quantitative estimation was carried out in capsule formulations by taking concentrations of 9-40 µg/ml. The brand of formulation shows the percentage purity values range from 100.8 to 102.0% w/w. The percentage deviation values were found to be between ±0.8 to ±2.0. The data was given in Table-1.

Table No 1: It shows a quantitative estimation of Cefuroxime axetil formulation

S. no	Concentration (µg/ml)	Label claim (mg)	Amount present (mg/ml)	Percentage Found (%w/v)	Percentage Deviation (%w/w)
1	50	100	101.7	101.7	±1.7
2	60	100	101.6	101.6	±1.6
3	70	100	101.9	101.9	±1.9
4	80	100	100.8	100.8	±0.8
5	90	100	101.2	101.2	±1.2

Table No 2: It shows statistical data of formulation

Drug Name	%Assay mean	Standard Deviation(S.D)	Relative Standard Deviation(R.S.D)
Cefuroxime axetil	101.5	0.012	0.0053

Repeatability:

The repeatability of the method was confirmed by the assay procedures with 3 different concentrations of 3 replicates each. The results obtained in the repeatability test expresses the precision of the given method. And the values were shown in Table 3**.**

Table No 3: It shows repeatability studies of formulation

S.no	Concentration (µg/ml)	Label claim (mg/tab	Amount present (mg/tab) (%w/w)	Percentage Label claim	Percentage Deviation
1	10	500	507.0	102.0	±2.0
2	10	500	507.0	101.2	±1.2
3	10	500	501.0	100.3	±1.3
4	20	500	502.9	100.7	±0.7
5	20	500	504.1	101.3	±1.3
6	20	500	505.2	101.7	±1.7
7	30	500	502.2	100.7	±0.7
8	30	500	504.3	101.4	±1.4
9	30	100	505.9	101.9	±1.9

Recovery:

The validation of the proposed method was further confirmed by recovery studies. The recovery data is given in table 4. The recovery values vary from 109.0 to 131.0% w/w. This serves as a good index of accuracy and reproducibility of the study.

Table No. 4: It shows recovery studies of formulation

S. no	Concentration	Amount Added	Amount Recovered	%Recovery	%Deviation
1	20	10	11.1	111.0	±1.0
2	20	10	11.0	110.0	±0.0
3	20	10	10.7	109.0	±1.0
4	30	20	23.7	118.9	±1.1
5	30	20	24.1	120.5	±0.5
6	30	20	23.6	118.0	±2.0
7	40	30	38.7	129.1	±0.9
8	40	30	38.8	129.6	±0.4
9	40	30	38.7	129.1	±0.9

CONCLUSION:

The proposed method of analysis is novel, simple, cost-effective, safe, accurate, and reproducible. This method can be routinely employed in the analysis of Cefuroxime axetil in tablet formulations precluding using ethanol and distilled water as solvents.

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