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Research Article

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Development and validation of analytical method for estimation of cefixime in bulk drug and pharmaceutical dosage form

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ABSTRACT

A new simple, specific, sensitive and cost effective UV-spectrophotometric method has been developed for the estimation of Cefixime in pharmaceutical dosage form.Wavelength selected for estimation of Cefixime was 290.60 nm. The developed method was validated statistically with respect to precision, accuracy, specificity, linearity and range. Linearity was studied over concentration range of 2-40 µg /ml and correlation coefficient was found to be 0.9997 for regression line. The method described can be successfully employed for assay of Cefixime in bulk drug and tablet dosage form.

Key words: Cefixime trihydrate , Spectrophotometric, Tablet dosage form, Validation.

INTRODUCTION

Cefixime is an third generation cephalosporin antibiotics. Chemically it is a 5-Thia-1- azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[(2 amino-4thiazolyl) {(carboxymethoxy) imino]acetyle}amino]3ethynyl-8-oxo-trihydrate[1-3]. Cefixime clinically used in the treatment of susceptible infections including gonorrhea, otitis media, pharyngitis, lower respiratory-tract infections such as bronchitis, and urinary tract infections[3-5]. It is soluble in methanol and 0.1M NaOH, insoluble water and 0.1M HCl.

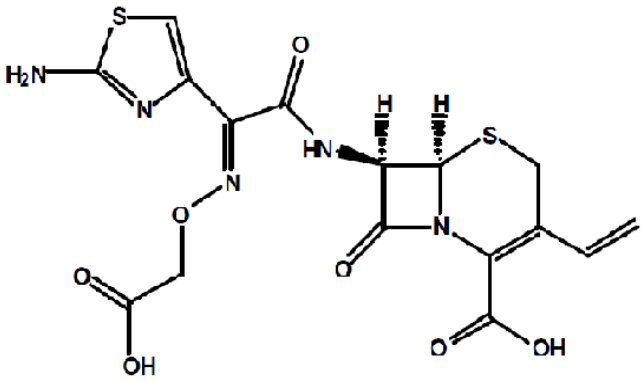

Figure 1: Chemical structure of Cefixime[6,7]

Extensive literature survey revealed that simultaneous estimation of Cefixime in combination with other drugs[3-7]. Estimation of this single drug has been reported in swab sample[8]. The present study was undertaken to develop and validate a simple, sensitive, accurate, precise, and reproducible UV spectrophotometric method for determination of Cefixime.

EXPERIMENTAL SECTION

Reagents and Chemicals-
Cefixime trihydrate was procured by Liben Pharma., Akola as gift sample and methanol was purchased from S.D. fine chemical ltd. India. The commercial formulation of Cefixime [(Ceftas)50mg/tablet] were purchased from the local market.

Equipments-
Shimadzu UV-1700 spectrophotometer with 1 cm match quartz cells were used for spectral mesurement connected to computer and loaded with UV Probe 2.33 software

Preparation of Standard Solution
An accurately weighed quantity of about 10 mg of pure Cefixime was taken in 10 ml volumetric flask, dissolved in methanol and volume was made upto the mark with same solvent to get concentration 1 mg/ml.

Determination of Absorption Maxima-
For selection of analytical wavelength, 10µg/ml solution of Cefixime was prepared by appropriate dilution of standard stock solution and scanned in the range of 400 nm to 200 nm. From the spectrum, wavelength selected for the analysis of Cefixime was 290.60 nm. The calibration curve was prepared in the concentration range 2-40 µg/ml by diluting suitable aliquots of standard stock solutions.

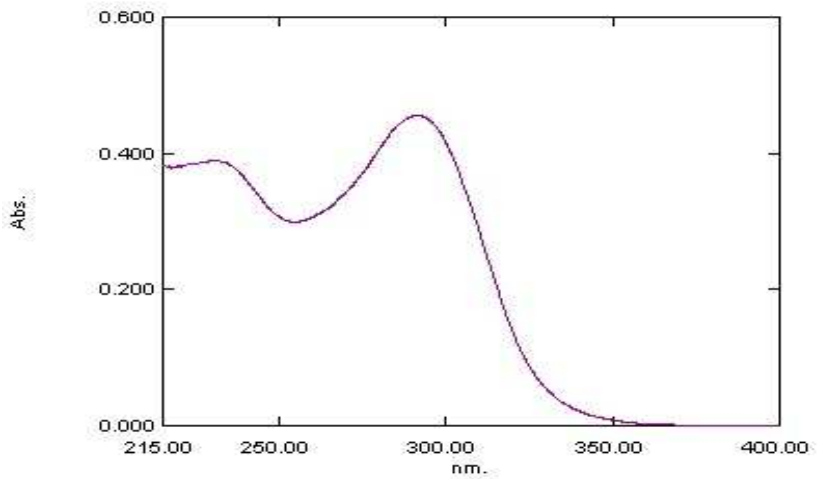

Fig. 1: Absorption maxima for Cefixime trihydrate

Application of the proposed method for the determination of Cefixime in tablet
Twenty tablets were weighed , their mean weight was determined and finely powdered. Tablet powder equivalent to 10.0 mg of Cefixime was weighed and transfer to 10.0 ml volumetric flask and dissolved with methanol and further diluted upto mark. It was kept for ultrasoniction for 30 min. and filtered through Whatman filter paper No.41. The aliquot portion of filtrate was further diluted with methanol to get final concentration of about 10 µg/ml. Absorbance was recorded. Five replicate estimations were done in similar way. The content of Cefixime was calculated and % label claim was determined and results are shown in table III.

Development and validation of analytical method
Validation of the proposed method was carried out as per ICH guidelines for the parameters like linearity, precision, accuracy, LOD and LOQ. Detection wavelength selected for analysis was 290.60 nm.

Linearity
Linearity was studied over a small drug concentration range from 2–40 µg/ml. The correlation coefficient (R^2=0.9997) obtained for regression line showed excellent linearity relationship between absorbance and concentration of Cefixime trihydrate. Result of linearity studies are shown in table I.

Precision
Precision was studied by analysing five replicates of sample solutions and concentration was calculated. Precision of the method reported as % RSD was estimated by repeatability, reproducibility and intermediate precision by

measuring absorbance of five replicates of 2 µg/ml of Cefixime trihydrate. % RSD values as in table II is less than 1% that illustrate the good precision of the analytical method.

Accuracy

Accuracy was ascertained on the basis of recovery studies. Accuracy of the proposed method was determined by comparing the analytical amount determined Vs known amount spiked at 80%, 100% and 120% level of LOQ concentration with measurements for each concentration level achieved.

Limit of Detection and Quantitation

The LOD and LOQ of Cefixime trihydrate were estimated from the standard deviation of the response and the slope of the calibration curve by using following formula.

LOD =3.3 x σ/ S , LOQ = 10 x σ/S

Where σ = the standard deviation of the response and S = the slope of the calibration curve

LOD and LOQ were found to be 0.0004801 µg / ml [0.4801 ng/ml] and 0.0014311 µg/ml [1.4311 ng/ml] respectively. And results are indicated in Table II.

Table I: Linearity for Cefixime trihydrate

Sr.No.	Concentration(ug/ml)	Absorbance
1	2	0.087
2	4	0.177
3	6	0.244
4	8	0.354
5	10	0.456
6	12	0.527
7	20	0.892
8	40	1.785

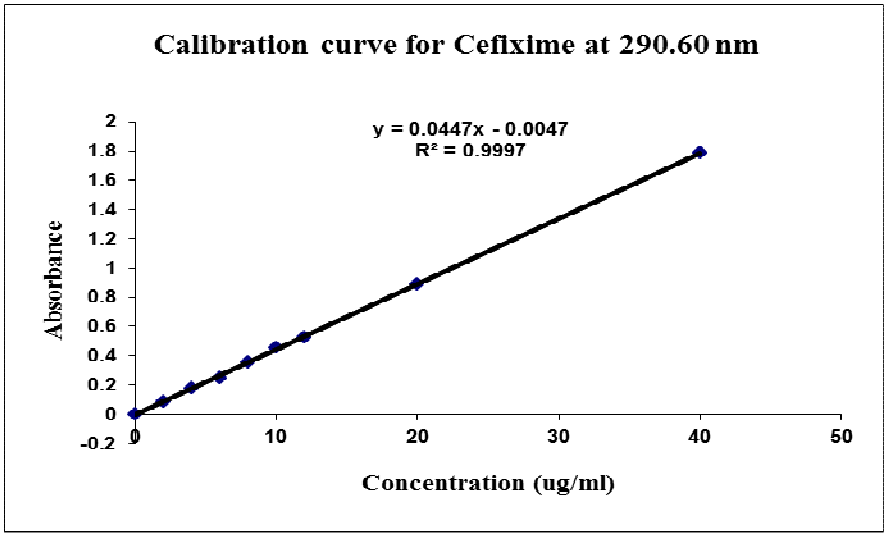

Fig. 2: Calibration Curve for Cefixime trihydrate

Table II. Results for Validation Parameters

Sr. No.	Validation Parameter	Results
1	Linearity	R^2 =0.9997
2	Accuracy 80% 100% 120%	Percentage Recovery(%) 99.94% 101.82% 98.60%
3	Precision A)Intraday precision(n=6) C)Intraday precision(n=6)	S.D. 0.19-0.48 0.73-0.91
4	LOD	0.0004801 µg / ml
5	LOQ	0.0014311 µg/ml

n=number of observations

Table III:- Marketed Formulation analysis:-

Sample	Label claim(mg)	Amount recovered	% Recovery
Ceftas	50	49.71±1.18	99.41
Ceftas	50	49.62±1.74	99.23
Ceftas	50	49.18±1.62	98.35

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