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Spectrophotometric Method Development, Validation and Estimation of Cefuroxime in Marketed Tablet Dosage Form

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Abstract

From the family of Cephalosporins, Cefuroxime belongs to 2nd generation; use for the treatment of certain bacterial infections includes both gram negative and gram positive bacteria. A simple easier and accurate spectrophotometric method has been developed for the analysis of cefuroxime and validated as per ICH guidelines. The method was performed on UV spectrophotometer using 20% methanol. The maximum absorbance was detected at 281 nm. To obtain the analytical curvet the linearity range was between 2ppm-25ppm. The proposed method is also validated following the accuracy, regression, linearity and robustness. All the results stretch out within the range and the regression correlation is found to be 0.999%withRSD 0.23% (NMT 2.0%).An assay of the marketed drug also carried out to check the application of the proposed method and results were foundprecisely within the range (90%-110%).The developed method is simple, accurate and found to be cost effective that can be used for the routine analysis of Cefuroxime in industries as well as in researchlabs.

Introduction

From the class of Cephalosporins, 2nd generation, cefuroxime is a semi synthetic antibiotic used for the treatment of skin infections, bone and urinary tract infections [1, 2](Figure1). Cefuroxime is shown high extent of stability against beta lactamase and has high appreciative activity against the wide variety of both beta-lactam and non-beta-lactam gram negative and gram positive organisms. [3]

Assessment of literature concerning the analysis and determination of cefuroxime shows that different analytical techniques have been reported for both bulk and in dosage form. An electrophoretic method is reported which requires more reagents preparations with a lengthy and time consuming procedure [4]. Another method has been reported by mass spectroscopy [5]. Flourimetric method [6], HPTLC [7]HPLC [8-11] and numerous UV spectroscopic methods has been developed earlier[12-15], however the presenting work is more sophisticated, easier and cost effective than the other methods.

The proposed study illustrates the development of simple, easy, cost efficient and effectual spectrophotometric method for the analysis of Cefuroxime. The whole method is carried out on UV -1800 Shimadzo spectrophotometer using the dilution of methanol and water (20% methanol solution). The scheme is also validated in terms of linearity, accuracy, precision and ruggedness. The anticipated method is relatively inexpensive and can be profitably use in labs for the investigative purposes of cefuroxime.

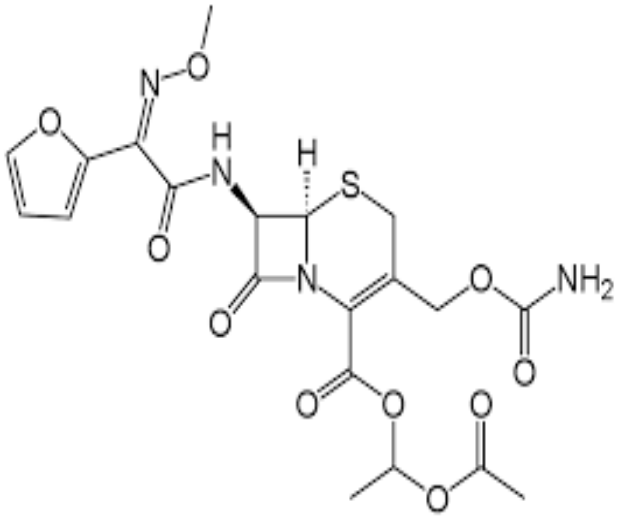

Figure 1: Cefuroxime

Experimental

A double beam UV 1800 Shimadzu spectrophotometeris used for the measurement of spectra. The UV is connected with the UV- Probe Shimadzu software (Version 2.0).The diluents used are Methanol AR Grade (Analytical reagent) and distil water.

1. Stock Solution Preparation:

To prepare 100 ppm stock solution, accurately weigh 10 mg of the drug and transfer into 100 ml volumetric flask. Add 20 ml methanol (AR grade) and shake vigorously until drug completely dissolved, then make up the volume up to 100 ml with distil water.

2. Wavelength Selection:

To select the wavelength, the 100 ppm stock solution is scanned between the ranges of 200nm-400nm with medium scanning speed. The maximum absorbance is achieved at 281 nm which is used for the further processing.

3. Calibration Curve & Linearity:

For the linearity and calibration curve, aliquots from the stock solution were prepared diluting serially from 2ppm, 4ppm, 6ppm, 8ppm, 10ppm, 12ppm, 15 ppm and 25 ppm. A calibration curve was obtained (Figure 2) by measuring the absorbance escalating with raise in concentration. In addition statistical tools such as Y-intercept, slope, Beer's Lambert Law was determined (Table 01).

4. Precision:

Precision of the proposed method is premeditated by repeatability. The intraday precision was determined by analysing each solutions 3 times.

5. Robustness:

The robustness of the projected method was establish by small variation in the in the wavelength, the solutions were analysed at different wavelengths i.e. 279nm and 283 nm.

6. Accuracy:

The accuracy of the proposed method was determined by preparing samples of concentration 80%, 100% and 120%. Samples of each concentration of both drug and tabulated dosage form were prepared and % recovery of the drug was analysed.

Assay

An assay has been carried out from the marketed and running drug product of cefuroxime. Solutions of different concentration have been prepared to get more trustworthy application of the proposed method. The results were come within the range (90%-110%).

Result

In this proposed study, a method for Cefuroxime has been developed and validated according to ICH guidelines for parameters like linearity, precision, robustness and accuracy. An assay has been also carried out from the marketed formulation and found satisfied results. The spectral analysis shows the maximum absorbance at 281 nm and all procedure carried out at this wavelength.

The solvent used is 20% methanol and the drug shows maximum absorbance at 281 nm. The linearity curve was obtained (Figure 2) shows straight line following Beer's Lambert law with the regression correlation 0.999 with y-intercept 0.048%and RSD 0.23%(NMT 2.0%) (Table 01).For robustness, solutions of different concentrations were run at different wavelengths and the results revealed that the anticipated method shows stability with slight variations in the wavelengths (Tables 02, 03 and 04). The inter day precision was determined by repeating each solution 3 times at lambda max (281nm) with the mean %RSD 0.2% (NMT 2.0%) (Table 05). For accuracy, the proposed method was evaluated and the percentage recovery of the of each solution was found within the range (±4%)(Table 06).The assay of widely running drug also carried out by preparing solutions of different concentration (20 ppm, 40 ppm, 60 ppm) and the results are 99.44%, 100.72%, 101.21% respectively(limit 90%-110%)(Table 07). The results of validation parameters and assay revealed that the developed method is accurate, simple and decidedly cost effective and can be easily carried out for the routine analysis. The outcome of the anticipated method showed more reproducible and can be successfully applied for the analysis of pharmaceutical formulation.

Table 01

Parameters	**UV method**
Linearity Range	0-25ppm
λ Max	281 nm
Correlation Coefficient	0.999
Standard Deviation	0.00057
Slope(m)	0.0048
%RSD	0.23%

Table 02

Precision & Robustness at 279 nm		
Solution (ppm)	**Mean Absorbance**	**SD**
2	0.09	0.00057
4	0.197	0.00057
6	0.288	0.00057
8	0.387	0.001
10	0.487	0.001
12	0.599	0.0011
15	0.733	0.0011
25	1.203	0.00057

Table 03

Precision & Robustness at 281 nm		
Solution (ppm)	**Mean Absorbance**	**SD**
2	0.092	0.00057
4	0.197	0.00115
6	0.289	0.00057
8	0.388	0.00057
10	0.487	0.00057
12	0.601	0.00057
15	0.735	0.00057
25	1.207	0.00057

Table 04

Precision & Robustness at 283 nm		
Solution (ppm)	**Mean Absorbance**	**SD**
2	0.091	0.00057
4	0.195	0.0015
6	0.286	0.0011
8	0.386	0.0011
10	0.487	0.0011
12	0.599	0.002
15	0.733	0.0015
25	1.204	0.001

Table 05

Precision			
Solutions	**Mean value**	**Standard deviation**	**%RSD**
2	0.092	0.00057	0.62%
4	0.197	0.00115	0.59%
6	0.289	0.00057	0.20%
8	0.388	0.00057	0.15%
10	0.487	0.00057	0.12%
12	0.601	0.00057	0.10%
15	0.735	0.00057	0.08%
25	1.207	0.00057	0.05%

Table 06

	Percentage Recovery	
Concentration	**% Recovered**	**Limit±4%**
80%	79.71%	76%-84%
100%	99.59%	96%-104%
120%	122.95%	116%-124%

Table 07

Assay (90%-110%)	
Concentration(ppm)	**Assay Results**
60	99.44%
40	100.72%
20	101.21%

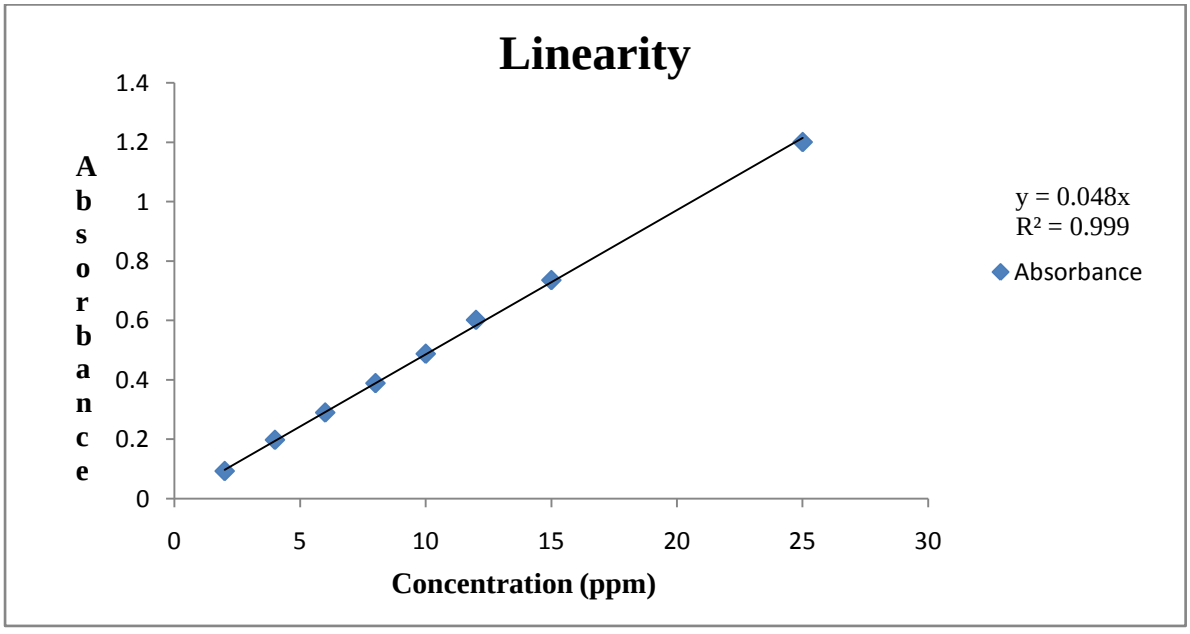

Figure 02: Calibration Curve

Conclusion

The proposed spectrophotometric method is simple, easier, accurate and relatively cost effective as compare to other reported methods. The method is also validated as per the international guidelines and the statistical analysis shows good agreement. Thus the proposed method is very particular and can be practice for the routine analysis of cefuroxime.

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