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Development and validation of spectrophotometric methods for the estimation of Cefadroxil in tablet dosage forms

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Abstract

A simple and sensitive spectroscopic method was developed for the estimation of CEFAD in pharmaceutical dosage forms. This method is based on CEFAD, showing absorbance at 257 nm in methanol. This method obeys Beers law in the concentration range of 10 to100 µg mL^{-1} respectively. The proposed method is precise, accurate and reproducible and can be extended to the analysis of CEFAD in bulk and tablet formulations.

Key-words: Cefadroxil (CEFAD), UV Spectroscophotometric Method, Methanol.

Introduction

Cefadroxil is chemically, 5-thia-1-azabicyclo [4.2.0] oct-2-ene carboxylic acid, 7[(amino-(4hydroxyl phenyl) acetyl) amino]-3-methyl-8-oxo-monohydrate [6R (6a, 713 (R^+))]. Anti-infective agents [1] treat infection by suppressing or destroying the causative microorganisms like bacteria, mycobacterium, fungi, protozoa, or viruses. Anti-infective agents derived from natural substances are called as antibiotics and those produced from synthetic substances are called antimicrobials. However, these two terms are now used interchangeably. An anti-infective agent should be chosen on the basis of its pharmacological properties and spectrum of activity as well as on various host (patient) factors. A combination of drugs should be given only when clinical experience has shown such therapy to be more effective than single-agent therapy in a particular treatment. A multiple agent regime can increase the risk of toxic drug effects and in a few cases result, a drug antagonism and subsequent therapeutic ineffectiveness.

Materials and methods

Experimental section

Apparatus and software

Shimadzu UV 1601 double beam spectrophotometer connected to a computer loaded with Shimadzu UVPC software was used for all the spectrophotometric measurements. The spectral bandwidth was 1 nm and the wavelength scanning speed was 2800 nm min^{-1}. The absorption spectra of the reference and test solutions were carried out in a 1 cm quartz cells over the range of 200 - 350 nm.

Reagents and Pharmaceutical Preparations

CEFAD was kindly supplied by Dr.Reddy laboratories (Hyderabad, A.P, India) the drug was used without further purification. All the solvents used in Spectrophotometric analyses were of spectroscopic grade. Commercial pharmaceutical preparations of CEFADROX from Dr. Reddy laboratories (Hyderabad, A.P, India) which were claimed to contain 100mg of CEFAD as used in analysis.

Preparation of standard CEFAD solution

It was used stock solutions of 1mg mL^{-1} CEFAD in mixture of methanol. The working solution of 0.1 mg mL^{-1} prepared by transferring 5mL from respective stock solution to a 50 ml volumetric flask and completing to volume with the mixture of methanol.

Sample preparation

A total of powder from 10 tablets was accurately weighed and an amount equivalent to 100mg was taken and dissolved in 60 ml of methanol and sonicate for five minutes. About 10 ml of methanol was added and sonicate for another 5 minutes. The mixture was shaked well for 2 minutes and transferred to a 100ml volumetric flask through a Whatman No. 40 Filter paper. The residue was washed thrice with 10ml methanol and the combined filtrate was made up to the mark with methanol. The sample solution thus prepared was diluted with methanol to get the solutions containing different concentrations of CEFAD.

Calibration sets

A calibration set of 09 samples was prepared in methanol, UV spectra were recorded in the wavelength range 200-400 nm versus solvent blank and digitized absorbance was recorded at 1 nm intervals. The overlay zero orders spectra were recorded. Absorbance measured at 257 nm (λ max) was used to preparation of calibration curve.

Result

UV Spectrophotometric method was applied without using any prior chemical pretreatment [2]. Accurate results were obtained by utilizing the proposed method for the quantitation of CEFAD and a good agreement with the results obtained by the reported methods was found [3, 4, 5]. For UV spectrophotometric method, linearity was obtained in concentration range of 10-100 $\mu g\ mL^{-1}$ for CEFAD respectively. The % recovery greater than 98 % shows that the method was free from the interference of excipients used in the formulation. The value of standard deviation and % R.S.D. were found to be less than 2 shows the high precision of the method.

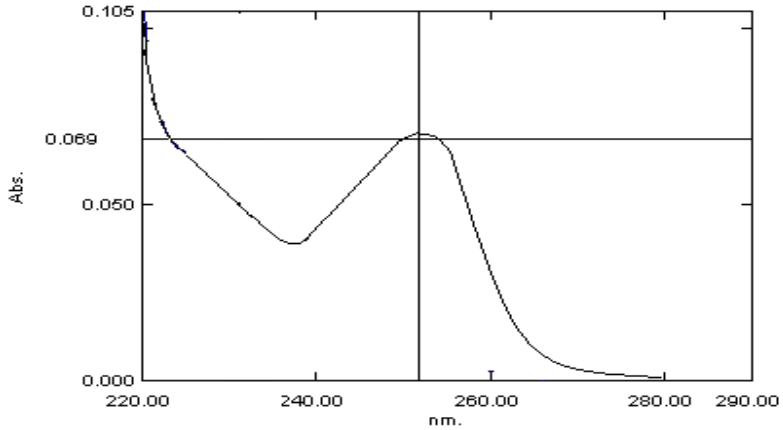

Figure 1: Absorption spectra of CEFAD (20 µg mL^{-1})

Table 1 Optical characteristics and other Parameters of Method

Parameter	Results
Absorption Maxima (nm)	257
Beer's Law limits(µg/ml)	10-100
Molar extinction coefficient (mole^{-1} cm^{-1})	0.009274
Sandell's sensitivity (µg/cm^2/0.001absorbance units)	0.0927919
Regression equation (y)* Slope (b) Intercept (a)	0.9997 0.0093 0.0028
Standard deviation **	0.00332
Limit of detection µg ml^{-1}	0.088749
Limit of quantification µg ml^{-1}	0.268938

*y = a + bx; when x is the concentration and y is absorbance unit.

Table 2: Recovery study from standard solution

S.No	Concentration taken in (µg mL^{-1})	% Standard addition	*Average amplitude at 257 nm	%Recovery of CEFAD
1	10	60	0.55± 0.0014	100.1 ± 0.9539
2	10	80	0.75± 0.0015	99.42 ± 0.9814
3	10	100	0.935± 0.0026	99.552 ± 0.9757
4	10	120	1.11 ± 0.0016	99.186 ± 0.9627
5	10	140	1.32 ± 0.0033	100.914 ± 0.9648

* Average amplitude at 257nm of three trials with SD

Table 3: Recovery study from formulation

S.No	Conc. of sample (µg mL^{-1})	Conc. Of standard (µg mL^{-1})	*Average amplitude at 257 nm	%Recovery of CEFAD
1	10	6	0.59 ± 0.001	99.93 ± 0.9841
2	10	8	0.79± 0.0017	99.42 ± 0.9937
3	10	10	0.939± 0.0029	100.51 ± 0.9867
4	10	12	1.15 ± 0.0021	100.084 ± 0.9957
5	10	14	1.36 ± 0.0039	101.196 ± 0.9867

**Average amplitude at 257nm of three trials with SD*

Table 4: Analysis of tablet formulation

Tablet	Label claimed (mg)	Conc. found (mg)	%Recovery ± SD
	CEFAD	**CEFAD**	**CEFAD**
CEFADROX	100	99.98	99.69 ± 0.909

** Values in parentheses correspond to the parameters calculated after accounting for CEFAD, that is, values without standard addition.*

Conclusion

The UV spectroscopic methods demonstrated herein, is applicable to the estimation of Cefadroxil in pure as well as in existing dosage forms. In order to ensure that the data generated of the above method is accurate and precise. The experiments have been performed on calibrated equipments using suitable reference standards. To prove and documents the reliability of the methods have been carried out to a possible extent. The results expressed in Table 1, 2 & 3 for spectrophotometric method. In addition to positive requirements for analytical methods, the striking advantage of all the presently developed methods is that they are economical.
The proposed methods are found to be simple, sensitive, selective, accurate, precise and economical and can be used in the determination of cefadroxil in bulk drug and its pharmaceutical dosage forms (tablets) in a routine manner.

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