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Spectrophotometric Estimation of Cefprozil from Tablet Dosage Form

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A simple, rapid, sensitive and precise spectrophotometric methods in ultraviolet (UV) region and visible region has been developed for the estimation of cefprozil in bulk and pharmaceutical dosage forms. The visible method is based on formation of extractable coloured complex of drug with colouring agent. *i.e.*, methyl red. Cefprozil showed maximum absorbance at 280 nm in UV region and at 536 nm in visible region. Beer's law was obeyed in concentration range of 5-40 µg/mL in UV region and 50-300 µg/mL in visible region. Regression equation was found to be y = 0.0276x + 0.0085 and coefficient of correlation was 0.9993 by UV method and y = 0.0049x - 0.0123 and coefficient of correlation was 0.9989. Results of the analysis were validated statistically and by recovery studies. The method is applied to marketed tablet formulation. Result of analysis of tablet formulation by both UV and visible, given as percentage of label claim ± standard deviation is 99.640 ± 1.198 and 99.920 ± 0.587, respectively. The precision and accuracy was examined by performing recovery studies and was found to be 99.150 ± 0.472 and 99.620 ±0.213 for both UV and visible, respectively. Sandell's sensitivity is calculated as 0.03640 and 0.0212 for both UV and visible spectrophotometry, respectively.

Key Words: Cefprozil, Methyl Red, UV, Visible.

INTRODUCTION

Cefprozil[1], chemically 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[amino(4-hydroxyphenyl)acetyl]amino]-8-oxo-3-(1-propenyl)-,(6 R,7R)-7-[(R)-2-amino-2-(*p*-hydroxyphenyl)acetamido]-8-oxo-3-propenyl-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid is a semisynthetic, second-generation cephalosporin, is used to treat otitis media, soft-tissue infections and respiratory tract infections. Literature survey reveals that HPLC[2] and HPTLC[3] methods are reported for the estimation of cefprozil from formulation and in human plasma.

The developed UV method is simple single point standardization method[4] and the developed visible method is based on formation of extractable coloured complex of drug with colouring agent *i.e.*, methyl red to give a coloured complex with λ_{max} at 536 nm. Reaction conditions are optimized to obtain maximum colour intensity.

The methods are simple, reproducible and requires low cost and methods are applied successfully to the analysis of the marketed tablet formulation.

EXPERIMENTAL

A double beam thermospectronic India SL-159 model UV/vis spectrophotometer with 1 cm, matched quartz cells was used. Pure cefprozil was gift from Ranbaxy Lab. Ltd., Dewas. High purity water was used in the UV method. Double distilled water, chloroform and 0.1 N HCl was used in visible method. Cefprozil tablets were procured from local pharmacy.

Method 1 (UV method)[5]: 50 mg of cefprozil was accurately weighed and add in a 100 mL of volumetric flask containing 50 mL of high purity water. Solution was shaked to dissolve it completely. Solution was further dilute suitably to obtain concentration range from 5-40 µg/mL. The analyte give maximum absorbance at 280 nm.

Sample preparation: Twenty tablets were accurately weighed and their average weight was determined. 50 mg of powder equivalent to anhydrous cefprozil was accurately weighed and add in a 100 mL of volumetric flask containing 50 mL of high purity water. Solution was sonicated for 5 min to dissolve it completely. Solution was further diluted suitably to obtain final concentration of 20 µg/mL.

Method 2 (visible method)[6]: 0.2 % w/v solution of methyl red was prepared in 0.1 N HCl and was extracted several times with chloroform so as to remove chloroform soluble impurities.

In a series of 10 mL volumetric flask, aliquots of standard drug solution (200 µg/mL) in double distilled water were transferred and diluted with same so as to give several dilutions in concentration range of 50-300 µg/mL of cefprozil. To 5 mL of each dilution taken in a separating funnel, 5 mL of methyl red (0.2 % w/v) reagent and 5 mL of chloroform were added. The reaction mixture was shaken gently for 5 min and allowed to stand so as to separate aqueous and chloroform layers. The chloroform layer was separated out and absorbance maxima of aqueous layer were measured at 536 nm against reagent blank. Calibration curve was plotted between concentration of cefprozil and measured absorbance.

Procedure for analysis of tablet formulation: For analysis of tablet formulation, 20 tablets (250 mg) of cefprozil was weighed accurately and finely powdered. An accurately weighed powdered sample of cefprozil (100 mg) was taken in a 100 mL volumetric flask containing 50 mL of double distilled water and sonicated for 10 min. The resultant mixture was filtered through Whatman filter paper No. 41 into another 100 mL volumetric flask. The filter paper was washed several times with double distilled water. The washings were added to the filtrate and final volume was made up to the mark with double distilled water. Then 1 mL of filtrate of sample solution was diluted to 10 mL with double distilled water. These were treated as per the procedure for preparation of calibration curve and the amount of drug present in the sample was computed from respective calibration curve.

RESULTS AND DISCUSSION

Cefprozil showed maximum absorbance at 280 nm in UV region and at 536 nm in visible region. Beer's law was obeyed in concentration range of 5-40 µg/mL in UV region and 50-300 µg/mL in visible region. Regression equation was found to be y = 0.0276x + 0.0085 and coefficient of correlation was 0.9993 by UV method and y = 0.0049x - 0.0123 and coefficient of correlation was 0.9989. Sandell's sensitivity is calculated as 0.0364 and 0.0212 for both UV and visible spectrophotometry, respectively (Table-1).

TABLE-1
OPTICAL CHARACTERISTICS FOR CEFPROZIL BY UV AND VISIBLE METHOD

Regression parameter	UV Method	Visible method
Regression equation	y = 0.00276x + 0.0085	y = 0.0049x - 0.0123
Slope of curve (m)	0.0276	0.0049
Intercept (C)	0.0085	0.0123
Correlation coefficient (r^2)	0.9993	0.9989
Linearity range (µg/mL)	5-40	50-300
Molar absorptivity (L mol^{-1} cm^{-1})	2.79×10^4	0.96×10^4
Sandell's sensitivity µg/mL/0.001 absorbance unit	0.0364	0.0212

Results of the analysis were validated statistically and by recovery studies. The method is applied to marketed tablet formulation (Zemetril and Refzil-O). Result of analysis of tablet formulation by both UV and visible, given as percentage of label claim ± standard deviation is 99.640 ± 1.198 and 99.920 ± 0.587, respectively (Table-2).

TABLE-2
TABLET ANALYSIS FOR CEFPROZIL BY BOTH
UV AND VISIBLE SPECTROPHOTOMETRY

	BY UV		BY VISIBLE	
Parameter	Zemetril	Refzil-O	Zemetril	Refzil-O
Amt. found	248.432	249.094	249.349	249.790
Purity (%)	99.370	99.640	99.740	99.920
SD	0.997	1.198	0.362	0.587
RSD	0.004	0.005	0.001	0.002

The precision and accuracy was examined by performing recovery studies[7] and was found to be 99.150 ± 0.472 and 99.620 ± 0.213 for both UV and visible, respectively (Table-3).

In the UV method the diluent used was economical and the method is easy to perform in analytical laboratories. Cefprozil shows the maximum absorbance at 280 nm. The calibration curve derived from eight different concentration points ranging from 5-40 µg/mL shows the linear relationship between absorbance and concentration. In the visible method the methyl red in 0.1 N HCl reacts with the cefprozil and form a red chromogen which gives the λ_{max} at 536 nm and shows the

TABLE-3
VALIDATION RESULTS FOR CEFPROZIL BY BOTH
UV AND VISIBLE SPECTROPHOTOMETRY

Validation Parameter	UV Method		Visible Method	
	SD	RSD	SD	RSD
Accuracy	0.472	0.005	0.213	0.002
Repeatability	0.997	0.004	0.362	0.001
Intermediate precision				
Intra day	0.454	0.005	0.139	0.001
Inter day	0.854	0.009	0.799	0.008

linear relationship between concentration and absorbance from 50-300 µg/mL. The validation results obtained from the developed method are satisfactory and well under the acceptance limit. Proposed method used for pure bulk drug as well as marketed formulation. The result obtained compared favorably with labeled amount of drug as well as that of the formulation. None of the usual diluents, lubricant, film formers employed in preparation of tablet dosage form was found to interfere in the proposed procedure. The proposed method is specific, precise, accurate and reliable.

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