www.journalofresearch.us
info@journalofresearch.us

Health Science: Pharmacology and Toxicology

"METHODS DEVELOPMENT AND VALIDATION OF CEFPROZIL BY UV-VIS SPECTROPHOTOMETRY"

Thorat D.B, Paunikar Ashwini
PERS, Institute of Pharmacy, Loni (kd),
Tal-Rahata, Dist- A'nagar (MS).
Email.id-dattatraya_thorat@rediffmail.com.

http://dx.doi.org/10.26739/2573-5616-2018-3-2-7

Abstract: the present work describes which deals to developed and validate a simple, accurate, precise, economically effective US-VIS Spectrophotometric method for the estimation of cefprozil. These methods are developing using 280 nm as the λmax of cefprozil respectively. Calibration curves were linear over the concentration ranges of 10-50xg/ml.These result demonstrate that the procedure is accurate, precise and reproducible (relatively standard deviation ≥1%) while being simple cheap and less time consuming and hence can be suitably applied for validation of these drug in laboratory.

Key words: cefprozil, λmax, UV-VIS Spectroscopy.

INTRODUCTION

Cefprozil is chemically (6R, 7R)-7-((R)-2-amino-2-(p-hydroxyl-phenyl) acetamido)-8-oxo -3-propenyl-5-thia-1-azabicyclo (4.2.0) oct-2-ene-2-carboxylic acid. Cefprozil is a semi synthetic broad spectrum cephalosporin antibiotic, which is currently available in a oral dosage form (i.e. tablet and suspension) for the treatment of respiratory tract and skin or skin structure infection in both adults and children's. The bactericidal action of cefprozil results from inhibition of cell wall synthesis. Literature survey reveals that HPLC method for the simultaneous determination of cefprozil diasteriomers, HPTLC for estimation cefprozil, Flow injection chemiluminscent determination of cefprozil spectrophotometric determination and spectroflurometric determinations of cefprozil have been developed.

EXPERIMENTAL PROCEDURE

Materials:

UV-visible double beam spectrophotometer, spectroscanUV model 2600 version 6.67 having two match pair of quartz cells with 1cm path length.

Selection of common solvent

After assessing the solubility of drugs in different solvents ethanol-water 50:50 has been selected as common solvent for developing methods.

Preparation of stock and calibration curve

Standard stock solution of cefprozil was prepared by 0.174gm dissolve in 100 ml of ethanol - water (50:50) gives 100ppm concentration.

From the above stock solution to make working standard solution of 10xg/ml UV-visible spectrophotometer in the range of 600-400nm.

Validation

Linearity:

Various aliquots were prepared from secondary stock solution (100ppm) ranging from 10-50ppm. The samples were scanned in UV - visible spectrophotometer against water-ethanol as blank. It was found that the selected drug shows linearity between the ranges of 10-50ppm.

Accuracy:

Solutions were prepared in triplicate at levels 80%, 100% and 120% of test concentration using cefprozil working standard as per the test method and taken absorbance of each solution in triplicate. The recovery result show that the proposed method has an acceptable level of accuracy of cefprozil which is from 80-120% of test concentration is 99.51-100.01%. Table 1.

Precision:

Precision was determined by studying the repeatability and intermediate precision. Precision of the method was demonstrated by intra-day and inter-day variation studies. In intraday study concentration of drugs were calculated on the same day at an interval of 3 hour. In inter day study the drug contents were calculated on three different days. In both intra and inter -day precision study for result mean, standard deviation and % RSD was calculated. It is given in table 3.

Ruggedness:

Ruggedness of the method was determined by carrying out the analysis by different analyst and the respective absorbance of 20ppm was noted. The result was indicated as %RSD and given in table 4.

Result and discussion:

The developed method was found to be precise as % RSD values for intraday and inter-day were found to be less than 2%. Good recoveries of the drug were obtained at each added concentration, indicating that method was accurate. The method was also found to be specific indicated by % recoveries ranging from 7.64-9.56%. The method was also found to be rugged as indicated by the % RSD values which are less than 2%.

Table 1: Result of accuracy studies

No. of prepar	Concentratior (ppm) formulat	Pure drug	% Recovery	Mean	SD	% RSD
80 %	10	8	8.68			
80%	10	8	8.68	8.68	0.70	0.081
80%	10	8	8.69			
100 %	10	10	8.082			
100 %	10	10	8.082	8.08	1.90	0.035
100%	10	10	8.076			
120%	10	12	7.64			
120%	10	12	9.56	8.27	0.17	0.058
120%	10	12	7.63			

Table 2: Optical characteristics of data and validation parameter

Parameter	Result
Linearity	1.40
Accuracy indicated by % recovery	0.058
Precision indicated by % RSD	1.04%
Ruggedness indicated by % RSD	0.17%
Range	10-50 ppm

Table 3: Precision

Concentration(ppm)	Absorbance	SD	% RSD
10	0.847	0.468414	0.3492
20	0.775	0.47988	0.22169
30	1.864	3.44401	1.45268

Table 4: Ruggedness

Instrument 1 (Spectroscan uv model 2600)

Concentration(ppm)	Absorbance	Statistical analysis
10	2.184	Mean – 0.41
20	2.141	S.D. – 0.20
30	2.184	%RSD – 0.13
40	2.156	
50	2.615	

Instrument 2 (SEMATZU)

Concentration(ppm)	Absorbance	Statistical analysis
10	2.578	Mean – 1.13
20	4.000	S.D. – 0.56
30	4.000	%RSD – 0.22
40	4.000	
50	4.000	

CONCLUSION:

The methods reported here are found to be simple, sensitive, accurate and precise. Further spectrophotometric methods involve simple instrumentation which is cost effective compared with other instrumental techniques, which ordinary laboratories cannot afford to have. The present method involves the formation of highly stable colored species which may it easier for the determination of cefprozil from pharmaceutical dosage form in a routine manner.

ACKNOWLEDGEMENTS:

On the occasion of presenting this work, it my privilege to express my sincere thanks to PRES, Institute of Pharmacy, Loni Kd, and Pravara Rural College of Pharmacy, (Dept of Pharmaceutical Chemistry), Pravaranagar, Tal-Rahata, Dist-Ahmednagar (MS).

References

1. Park TH, Kim JK, Jee JP et al (2004), J Pharm Biomed Anal 36:243-248.
2. Alarfaj NA, and Abd El-Razeq et al (2006) J Pharm Biomed Anal; 41:1423-1427.
3. T.H.Park, J.K. Kim, J.P. Jee, J.S.Park, C.K. Kim et al (2004), J. Pharm. Biomed. Anal; 36: 243-248.
4. L. Manna, L. Valvo, (2004) Chromatographia. 60:645-649
5. W.C. Shyu, U.A. Shukla, V.R. Shah, E.A. Papp, R.H. Barbhaiya et al (1991), Pharm Res. 8:1992-1996.
6. Smith, P.E. Heckelman, in: M.J. O'Neil, S. Budavari et al (2001), The Merck Index, 13th ed. Merck and Co Inc., White House Station,NJ,USA,..
7. The official compendia of standard USP 32, NF 27, US Pharmacopeia and National Formulary, Asian edition 2009; 1855-7.
8. Park TH, Kim JK, Jee JP et al (2004), al J Pharm Biomed Anal; 36: 24.
9. P. Vikas,T Santosh, B. Santosh, S. Rupali,et al Lalit (2010), Int. J. Pharm. Pharmaceu. Sci.,2: 82
10. A.G. Elrasheed, M.M. Mohammed, E.E.I. Kamal, A.H. El-Obeid et al (2009), Int. J. Biomed. Sci., 5:267.
11. Shukla Ravi, Patel Asha, Soni M, Modi Vishesh Jaliwala Y. et al (2008), Asian Journal of Pharmaceutics., 9:256.