Spectrophotometric Methods for the Estimation of Cephalexin in Tablet Dosage Forms

S. A. PATEL*, N. M. PATEL[1] AND M. M. PATEL

Shree S. K. Patel college of Pharmaceutical Education and Research, Ganpat vidyanagar, Kherava, Dist-Mehsana-382 711, [1]B. M. Shah College of Pharmaceutical Education and Research, Modasa-383 315, India.

Two simple, sensitive, accurate, rapid, and economical spectrophotometric methods, have been developed for the estimation of cephalexin in tablets. Method A is based on the reaction of cephalexin with Folin-Ciocalteu reagent, in presence of 20% sodium carbonate solution, giving a blue colour chromogen, which shows maximum absorbance at 753 nm against reagent blank, while method B is based on the estimation of cephalexin in distilled water, at 263 nm. Beer's law was obeyed in the concentration range of 10-160 µg/ml in method A, and 5-50 µg/ml in method B. Results of the analysis were validated statistically, and by recovery studies.

***For correspondence**

E-mail: satishpatel_77@yahoo.com

Chemically, cephalexin (CPX) is (6R,7R)-7[[(2R)-aminophenylacetyl]amino]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid1[1]. Cephalexin is a first generation cephalosporins for oral administration which is bactericidal, and mainly used in the treatment of various bacterial infections caused by gram +ve and gram –ve microorganisms[2]. Cephalexin is official in IP, USP, and BP. The IP[3] describes a titrimetric method, while USP[4] and BP[5] describes a HPLC method, for estimation of cephalexin from formulations. Literature survey revealed a HPTLC[6-7], polarimetry[8], spectrophotometric[9-13], and HPLC[14-16] methods, for determination of cephalexin in pharmaceutical formulations, and in biological fluids. The present communication describes simple, sensitive, accurate, rapid, and economical spectrophotometric methods, for the estimation of cephalexin in tablet dosage forms.

A Shimadzu model 1601 double beam UV/Vis. spectrophotometer with spectral width of 2 nm, wavelength accuracy of 0.5 nm, and a pair of 10 mm matched quartz cells, was used to measure absorbance of the resulting solutions. A Sartorius CP224S analytical balance, an ultra sonic cleaner (Frontline FS 4), cephalexin (Mann Pharmaceuticals Ltd., Mehsana), Folin-Ciocalteu's (FC) reagent (diluted to 1:4 with glass-distilled water), 20% sodium carbonate solution, and double glass-distilled water, were used in the study.

The standard stock solution of cephalexin was prepared, by dissolving 50 mg of Cephalexin in a 100 ml volumetric flask, using glass-distilled water (500 µg/ml for method A). The above stock solution was further diluted using glass-distilled water to 100 µg/ml, for method B.

In the method A, aliquots of 0.2 to 3.2 ml portion of standard solution were transferred to a series of 10 ml corning volumetric flasks. To each flask, 2.5 ml 20% sodium carbonate solution and 3.5 ml FC reagent was added. After thoroughly shaking, the flasks were set aside for 10 minutes, for the reaction to complete. The volumes of each flask were adjusted to 10 ml with glass-distilled water. The absorbance of solution in each flask was measured at 753 against reagent blank, and the calibration curve was plotted. Similarly, the absorbance of sample solution was measured, and the amount of cephalexin was determined, by referring to the calibration curve.

In the method B, aliquots of 0.5 to 5 ml portion of standard solution were transferred to a series of 10 ml corning volumetric flasks, and were suitably diluted with glass distilled water, to give final concentrations of 5.0 to 50 µg/ml. The absorbance of solution in each flask was measured at 263 nm against distilled water as a blank, and the calibration curve was plotted. Similarly, the absorbance of sample solution was measured, and the amount of cephalexin was determined by referring to the calibration curve.

Twenty tablets were weighed and powdered. An accurately weighed powder equivalent to 50 mg of Cephalexin was transferred to a 100 ml volumetric flask. The content was dissolved in glass-distilled water, and diluted up to the mark with glass-distilled water, and the solution was filtered through Whatman filter paper No.41 (500 µg/ml for method A). The above solution was further diluted using glass-distilled water to 100 µg/ml, for method B. From this solutions, aliquots containing required concentrations of the drug were taken for analysis, and the solutions were then analyzed as described, under the respective calibration curve procedure. The amount of cephalexin was determined by referring to the respective calibration curve. The analysis procedure was repeated five times with pharmaceutical formulation, and the result of analysis of the pharmaceutical formulation is shown in Table 1.

To study the accuracy and precision of the proposed method, recovery studies were carried out by addition of known amount of standard drug solution of cephalexin, to the preanalyzed formulation. The resulting solution was then reanalyzed by proposed methods. Results of recovery studies were found to be satisfactory, and are reported in Table 1.

In the present work, the quantitative reaction of the drug with FC reagent is proposed. The reaction is based on the reduction of phosphomolybdotungstic acid, the F.C reagent by cephalexin, in presence of 20% sodium carbonate solution, thereby producing reduced species of molybdenum blue, having characteristic blue colour with maximum absorption at 753 nm.

In method A, it was found that 3.5 ml FC reagent with 2.0 ml 20% sodium carbonate solution, was sufficient for the development of maximum colour intensity. Stability study of the developed chromogen was carried out, by measuring the absorbance values at time intervals of 20 min for 4 h, and it was found to be stable for more than 3 h at room temperature. The linearity was found in the concentration range of 10 to 160 µg/ml (r^2=0.9968) in

TABLE 1: ANALYSIS OF CEPHALEXIN IN TABLET DOSAGE FORMS

Formulation	Label claim (mg/tab)	Method	Amount found (mg/tab)	% of label Claim* ±S.D	% Recovery* ±S.D
Tablet 1	250	A	248.3	99.3 ± 0.79	101.4 ± 0.54
		B	247.3	98.9 ± 0.92	100.5 ± 0.65
Tablet 2	125	A	125.9	100. 7 ± 0.48	99.8 ± 0.62
		B	126.0	100.8 ± 0.43	99.1 ± 1.02

*Mean of five determinations

TABLE 2: OPTICAL CHARACTERISTIC, PRECISION AND ACCURACY OF THE PROPOSED METHODS

Parameters	Method	
	A	B
λ max (nm)	753	263
Beer's Law limits (µg/ml)	10-160	5-50
Sandell's sensitivity (µg/cm^2/0.001 A.U.)	0.1205	0.0566
Molar extinction coefficient (l/mol.cm)	2.888×10^3	6.137×10^3
Correlation coefficient (r^2)	0.9968	0.9991
Regression equation (b+ac)		
Slope (a)	0.0067	0.0170
Intercept (b)	0.0469	0.0259
Standard Deviation (S.D)	±0.0042	±0.0032
% Relative Standard Deviation (C.V)	±1.103	±0.874
Standard Error of Mean (S.E.M)	±0.0019	±0.0014

y* = b+ac Where 'c' is the concentration and y is absorbance unit.

method A, and 5 to 50 µg/ml (r^2=0.9991) in method B. The reproducibility, repeatability, and precision of method, are very good as shown by the low values of standard deviation and coefficient of variation (CV). The % recovery value in the range of 99.8 to 101.4% in method A, and 99.1 to 100.5% in method B, indicates non-interferences from the formulation excipients. All the validated parameters are summarized in Table 2. In conclusion, the proposed methods are simple, sensitive, accurate, precise, and economical, and can be successfully employed for the routine analysis of cephalexin in tablet dosage forms.

REFERENCES

1. Budavari, S., Eds., In; The Merck Index. 13th Edn., Merck & Co., Inc., Whitehouse Station. NJ, 2001, 339.
2. Mishra, L., Eds., In; Drug Today. Vol. 12, Issue 1, Lorina Publications Inc. Delhi, 2004, 232.
3. Indian Pharmacopoeia, Vol. I, Government of India, The Controller of Publications, Delhi, 1996, 152.
4. The United States Pharmacopoeia, 26th Rev., U.S. Pharmacopoeial Convention, Inc., Rockville, MD., 2003, 395.
5. British Pharmacopoeia, Vol. I, Her Majesty's Stationary Office, London, 2000, 1788.
6. Coran, S.A., Bambagiotti-Alberti, M., Giannellini, V., Baldi, A., Picchioni, G. and Paoli, F., **J. Pharm. Biomed. Anal.,** 1998, 18, 271.
7. Aqbaba, D., Eric, S., Zivanow, S.D. and Vladimiroy, S., Biomed. **Chromatogr**. 1998, 12, 133.
8. Devi, A.R, Rani, K.S. and Rao, V.S., **Indian J. Pharm. Sci**., 1994, 56, 64.
9. Metwally, F.H., Alwarthan, A.A. and Al-Tamini, S.A., **Farmaco**, 2001, 56, 601.
10. Al-Momani, I.F., **J. Pharm. Biomed. Anal**., 2001, 25, 751.
11. Kanna Babu, S., Udaya Shankar, P. and Madhu kumar, G., **Eastern Pharmacist**, 1996, 467, 129.
12. Abdel-Hamid, M.E., Mahrous, M.S., Daabes, H.G. and Beltagy, Y.A., **J. Clin. Pharm. Ther**., 1992, 17, 91.
13. Matousova, O. and Peterkoya, M., Cesk. **Farmaco**, 1979, 28, 382.
14. Samanidou, V.F., Hapeshi, E.A. and Papadovannis, I.N., **J. Chromatogr. B. Analyt. Technol. Biomed. Life. Sci**., 2003, 788, 147.
15. Emm, T.A, Leslie, J., Chai, M., Lesko, L.J. and Perkal, M.B., **J. Chromatogr**., 1988, 427, 162.
16. Lecaillon, J.B., Rouan, M.C., Souppart, C., Febure, N. and Juge, F., **J. Chromatogr**., 1982, 228, 257.

Accepted 31 March 2006
Revised 27 June 2005
Received 10 March 2005
Indian J. Pharm. Sci., 2006, 68 (2): 278-280