ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Spectrophotometric determination for prulifloxacin

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ABSTRACT

Two simple and sensitive spectrophotometric methods have been developed for the estimation of Prulifloxacin in pure and pharmaceutical dosage forms. Method BTB is based on ion-association complex formation of the drug with (BTB λ_{max} 420 nm). Method Fe(III)/PTLis based on oxidation followed by complex formation of the drug reacts with (Fe(III)/PTL λ_{max} 520nm). These methods have been statistically evaluated and found to be precise and accurate.

Keywords: Prulifloxacin, Bromothymol blue, PTL.

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ISSN: 0975-8585

INTRODUCTION

Prulifloxacin is a prodrug[1], and metabolized[2] in the body to the active compound Prulifloxacin. Prulifloxacin appeared as effective as ciprofloxacin, co-amoxiclav[3] or prefloxacin[4] in the treatment of bronchitis exacerbations[5] or lower urinary tract infections. It was tolerated as well as ciprofloxacin. Prufloxacin has a long half-life and may therefore be taken only once a day. Prulifloxacin has been approved for use in Japan. In the United states, it is undergoing phase III clinical trials for the treatment of traveler's diarrhea[6]. It has been proven that Prulifloxacin is more effective than Ciprofloxacin in the treatment of adults with complicated urinary tract infections. Prulifloxacin, the lipophilic[7] prodrug of ulifloxacin, is an oral fluoroquinolone antibacterial[8] agent with broad-spectrum in vitro activity against Gram-negative and positive bacteria, and a long elimination half-life, which allows the once-daily administration. In addition, it penetrates extensively into lung tissues. In well-designed clinical trials, Prulifloxacin 600mg administrated once daily for 10 days in patients with AECB[9](Acute Exacerbation Chronic Bronchitis) showed good clinical and bacteriological[10] efficacy (similar to that of ciprofloxacin or co-amoxiclav). Prulifloxacin, a new thiazeto-quinoline[11] derivative with antibiotic properties, was evaluated for cardiac risk both in vitro on the ether-a-go-go-related gene (HERG) K^+ channel, and in vivo in the conscious dog monitored by telemetry.

EXPERIMENT

FOR METHOD M_1:

Bromothymol blue: prepared by dissolving 200mg of bromothymol blue in 100ml of distilled water and washed with chloroform.

Glycine buffer P^H 2: prepared by mixing 50ml of glycine solution(0.1M) with 50ml of HCl(0.1M) solution and the P^H is adjusted to 2.0

FOR METHOD M_2:

PTL solution: prepared by dissolving 198mg of 1,10-phenanthroline in 100ml of 0.1N hydrochloric acid

ASSAY PROCEDURES:

METHOD 1:

Twenty tablets of PRF were weighed and powdered. A quantity of tablet powder equivalent to 50mg of PRF was accurately weighed and transferred into a 100ml volumetric flask containing 50ml of 0.1N HCl. The solution was sonicated for extracting the drug for about

15mintues, filtered through a cotton wool and the filtrate was made up to volume with 0.1HCl. The solution was further diluted with the solvent.

METHOD 2:

Twenty tablets of PRF were weighed and powdered. A quantity of tablet powder equivalent to 50mg of PRF was accurately weighed and transferred into a 100ml volumetric flask containing 50ml of acetonitrile. The solution was sonicated for extracting the drug for about 15mintues, filtered through a cotton wool and the filtrate was made up to volume with acetonitrile to get the strength of 100µg/ml and 1000µg/ml solution.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, Molar Extinction coefficient, percent relative standard deviation, percent range of error (0.05 and 0.01 confidence limits) were calculated for all the methods and results are summarized in Table 1. The values obtained for the determination of prulifloxacin in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interfere in the proposed methods.

Table-1: Optical characteristics, precision and accuracy of the proposed method PRF

Parameters	Method 1	Method 2
λ_{max} (nm)	400	545
Beer's law limit(µg/mL)	5-25	50-120
Sandell'sensitivity(µg/cm^2/0.001abs.unit)	0.04292	0.3486
Molar absorptivity(litre.mole^{-1}.cm^{-1})	8.654×10^3	7.287x 10^3
Regression equation(Y*)		
Slope(b)	0.0245	0.028
Intercept(a)	-0.00226	-0.0019
Correlation coefficient(r)	0.9998	0.9990
%Relative standard deviation**	0.765	0.647
%Range of error		
0.05 significance level	0.9691	0.5180
0.01 significance level	1.5510	0.8531

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of prulifloxacxin µg/mL
**For six replicates

ISSN: 0975-8585

Table-2: Estimation of Prulifloxacxin in Pharmaceutical Formulations PRF

Formulations	Labelled Amount (mg/ml)	Amount found* by proposed method		% recovery** by proposed method	
		Method 1	Method 2	Method 1	Method 2
Tablet 1	50	49.8	49.9	99.3	99.6
Tablet 2	100	99.89	99.79	99.5	99.9

***** Average of six determinations
******Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

CONCLUSION

The proposed methods are simple, selective, and reproducible and can be used in the routine analysis of prulifloxacxin in bulk drug and formulations with reasonable accuracy and precision.

REFERENCES

[1] Bauman RP, Absorption spectroscopy, John Wiley and Sons, New York, 1962, chapter 9.
[2] David G Watson, Pharmaceutical Analysis, 1st edition, Churchill Livingston, Harcourt Publishers limited, 1999.
[3] William O. Foye, Edt., Principles of Medicinal Chemistry, 3rd edition., Varghese, Bombay, 1989.
[4] Denny RC, "A Dictionary of Spectroscopy" 1973, Mac Millon, London.
[5] Ringbom AZ. Anal Chem 1938; 115: 332.
[6] Yoe JH and Jones AL. Ind Engg Chem Analyst 1944; 16: 111.
[7] Validation of analytical procedures text and methodology Q^2 (R1), International conference on harmonization of technical requirements for registration of pharmaceuticals for human use (ICH). November 2005.
[8] United States Pharmacopoiea, 24, national formulary 19, section <225> "validation of compendia methods". US Pharmacopoieal convention, Rockville, 2000.
[9] S.C.Sweetman (Ed.) Martindale- The complete Drug Reference, Pharmaceutical Press London (U.K.), 33rd edition.
[10] European Pharmacopoiea, 3rd Edition, 1997 and Supplement, Council of Europe, Strasburg, 1999.
[11] Skibinski R, Komsta L, Hopkala H, Suchodolska I. Anal Chim Acta 2007 May 8;590(2):195-202.