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(Research Article)

Development and Validation of Spectrophotometric Method for Estimation of Prulifloxacin in Tablet Dosage Forms Using Acetonitrile As a Solvent

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ABSTRACT

A new, simple UV spectrophotometric method has been proposed for the determination of Prulifloxacin in tablet dosage. The drug was soluble in acetonirile as a solvent. Quantitative analysis was performed by densitometric scanning at 278 nm. The method was validated for linearity, accuracy, precision and robustness. The calibration curve was linear over the range 1 to 14 µg/ml for Prulifloxacin. The proposed method is rapid, precise and accurate and can be applied for routine estimation of Prulifioxacin in the laboratory.

Key Words: UV Spectrophotometry, Prulifloxacin, Validation, Calibration curve.

INTRODUCTION

Prulifloxacin (Fig.1) is the lipophilic prodrug of Ulifloxacin, a new thiazeto-quinolone antibacterial agent with broad-spectrum activity against various Gram- positive and Gram-negative bacteria, acts directly on bacterial DNA gyrase inhibiting cell reproduction that leads to cell death. Prulifloxacin has a chemical structure that allows its absorption from the gastrointestinal tract and can therefore administered orally. Its half-life is quite long and the molecule remains in the bloodstream for about 11 hours. This characteristic allows a 600 mg tablet to be administered only once a day, for a very convenient dosing. The active metabolite of Prulifloxacin (Ulifloxacin) is mostly cleared, in an unchanged form, through the urinary tract, thus allowing the drug to be consistently active until its clearance. Literature survey revealed that only a few methods on validation have been reported for quantitative estimation of Prulifloxacin in biological samples and tablet dosage forms. In the present paper, we describe a simple, accurate, precise and sensitive UV spectrophotometric method for determination of Prulifloxacin in tablet dosage forms[1,2].

The standard stock solution of Prulifloxacin was prepared by dissolving 10 mg drug in 100 ml acetonitrile in order to make a concentration of 100 µg/ml. For calibration curve, the standard solutions were prepared by diluting the stock solution with acetonitrile to reach a concentration range 1-14µg/ml for Prulifloxacin. The absorbance was was performed on a Jasco V 630 UV-Visible Spectrophotometer at 278 nm using 1.0 cm quartz cells and were plotted against the corresponding concentrations to obtain the calibration graph (Prulifloxacin showed maximum absorbance at 278 nm (Fig 2.).

To determine the content of Prulifloxacin in conventional tablets (Label Claim : 600 mg Prulifloxacin per tablet), twenty tablets were weighed accurately and finely powdered. A quantity of powder equivalent to 1 tablet of Prulifloxacin was weighed. Equivalent weight of the drug was transferred into a 10 ml volumetric flask containing 10 ml acetonitrile. The mixture was ultra sonicated for 20 min and diluted to the volume with acetonitrile. The solution was filtered using 0.45micron filter (Millipore). Different aliquots of the filtrate were measured for their absorbance[3,4].

VALIDATION OF UV METHOD

The analytical method was validated as per ICH guidlines[5,6] for following parameters:

1. Linearity and range

The response for Prulifloxacin was linear in the concentration range of 1 – 14 µg/ml (Fig. 2)**.** The regression equation calculated by least square method was y = 0.1044x with coefficient of correlation r^2 = 0.9987.

2. Accuracy

To check the accuracy of the method, recovery measurements were performed by the addition of standard drug solution at three different levels (1, 8, 14 µg/ml) to pre-analysed sample solution. Three replicate estimations were carried out for each concentration level as shown in Table 2.

3. Precision

To study intra-day and inter-day precision, three different concentrations (1, 8, 14 µg/ml) of sample solutions were prepared and analysed in triplicate on the same day and on three different days to record intra-day and inter-day variations in the results respectively.

4. Specifity

Specificity is a procedure to detect quantitatively the analyte in presence of component that may be expected to be present in the sample matrix. According to the results obtained by UV Spectrophotometric method is able to access the analyte in the presence of excipients and hence, it can be considered specific. It has been concluded that there was no spectral interaction in the analysis of pharmaceutical preparation of Prulifloxacin. Therefore, calibration curve method was chosen for analysis of drug.

5. Analysis of Marketed Formulation[7]

Experimental results of the amount of Prulifloxacin in tablets, expressed as percentage of label claim were in good agreement with the label claims thereby suggesting that there is no interference from any excipients, which are normally present in tablets. The drug content was found to be 101.14 % for Prulifloxacin.

The method for the estimation of Prulifloxacin in tablet dosage form was developed. Drug shows absorption maximum at 278nm. Spectrophotometric method linear response obtained was in the concentration range of 1-14 µg/ml with correlation coefficient 0.9995, recovery of the drug was found to be 101.14%. The method was statistically validated according to ICH guidelines. The reproducibility, repeatability and accuracy of this method were found to be good evidenced by low standard deviation and newly developed methods can be used for routine analysis of Prulifloxacin in tablet dosage forms.

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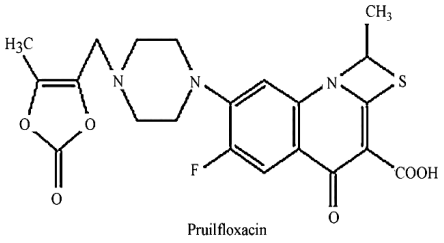

Fig. 1: Chemical structure of Prulifloxacin

Table-1: Data of Calibration curve

Sr. no	Conc. (µg/ml)	Area
1	1	0.124
2	2	0.229
3	4	0.448
4	6	0.636
5	8	0.844
6	10	1.036
7	12	1.242
8	14	1.455

*Average of six determinations.

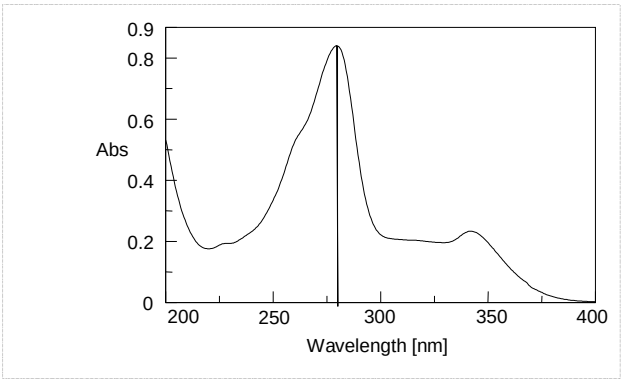

Fig. 2: Spectrum of Prulifloxacin between wavelengths 200nm to 400nm

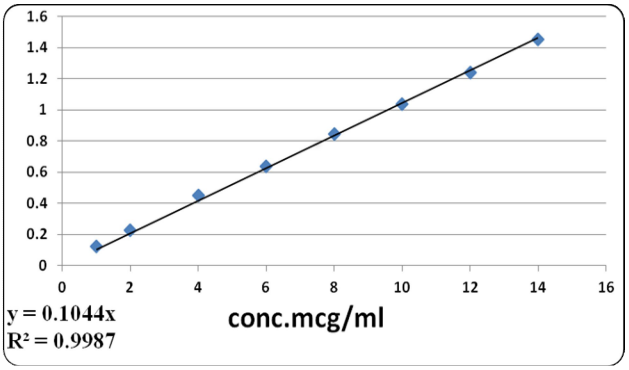

Figure: 3 Calibration Curve of Prulifloxacin

Table-2: Results of Accuracy and Precision

Intraday			
	1µg/ml	8µg/ml	14µg/ml
	0.123	0.840	1.450
	0.122	0.838	1.448
	0.122	0.834	1.448
	0.122	0.838	1.450
	0.123	0.838	1.448
	0.121	0.834	1.449
Mean	0.121667	0.8367	1.4478
Std Dev.	0.000816	0.001633	0.001472
%RSD	0.6706	0.1951	0.1017
%Accuracy	100.64	99.98	99.96
Interday			
	1µg/ml	8µg/ml	14µg/ml
	0.122	0.840	1.450
	0.124	0.835	1.448
	0.124	0.840	1.444
	0.123	0.841	1.449
	0.121	0.841	1.448
	0.122	0.834	1.446
Mean	0.1226	0.8385	1.447
Std Dev.	0.001211	0.002966	0.002422
%RSD	0.9558	0.3539	0.1674
%Accuracy	101.34	100.23	100.12

*Average of six determinations.

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