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Research Article

NEW SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF PRULIFLOXACIN

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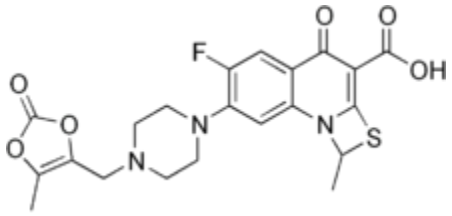
ABSTRACT

New Spectrophotometric methods (A, B and C) are described for the determination of prulifloxacin in pure form. The methods involve the formation of coloured ion pair complexes with 3-methyl-2-benzo thiazoione hydrazine (MBTH) and folin ciocalteu (FC) reagents[2]. The complexes from MBTH with Cerric Ammonium Sulphate(CAS) and FC with sodium carbonate, MBTH with ferric chloride shows absorbance at 630nm,732nm and617nm respectively. The colours were stable for different time intervals after reaction and beers law obeyed in the concentration range of 5 to 40 µg/ml and 2.5-25µg/ml for MBTH with CAS, FC, MBTH with ferric chloride respectively[1]. The molar absorptivities, standard deviation and percent recoveries were evaluated. Results of analysis were validated.

Keywords: Prulifloxacin, UV-Visible spectrophotometer, Validation.

INTRODUCTION

Prulifloxacin is an synthetic chemotherapeutic antibiotic of fluoroquinoline drug class.It is a prodrug which is metabolised in the body to the active compound ulifloxacin[1]. It has been approved for the treatment of uncomplicated and complicated urinary tract infections, community acquired respiratory tract infections and including infectious diarrhoea. The chemical name of prulifloxacin is 6-fluoro-1-methyl-7-[4-(5-methyl-2-oxo-1,3-dioxolen-4-yl)methyl-1-piperazinyl]-4-oxo-4H-[1,3]thiazeto[3,2-α]quinolone-3-carboxylic acid as shown in chemical structure of prulifloxacin in Figure.



Structure of prulifloxacin

The drug is not yet official in any pharmacopoeia. Literature survey reveals HPLC[2-11], UV Spectrophotometric[2,12], Potentiometric[4] and Conductometric[4] methods for the determination of prulifloxacin in biological fluids and pharmaceutical formulations[4]. The proposed spectrophotometric methods are based on the formation of coloured complexes with MBTH, CAS & FC & MBTH, $FeCl_3$.

MATERIALS AND METHODS

Instrument

Spectral and absorbance measurements were made on Systronics UV visible Spectrophotometer (2201).

Reagents

All the reagents used were of analytical grade. Method A-MBTH (0.2%) in water, Cerric Ammonium Sulphate (CAS-1%) in 0.36N H_2So_4.Method B-FC [0.5ml diluted in 0.5ml water (1:1)], Sodium carbonate (10%) .Method C-MBTH (0.2%) in water, ferric chloride [$FeCl_3$(0.5%)]in 0.36N H_2SO_4.

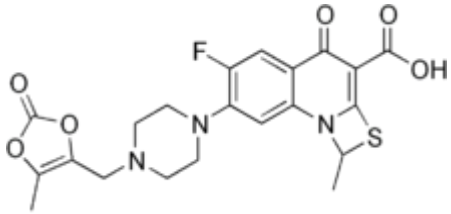
Standard and Sample solution

About 100mg of prulifloxacin was accurately weighed and dissolved in distilled water and made up to 100ml with water. Further dilutions were made with distilled water to get working standard solutions of 100µg/ml.

Assay Procedures

Method –A

Aliquots of working standard prulifloxacin solution (1ml=100µg) ranging from 1-5ml were transferred into series of test tubes. To that add 1mlof CAS wait for 2min then add 1ml of MBTH then shake it thoroughly and the total volume was brought to 10ml with distilled water and the absorbance was measured at 630nm.

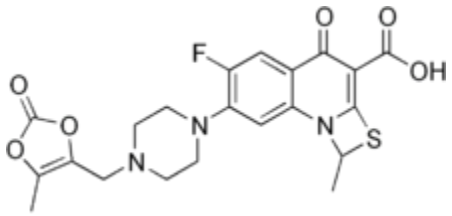


+ CAS +MBTH measured at 630nm

Method –B

Aliquots of working standard prulifloxacin solution (1ml=100µg) ranging from 0.5-2.5ml were transferred into series of test tubes. To that add 0.5ml of FC reagent and then 1ml of 10% sodiumcarbonate. Keep aside for 1min and the total

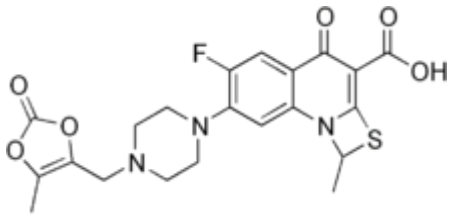
volume was brought to 10ml with distilled water and the absorbance was measured at 732nm.



+Fc +Na_2CO_3 measured at 732nm

Method- C

Aliquots of working standard prulifloxacin solution (1ml=100µg) ranging from 1-5ml were transferred into series of test tubes. To that add 1ml of $FeCl_3$ wait for 2min then add 1ml of MBTH then shake it thoroughly and the total volume was brought to 10ml with distilled water and is kept aside for 20min till the reaction is completed and the absorbance was measured at 617nm.



+ $FeCl_3$+ MBTH measured at 617nm

RESULTS AND DISCUSSION

The optical characteristics such as beers law limit, sandal sensitivity, molar extinction coefficient, stability of coloured species, percent relative standard deviation (calculated from samples containing 3/4th amount of the upper beers law limits of prulifloxacin in each method), percent range of error (0.05 and 0.01 confidence limits), correlation coefficient, slope and intercept of regression analysis using least square method were calculated and summarised in the table.

Table: Optical Characteristics and Precision

Parameters	Method A	Method B	Method C
Beer's Law Limit	2.5-25µg/ml	2.5-25µg/ml	2.5-25µg/ml
Sandal Sensitivity	0.00806	0.00431	0.00949
Molar Extinction Coefficient	$10.473x10^3$	$1.015x10^3$	$11.073x10^3$
% RSD	46.53	60.02	48.76
% Range of Error 0.05 Confidence limits 0.01 Confidence Limits	 ±0.5010 ±0.6825	 ±0.3656 ±0.5869	 ±0.3733 ±0.5010
Correlation Coefficient(r)	0.99	0.98	0.99
Regression Equation(Y) Slope(a) Intercept(b)	0.0422+0.107x 0.107 0.0422	0.0464+0.2904x 0.2904 0.0464	0.020+0.1036x 0.1036 0.020

Y= b+ax Where X is the concentration in µg/ml, Y is the concentration at specific λ_{max}

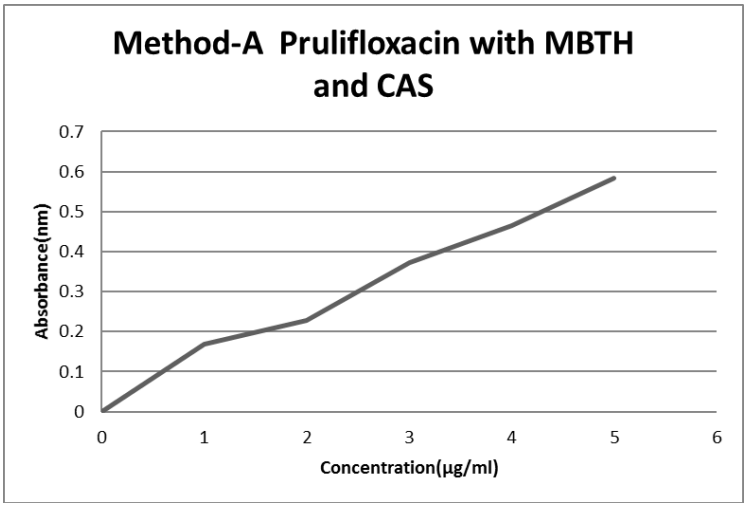


Figure 1

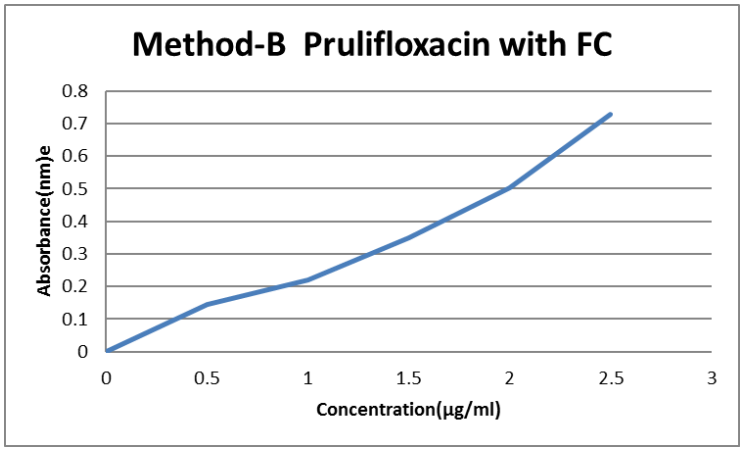


Figure 2

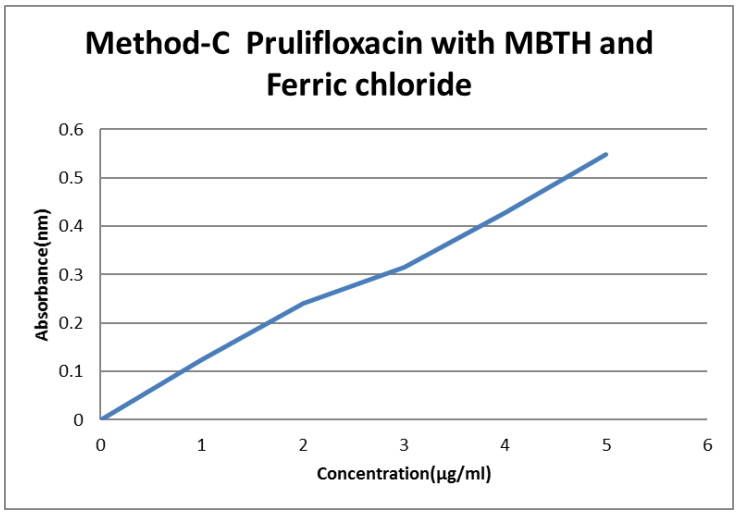


Figure 3

CONCLUSION

A Novel UV visible spectrophotometer method for quantitative determination of prulifloxacin in bulk form is established. This method is simple, reliable, linear, accurate, sensitive and reproducible as well as economical for the effective quantitative analysis ofprulifloxacin. The method was completely validated showing satisfactory data for all the method validation parameters tested. Therefore, the method is suitable for use for the routine analysis of Prulifloxacin.

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