Asian Journal of Chemistry Vol. 20, No. 7 (2008), 5223-5228

Simple Spectrophotometric Methods for the Estimation of Ofloxacin in Dosage Forms

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For the estimation of ofloxacin from dosage forms two simple, sensitive, visible and UV spectrophotometric methods were developed. The visible method is based on the formation of an amber coloured complex with ferric chloride. The coloured product is quantitated spectrophotometrically at 381 nm and was found to obey the Beer's law in the concentration range of 12-50 μg mL^{-1}. The UV method is based on the ionization of ofloxacin in acid medium and the maximum absorption was found at 291 nm and obeyed the Beer's law in the concentration range of 2-10 μg mL^{-1}. Both the proposed methods were applied for estimation of different ofloxacin tablets and infusion with mean percentage accuracies of 103.2 ± 4.1, 104.4 ± 2.2, 99.6 ± 3.08 and 99.9, respectively with visible spectrophotometric method and 101.0 ± 0.916, 99.03 ± 1.65 and 99.36 ± 1.04, respectively with UV spectrometric method.

Key Words: Ofloxacin, Spectrophotometry, Ferric(III) chloride.

INTRODUCTION

Ofloxacin is one of the most promising newer members of the fluoroquinolone family of antibacterials. Several methods were reported for the determination of this drug[1-4]. Oflaxacin is official in the USP[5]. The method of analysis for the bulk drug is based upon non-aqueous titration[5]. From the review of the literature, it is evident that there is a need to develop a simple and sensitive method(s) for the estimation of ofloxacin from its dosage forms. An attempt has been made to develop two simple, sensitive, quick and economic methods for the determination of ofloxacin in pharmaceutical dosage forms using visible and UV spectrophotometric techniques.

EXPERIMENTAL

Beckman DU 64 single beam spectrophotometer with 10mm quartz cell attached to a scanning speed of 250 nm/min was employed for all absorbance measurements.

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Ofloxacin USP was a gift. Ferric(III) chloride (anhydrous) (A grade, Merck), Lactose, (Merck), Di-calciumphosphate (Merck), sodium starch glycoate IP (Merck), Starch (Merck), ethylcellulose (CDH), polyvinyl pyrrolidine K30 (SRL), zanocin (Ranbaxy), oflamed (Aglowmed. Ltd) and of (J.B.Chemicals & Pharmaceuticals Ltd.) were purchased from local pharmacy. Hydrochloric acid (0.1 N) (Merck) solutions was prepared using double distilled water. Ferric(III) chloride anhydrous solution (1 % w/v) was prepared freshly by dissolving the appropriate amount in distilled water.

Method A (Visible method)

Preparation of standard curve: 0.1 N HCl was used to prepare a solution of ofloxacin (125 μg/mL). From this solution, varying volumes (10-40 mL) were transferred into 100mL volumetric flasks so as to obtain in concentration in the range 12.5-50 μg/mL. Freshly prepared 1 % w/v ferric chloride solution (1 mL) was added to each of the flasks and the contents were shaken and made up to volume with 0.1 N HCl in each case. The absorption spectra of the above solutions were recorded between 350-450 nm against a blank using a 10 mm Quartz cell in a Beckman DU64 single beam spectrophotometer. The observed values of the ΔA were then plotted against the concentrations to obtain the calibration curve.

Determination of drug content in tablet dosage form using method A: 10 Tablets of each of the three-marketed preparations of ofloxacin were weighed separately and finely powdered using a mortar and pestle. A quantity equivalent to 20 mg of ofloxacin from the powdered tablets was taken in a 100 mL volumetric flask and about 80 mL of 0.1 N HCl was added to it and the contents shaken. Then the volume was made up with 0.1 N HCl and the contents were filtered through Whatmann filter paper no. 1. The varying volumes (10, 15 and 20 mL) of above solutions were transferred into different 100 mL volumetric flasks. Freshly prepared 1 % w/v ferric chloride solution (1 mL) was added to each of the flasks, the contents shaken and made up to volume with 0.1 N HCl. From the absorbance values the drug content was determined.

Determination of drug content in ofloxacin infusion using method A: 10 mL of ofloxacin infusion (20 mg equivalent) was transferred to a 100 mL volumetric flask and made up to volume with 0.1 N HCl. Varying volumes (10, 15 and 20 mL) of the above solution was transferred into different 100 mL volumetric flasks. Then 1 mL of freshly prepared 1 % w/v ferric chloride solution was added to each of the flasks, the contents shaken and made up to volume again with 0.1 N HCl. From the absorbance values, the drug content of ofloxacin infusion was determined.

Method B (UV spectrophotometric method)

Preparation of standard curve: 20 mg of pure drug ofloxacin USP was dissolved in 100 mL of 0.1 N HCl. From the above solution, 10 mL was transferred into a 100 mL volumetric flask and made up volume with doubled distilled water to obtain a concentration of 20 μg/mL. Varying volumes (1-4 mL) of the above solution were transferred into different 10 mL volumetric flasks and made up to volume with double distilled water, so as to obtain concentration in the range 2-10 μg/mL. The absorption spectra of the above solutions were recorded in the wavelength range of 250-300 nm against the blank. The absorbances obtained were plotted against the corresponding concentrations to obtain the calibration curve.

Determination of drug content in tablet dosage form: 10 Tablets of each marketed preparation of ofloxacin were weighed and finely powdered using mortar and pestle. A quantity equivalent to 20 mg of ofloxacin from the powdered tablets was taken in a 100 mL volumetric flask and about 80 mL of 0.1 N HCl was added to it and the contents shaken. The volume was made up with 0.1 N HCl and the contents were filtered using Whatmann filter paper no. 1. From above solution, 10 mL was transferred into a 100 mL volumetric flask and made up to volume with double distilled water. Varying volumes (1, 2 and 3 mL) of each drug solutions were transferred into different 10 mL volumetric flasks and made up to volume with double distilled water. From the absorbance values, the drug content was determined.

Determination of drug content in ofloxacin infusion using method B: 10 mL of ofloxacin infusion (20 mg equivalent) was transferred to a 100 mL volumetric flask and diluted to volume with 0.1N HCl. From above solution, 10 mL was transferred into a 100 mL volumetric flask and made up to volume with double distilled water. Varying volumes (1, 2 and 3 mL) of the above drug solution were transferred into different 10 mL volumetric flasks and made up to volume with double distilled water. From the absorbance values, the drug content was determined.

Determination of drug in the presence of additives: 20 mg of ofloxacin USP and starch (tablet additive) were taken in a 100 mL volumetric flask. 0.1 N HCl was added, contents mixed and filtered. The drug content was estimated in a similar manner to that of as mentioned in the determination of drug content in tablet dosage forms of **method A** and **B**.

The same method as mentioned above was employed with other tablet additives such as lactose, dicalcium phosphate, sodium starch glycoate, ethylcellulose and polyvinyl pyrrolidine K30.

Validation of the methods: To validate the proposed methods, recovery studies were performed. Solutions containing a known amount of ofloxacin were added to a specified volume of the solution prepared for the determination of drug content for ofloxacin tablets. The amount of ofloxacin present in the above mixture was determined and the percentage recovery calculated.

Statistical analysis: The experimental results were expressed as mean ± SD analysis of variance was performed by Anova procedures (SSPS 9.0 for Windows).

RESULTS AND DISCUSSION

Compound with a -C=O and -COOH groups are capable of forming complexes[6] (Fig. 1). In case of ofloxacin, formation of similar complexes with a trivalent Fe^{3+} ion can form the basis for its spectrophotometric determination.

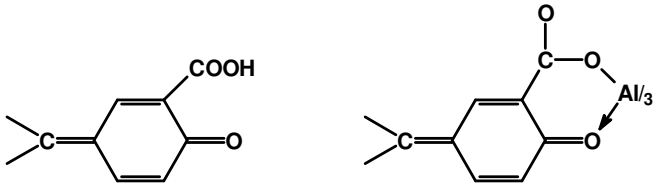

Fig. 1

For the visible method, the amber coloured complex between ferric ions and the ofloxacin was formed instantaneously at room temperature upon mixing the solutions. The complex formed was stable upto 24 h for the quantitative determination as a result of possible complexation between ofloxacin and ferric ion which obeyed Beer's law at the λ_{max} of 381 nm within a concentration range of 12-50 µg/mL. Linear regression equation was also obtained for the same. Thus, the above-mentioned coloured complex could be used for the determination of ofloxacin.

Studies undertaken using tablet additives such as lactose, dicalcium phosphate, sodium starch glycoate, starch, ethylcellulose, polyvinyl pyrrolidine K30, indicate that they did not interfere with the estimation of ofloxacin for both the visible and UV method.

The applicability of the proposed methods was tested by the determination of ofloxacin in commercially available tablets and infusion. The study was carried out on the same batch of samples and the results obtained are presented in Table-1.

The advantage of the visible method is that it is both quick and simple. For the UV spectrophotometric method compliance with Beer's law at the λ_{max} 293 nm and linear regression equation was obtained over a concentration range of 2-10 µg/mL.

Mean recovery percentages of the three ofloxacin concentrations in tablets and infusion were found to be 98.5, 99.4, 98.4 and 99.26, respectively [n = 3] in visible method and 98.8, 98.9, 99.2 and 99.9, respectively [n = 3] in UV method (Table-2).

TABLE-1
ESTIMATION OF OFLOXOCIN FORM TABLET DOSAGE FORM

	Visible absorption				UV absorption		
Name of the tablet	Claim as per label (mg)	Amount estimated (mg)	Mean ± SD	SE	Amount estimated (mg)	Mean ± SD	SE
Oflamed	200	201.4)	207.033 ± 9.15	5.2872	199.4	199.4 ± 1.00	0.5774
	200	217.6			198.4		
	200	202.1			200.4		
Zanocin	200	214	210.00 ± 4.58	2.6458	194.4	198.06 ± 3.30	1.9055
	200	205			199		
	200	211			200.8		
Of	200	195.7	198.36 ± 6.15	3.5507	200.4	202.0 ± 1.8	1.05
	200	194			201.6		
	200	205.4			204		
Zanocin infusion	200	199.0	199.9 ± 1.30	0.7549	198.1	198.73 ± 4.3	2.81
	200	199.3			203.9		
	200	201.4			194.2		

TABLE-2
REPEATED ESTIMATION OF OFLOXOCIN FROM THE TABLETS FOR VALIDATION OF ANALYTICAL METHOD A (VISIBLE) & B (UV) n = 3

	Visible		UV	
Name of the tablet	Recovery % Mean ± SD	Std. Error	Recovery % Mean ± SD	Std. Error
Oflomed (200 mg)	98.5±1.00	0.5774	98.8667±0.450	0.2603
Zanocin (200 mg)	99.4±1.64	0.9504	98.9000±0.529	0.3055
Of (200 mg)	98.4±1.73	1.0017	99.2667±0.404	0.2333
Zanocin infusion	99.26±0.404	0.2330	99.9±0.53	0.3050

The results show that both the methods are accurate, precise, very simple and statistically significant results where obtained for both the visible method and UV spectrophotometric method.

ACKNOWLEDGEMENT

One of the authors, B. Krishnamoorthy thankful to AICTE, New Delhi, India for providing financial assistance to this work.

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(*Received*: 25 June 2007; *Accepted*: 15 April 2008) AJC-6525