UV Spectroscopic and Colorimetric Methods for the Estimation of Gatifloxacin in Tablet Dosage Forms

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Two simple and sensitive spectroscopic methods in ultra violet and visible region, were developed for the estimation of gatifloxacin in pharmaceutical dosage forms. Method A is based on gatifloxacin, showing absorption maximum at 295 nm, in methanol. The method B is based on the reaction of gatifloxacin, with 0.2% w/v 3-methyl-2-benzthiazolinone hydrazone reagent in presence of 1% w/v ferric chloride solution, to yield a yellow orange colour. This colour has a characteristic light absorption in the visible region, with absorption maximum at 433 nm. These methods obey Beer's law in the concentration range of 2 to 10 µg/ml and 50 to 150 µg/ml, respectively. The proposed method is precise, accurate, and reproducible, and can be extended to the analysis of gatifloxacin in tablet formulations.

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Chemically, gatifloxacin is (±) 1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(3-methyl-1-piperazinyl)-4-oxo-3-quinolinecarboxylic acid sesquihydrate[1]. It is a synthetic broad-spectrum 8-methoxyfluoroquinolone antibacterial drug, used in the treatment of community-acquired pneumonia, acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and complicated and uncomplicated urinary tract infections. It acts intravenously by inhibiting topoisomerase II (DNA gyrase) or topoisomerase IV[2]. It is not official in any pharmacopoeia. A survey of literature, reveals that gatifloxacin has been estimated in plasma by HPLC, LC-MS and HPTLC[3-6] methods. No spectrophotometric methods are cited in the literature. We report two simple and sensitive spectrophotometric methods for the analysis of gatifloxacin from pharmaceutical dosage forms.

A Systronic UV/ Visible spectrophotometer model 119 with 1 cm matched quartz cell, was used for all the absorbance measurements. All the reagents used were of analytical grade. Aqueous solution of MBTH (0.2% w/v) and ferric chloride (1% w/v) were prepared freshly. A standard solution of gatifloxacin containing 1 mg/ml, was prepared by dissolving pure 100 mg gatifloxacin in 100 ml of methanol for method A, and distilled water for method B. It was further diluted to a concentration of 1 μg/ml for method A, and 100 μg/ml for method B.

In method A, aliquots of working standard gatifloxacin (1 to 5 ml) solutions were transferred into a series of 10 ml volumetric flask, and the volume was made up to 10 ml with methanol. The absorbance of each solution was measured at 295 nm against methanol as blank.

In method B, aliquots (0.5 to 3 ml) of the solutions were taken into 10 ml volumetric flasks, and 1 ml of ferric chloride solution was added, followed by 1 ml of MBTH reagent, and kept aside at room temperature for 10min. The absorbance of the resulting yellow orange colour chromogen was measured at 433 nm against the reagent blank.

Twenty tablets of gatifloxacin (Gatiquin 200 mg tablets from Cipla, Ahmedabad and Gaity 200 mg tablets from Dr. Reddy's Labs, Hyderabad), were weighed accurately and powdered. The amount of powder equivalent to 100 mg of gatifloxacin, was weighed and dissolved in respective solvents to make 100 ml, and filtered through Whatmann filter paper No. 41. The filtrate was further diluted to 1 μg/ ml for method A, and 100 μg/ml for method B. The amount of gatifloxacin present in tablets were estimated by interpolation, from the calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar absorptivity, and correlation coefficient for the proposed two methods, are summarised in Table 1. The recovery studies were carried out to ascertain the accuracy and precision of the proposed method, by adding a known amount of standard solution at three levels to the previously analyzed sample solution, and the absorbance was measured. The results obtained by the proposed methods were in good agreement with the labeled amount (Table 2).

In method A, gatifloxacin exhibited λmax at 295nm in methanol. Method B is based on the structure of gatifloxacin, the piperazine nitrogen, that may be subjected to oxidation to form stable nitroxides, which gives a yellow orange complex with MBTH reagent. Stability of the colour complex was determined by measuring absorbance of the chromogen at specified time intervals, and was found to be stable for 2hr. These results indicate, that the proposed methods are simple, sensitive, accurate, and reproducible, and can be employed for routine quality control analysis of

TABLE 1: OPTICAL CHARACTERISTICS AND PRECISION

Parameters	Method A	Method B
Absorption maxima	295 nm	433 nm
Beer's law limit (μg/ml)	2 to 10	50 to 150
Molar absorptivity (l/mol/cm)	3.069×10^4	2.293×10^{-3}
Sandell's Sensitivity (μg/cm²/0.001)	0.0122	0.164
Regression equation (Y = mx+C)		
Slope (m)	8.01×10^{-2}	5.6×10^{-3}
Intercept (C)	6.9×10^{-3}	4.4×10^{-2}
Correlation coefficient (r)	0.9997	0.9994

TABLE 2: ANALYSIS OF GATIFLOXACIN FORMULATION BY PROPOSED METHODS

Formulations	Label claim (mg)	Amount estimated*(mg)		% Recovery*	
		Method A	Method B	Method A	Method B
Tablet 1	200	198±0.04	201± 0.05	99.7±0.6	99.8±0.3
Tablet 2	200	198±0.07	201± 0.08	99.5±0.7	99.8±0.5

*Values are Mean+SEM of five determinations. Tablet 1 is Gatiquin 200 mg tablets from Cipla, Ahmedabad and Tablet 2 is Gaity 200 mg tablets from Dr. Reddy's Labs, Hyderabad.

gatifloxacin in bulk and dosage forms.

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