Spectrophotometric Estimation of Gatifloxacin in Tablets

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A simple, sensitive, rapid, accurate, and precise spectrophotometric method has been developed for estimation of gatifloxacin in pharmaceutical dosage forms. The method is based on formation of orange coloured chromogen due to reaction of gatifloxacin with ferric nitrate reagent solution, which exhibits maximum absorption at 470 nm against blank. Stability of chromogen was found up to 1 h, and chromogen obeyed linearity over 20-200 µg/ml.

Gatifloxacin (1-cyclopropyl-6-fluoro-1,4-dihydro-8methoxyl-7-(3-methyl-1-piperazinyl)-4-oxo-3quinolinecarboxylic acid)¹ is a fluoroquinolone antibacterial agent. It is widely used in the treatment of urinary tract infection, acute bacterial sinusitis, communityacquired pneumonia, and acute bacterial exacerbation of chronic bronchitis². Gatifloxacin is an antibacterial drug having selective antimicrobial activity against *Streptococcus pneumoniae* and penicillin-resistant *Pneumococci*. It is also active against anaerobic pathogen, *Bacteriodes fragilis*, and mouth anaerobes³. It is available in the tablet form and not official in any Pharmacopoeia. Literature survey reveals that the drug has been analysed by spectrophotometric methods⁴ and HPLC, HPTLC and LC-MS from its formulation and in biological fluids⁵⁻⁷.

The present work describes simple, rapid, accurate, and precise spectrophotometric method for the estimation of gatifloxacin based on formation of orange coloured chromogen due to reduction of ferric nitrate reagent by gatifloxacin, which shows maximum absorption at 470 nm. Literature survey reveals that ferric nitrate reagent can be used successfully for colorimetric estimation⁸.

Shimadzu 1700 UV spectrophotometer with 1 cm matched couvettes was used for estimation. Standard solution of drug was prepared in distilled water (1000 μ g/ml). Ferric nitrate reagent was prepared in 5% nitric acid (5% w/v). Twenty tablets of gatifloxacin were weighed and powdered in glass mortar. Amount equivalent to 100 mg was transferred to 100 ml volumetric flask, dissolved,

sonicated for 30 min and made up to the volume with distilled water and used as sample solution. Aliquots of 0.2 to 2.0 ml portions of standard solution were transferred to a series of 10 ml Corning test tubes; 0.5 ml of ferric nitrate reagent was added. The solution was kept for 2 min to complete the reaction, and volume in each test tube was adjusted to 10 ml with distilled water. The absorbance of the solutions was measured at 470 nm against reagent blank and calibration curve was constructed. Similarly, absorbance of sample solution was measured and amount of gatifloxacin was determined by referring to the calibration curve. Recovery studies were carried out by adding a known quantity of pure drug to the preanalyzed formulation, and the proposed method was followed. From the amount of drug found, percentage recovery was calculated.

The proposed method is based on redox reaction in which gatifloxacin is oxidized by ferric nitrate. The determination of gatifloxacin showed molar absorptivity of 1.991×10³ l/mol.cm and Sandell's sensitivity 0.1878 µg/cm²/ 0.001 absorbance unit. Linear regression of absorbance on concentration gave the equation y = 0.0154+0.0053xwith a correlation coefficient of 0.9995. Relative standard deviation of 0.0016 was observed for analysis of six replicate samples, indicating precision and reproducibility. Gatifloxacin exhibits its maximum absorption at 470 nm and obeyed Beer's law 20-200 µg/ml. The results of analysis and recovery studies are presented in Table 1. The percentage recovery value 99-99.5% indicates that there is no interference from the excipients present in formulation. The developed method was found to be sensitive, accurate, precise, and reproducible and can be used for the routine quality control analysis of gatifloxacin in bulk drug and formulations.

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Formulations	Label claim	Amount found ^a (mg)				% Recovery
	(mg)	Proposed method	C.O.V.	S.E.	Reference method*	
Gatilox (Sun Pharma)	400	399.24±0.49 t = 2.02 F = 1.21	0.49	0.24	398.60±0.54	99.07
Gatispan (Lupin)	200	199.48±0.46 t = 1.75 F = 1.18	0.46	0.23	198.95±0.50	99.35

TABLE 1: RESULTS OF ANALYSIS AND RECOVERY STUDIES

^aAverage \pm SD of four determinations. SE: Standard Error. COV: Coefficient of Variation. The t- and F- values refer to comparison of the proposed method with the reference method. Theoretical values at 95% confidence limits, t = 2.31, F = 10.29, *Spectrophotometric method (λ_{max} : 455 nm is 1% w/v ferric ammonium sulphate)

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