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*NOTE*

# Extractive Spectrophotometric Determination of Gatifloxacin

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Three simple and sensitive extractive spectrophotometric methods (A–C) have been developed for the determination of gatifloxacin (GTL) in bulk drug and pharmaceutical formulations. The developed methods involve formation of coloured chloroform extractable complexes of drug with wool-fast blue BL (WFB BL $\lambda_{max}$ 590 nm, Tropaeolineooo ($Tp_{000}$, $\lambda_{max}$ 480nm) and bromo phenol blue (BPB $\lambda_{max}$ 420 nm) in acidic medium. Beer's law is obeyed in the concentration ranges of 1–6 μg/mL, 1–6 μg/mL and 2–10 μg/mL respectively. The results of analysis for all three methods have been validated statistically and by recovery studies.

**Key Words: Spectrophotometric determination, Gatifloxacin.**

Gatifloxacin (GTL)[1] is a synthetic broad-spectrum 8-methoxyfluoroquinolone antibacterial agent for oral, intravenous administration and chemically known as 1-cyclopropyl - 6-fluoro - 1,4-dihydro - 8-methoxy - 7-(3-methyl-1-piperazinyl)-4-oxo-3-quinoline carboxylic acid sesquihydrate. A number of methods such as HPLC[2–4] were reported for the estimation of GTL. Literature survey reveals that visible spectrophotometric methods are not reported for its quantitative determination in bulk drug and pharmaceutical formulations. In the present investigation, three simple and sensitive extractive spectrophotometric methods (A–C) have been developed for the determination of GTL in bulk drug and pharmaceutical formulations. The developed methods involve the formation of coloured chloroform extractable complexes of drug with WFB BL, $Tp_{000}$ and BPB in acidic medium. Extractable complexes showed absorption maximum at 590, 490 and 420 nm respectively. Beer's law is obeyed in the concentration ranges of 0.5–3.0 μg/mL, 0.5–3.0 μg/mL and 0.5-3.0 μg/mL respectively. The result of analysis for all three methods has been validated statistically and by recovery studies.

**Preparation of reagents:** Aqueous solutions of WFB BL (Fluka, 0.2%, $3.26 \times 10^{-3}$ M), $Tp_{000}$ (Fluka, 0.2%, $5070 \times 10^{-3}$ M) and BPB (Fluka, $3.25 \times 10^{-3}$

M), glycine-HCl buffer solution of pH 1.5 (method A) and 0.1 M HCl (methods B and C) were prepared.

Spectral and absorbance measurements were made on Systronics UV-Vis spectrophotometer 117 with 10 mm matched quartz cells.

**Preparation of standard drug solutions:** A 1 mg/mL solution was prepared by dissolving 100 mg of pure GTL in 100 mL of distilled water and this stock solution was diluted stepwise with distilled water to obtain the working standard solutions of concentrations 50 μg/mL for methods A and B and 100 μg/mL for method C.

**For pharmaceutical formulations:** Tablet powder equivalent to 100 mg of GTL was accurately weighed and dissolved in chloroform and filtered for methods A, B and C; the filtrate was evaporated to dryness and the residue was dissolved in 100 mL of distilled water to achieve a concentration of 1 mg/mL, from which suitable dilutions were performed for methods A, B and C as mentioned above.

**Recommended Procedures**

Methods A, B and C: Aliquots of standard GTL solution (0.5 to 3.0 mL, 50 μg/mL for methods A and B and 0.5 to 2.5 mL, 100 μg/mL for method C) were placed in a series of 125 mL separating funnels; 6.0 mL of buffer solution (pH 1.5 for method A), 0.1 M HCl (methods B and C) and 2.0 mL of dye solution WFB BL (method A), $Tp_{000}$ (method B) and BPB (method C) were added. The total volume of aqueous phase in each separating funnel was adjusted to 15 mL with distilled water and 10.0 mL of chloroform was added. The contents were shaken for 2 min. The two phases were allowed to separate and absorbances of the separated organic layers were measured at 590 nm (method A), 490 nm (method B) and 420 nm (method C) against a similar reagent blank similarly prepared within the stability period (1–60 min) at laboratory temperature (28 ± 5°C). The amount of GTL in methods A, B and C was computed form their respective calibration curves.

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table-1. The % RSD and % range error (0.05 level of confidence limit) calculated from six measurements containing 3/4 amount of upper Beer's law limit of GTL are given in Table-1.

The values obtained from the determination of GTL in pharmaceutical formulations (tablets) by the proposed and UV methods are computed in Table-2. To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to the previously analyzed pharmaceutical formulations and the mixtures were analyzed by the proposed methods. The recoveries (average of six determination) are given in Table-2. Interference studies revealed that the common excipients and the additives usually present in the dosage forms did not interfere in the proposed methods.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION

| Parameters | Method A | Method B | Method C |
|---|---|---|---|
| $\lambda_{max}$ (nm) | 590 | 480 | 420 |
| Beer's law limit (μg/mL) | 0.5–3.0 | 0.5–3.0 | 0.5–3.0 |
| Sandell's sensitivity (μg/cm$^2$/0.001 abs. unit) | 0.0123 | 0.01162 | 0.0145 |
| Molar absorptivity (L mole$^{-1}$ cm$^{-1}$) | $3.259 \times 10^4$ | $3.46 \times 10^4$ | $2.776 \times 10^4$ |
| Regression equation (Y*) | | | |
| Slope (b) | 0.0802 | 0.0886 | 0.0702 |
| Intercept (a) | 0.0001 | –0.0021 | –0.0005 |
| Correlation coefficient (r) | 0.9996 | 0.9991 | 0.9997 |
| % RSD | 0.5819 | 0.5146 | 0.6068 |
| % Range of error (0.05 level confidence limit) | ±0.6100 | ±0.5400 | ±0.6370 |

Y = a + bX where X is the concentration of gatifloxacin in μg/mL and Y is the absorbance at the respective $\lambda_{max}$.

TABLE-2

| Sample* (tablets) | Labeled method (mg) | Amount obtained (mg) | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | UV* Method | Proposed method | | | Recovery (%) | | |
| | | | A | B | C | A | B | C |
| T1 | 200 | 198.32 | 199.2 | 198.64 | 199.4 | 99.6 | 99.3 | 99.7 |
| T2 | 400 | 398.7 | 398.8 | 398.6 | 398.2 | 99.7 | 99.6 | 99.5 |

*Tablets from different manufacturers.

## Conclusion

The proposed methods are applicable for the assay of drug (GTL) and have an advantage of wider range, under Beer's law limits. The proposed methods are simple, selective and reproducible and can be used in the routine determination of GTL in bulk samples and formulations with reasonable precession and accuracy.

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