IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, July 2025
Impact Factor: 7.67

RP-HPLC Method Development and Validation for Simultaneous Determination of Loteprednol Etabonate and Gatifloxacin in Bulk and its Pharmaceutical Dosage Form

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Abstract: *The simultaneous measurement of loteprednol etabonate (LOTE) and Gatifloxacin (GATI) in bulk and pharmaceutical dose forms was accomplished through the development and validation of a straightforward, quick, accurate, and precise reversed-phase high-performance liquid chromatographic (RP-HPLC) method. A Grace C18 column (4.6 × 250 mm, 5 µm) was used for the chromatographic separation. Acetonitrile and phosphate buffer (65:35, pH 4) were used as the isocratic mobile phase, and the flow rate was set at 1.0 mL/min. The wavelength of detection was 271 nm. It was discovered that the retention durations for GATI and LOTE were 4.21 and 7.13 minutes, respectively. With recovery percentages ranging from 98 to 102%, the approach demonstrated good accuracy and high precision, with relative standard deviation (RSD) values < 2%. The LOTE and GATI had respective limits of detection (LOD) and quantification (LOQ) of 0.981 µg/mL and 2.78 µg/mL and 0.865 µg/mL and 1.68 µg/mL. The technique demonstrated specificity, robustness, and reproducibility after being validated in accordance with ICH criteria. As such, it can be used for routine quality control analysis of LOTE and GATI in combination ophthalmic formulations. Simple, economical, and quick analysis without interference from excipients or degradation products are benefits of the developed method.*

Keywords: Gatifloxacin, Loteprednol etabonate, RP-HPLC, Validation

DOI: 10.48175/IJARSCT-28320