

Development and validation of microbiological method for analysis of gemifloxacin mesylate in pharmaceutical formulation

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ABSTRACT:

The gemifloxacin mesylate is a fourth generation synthetic broad spectrum fluorinated quinolone antibacterial agent for oral administration indicated for infections caused by gram-positive and gram-negative micro-organisms. Although this drug is studied and researched regarding the antimicrobial activity, pharmacokinetics and pharmacodynamics, there are few studies regarding the development of analytical methodology for this antibiotic. This study describes the development and validation of a microbiological analytical method using the turbidimetric method for the determination of gemifloxacin mesylate in tablets, using *Staphylococcus epidermidis* NCIM 2493 as test micro-organism and compared with an HPLC method which was optimized to the system and partially validated according to ICH guidelines. The developed and validated method showed excellent results of linearity, precision and robustness, in the concentration range from 0.5 to 4.5 µg/mL.

The microbiological analytical method which was developed can be used for routine quality control analysis of gemifloxacin mesylate in dosage forms.

KEYWORDS: Gemifloxacin ; Fluoroquinolone; Microbiological assay; HPLC; Turbidimetric method.