

MICROBIOLOGICAL ASSAY FOR DETERMINATION OF LEVOFLOXACIN INJECTION

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Levofloxacin is a highly active fluoroquinolone antibiotic used in the treatment of bacteria infections. The present work reports the development and validation of a stability indicating microbiological assay, applying the cylinder-plate method, for the determination of levofloxacin fluid for injection. The microbiological assay can be an alternative method to HPLC. This assay can reveal subtle changes not demonstrable by conventional chemical methods. Moreover, microbiological assay requires not only no specialized equipment but also no toxic solvents. The method was validated by determination of the following operation characteristics; linearity, precision and accuracy. Using a strain of *Staphylococcus epidermidis* ATCC 12228 as the test organism, levofloxacin at concentrations ranging from 2.0 to 8.0 µgml⁻¹ could be measured in injection. The results of assay were treated statistically by analysis of variance (ANOVA). A prospective validation of the method demonstrated that the method was linear ($r^2 = 0.9996$), precise (intra-assay: R.S.D. = 1,32; inter-assay: R.S.D.= 1,52) and accurate. The method shows results that confirm its precision, not differing significantly the other method described in the literature. The microbiological assay is satisfactory for quantitation of in vitro antibacterial activity of levofloxacin. The method uses simple preparation procedures, encouraging its application in routine analysis