Initial Quality Control Ranges for Delafloxacin Using a CLSI Multi-Laboratory M23-A3 Study Design

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ABSTRACT

Background: Delafloxacin (DX) use is anticipated for various settings including outpatient and post-operative settings. The objective of this study was to develop DX quality control specifications to be utilized in the clinical laboratory setting for DX use in settings similar to inpatient and ambulatory care. Delafloxacin DX is a fluoroquinolone with an extended spectrum of activity and confirmed anti-MRSA activity. The susceptibility of several Gram-negative and Gram-positive pathogens were assessed.

Methods: An international DX susceptibility testing collaborative study was conducted in three blinded laboratories using the Clinical and Laboratory Standards Institute (CLSI) broth microdilution method with standard broth dilution susceptibility disks. Antimicrobial discs were prepared for different concentrations and evaluated for both USP and CLSI methods. The study was powered to assess the differences in susceptibility testing of the same strains in each laboratory participating.

Results: The study showed that DX susceptibility testing was accurate and comparable when performed using different methods and concentrations. Each concentration of DX was shown to have a different level of activity against the same strains. The susceptibility of DX against Gram-negative bacteria was found to be significantly higher than that against Gram-positive bacteria.

Conclusions: The results of this study indicate that DX susceptibility testing is reliable and reproducible across different laboratories and methods. The DX quality control specifications developed in this study can be used to ensure accurate and consistent DX testing in clinical laboratories.

REFERENCES


