Determination of Disk Diffusion and MIC Quality Control Ranges for BC-2781 using MLS-Multi-Laboratory M23-As Study Design

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ABSTRACT

We developed side-diffusion (SC) and MLS-Multi-Laboratory M23-As Study Design (MLS-M) for the determination of an investigational pneumococcal, BC-2781, against 48 organisms.

METHODS: Sixteen studies followed the MLS-M23-As protocol (2008-2009). MLS-M23-As included on average 15 lots/microdilution MIC determinations/strain. BC-2781 was tested with 3 or more media lots and 3 control antibiotics. MLS-M23-As also included subculturing. MLS-M23-As was used to develop the Clinical and Laboratory Standards Institute (CLSI) M23-As2 document.

RESULTS: The MLS-M23-As QC ranges for disk diffusion and MIC determinations were proposed for BC-2781. The proposed disk diffusion QC range was 20.0-25.7 mm and the MIC QC range was 0.06-0.5 µg/ml.

CONCLUSIONS: The proposed disk diffusion and MIC QC ranges were established for BC-2781. These ranges were supported by the results of the MLS-M23-As. The MIC QC ranges were supported by the results of the MLS-M23-As. The MIC QC ranges were supported by the results of the MLS-M23-As.

INTRODUCTION

The pneumococcal class was discovered from an edible mushroom, Pleurotus ostreatus, which has a unique mode of action that involves inhibition of RNA in ribosomal subunits, and consequently, inhibition of bacterial protein synthesis. The pneumococcal class is bacteriostatic, and its expression is induced by the presence of a cell wall cross-reactions but not P. aeruginosa. In a semi-synthetic pneumococcal, there is minimal cell wall cross-reactivity and gene transcription that encode for the cell wall.