A Multi-Site Study Comparing a Commercially Prepared Dried MIC Susceptibility System to the CLSI Broth Microdilution Method for Delafloxacin using Non-Fastidious Gram-Positive Organisms


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RESULTS Cont.

Non-Fastidious Gram-positive isolates:

- The overall essential agreement for Delafloxacin within 1 log dilution was 98.5% for the manual method and 97.3% for the auto read method.

Interlabatory Reproducibility

- Reproducibility testing results for Delafloxacin within 11 log dilution from the modal MIC was 95.9% for the auto read method and 98.4% for the manual read method.

Table 3. Summary Data and % Essential Agreement of Non-Fastidious Gram-positive Organisms Using the Manual Read Method

<table>
<thead>
<tr>
<th>Organism Group</th>
<th>Number of Isolates</th>
<th>% Essential Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus (MRSA)</td>
<td>252</td>
<td>252</td>
</tr>
<tr>
<td>Enterococcus spp.</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Coagulase negative Staphylococcus spp.</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td>Total</td>
<td>320</td>
<td>318</td>
</tr>
</tbody>
</table>

INTRODUCTION and OBJECTIVES

Delafloxacin (Figure 1), a novel fluoroquinolone, developed by Melinta Therapeutics, was recently submitted to the FDA for the treatment of acute bacterial skin and skin structure infections (ABSSSI) including Staphylococcus aureus (MRSA) and methicillin-resistant S. aureus (MRSA) and Enterococcus spp. (Table 1). As series of studies were conducted to evaluate the performance of Delafloxacin on the commercially manufactured Sensititre®-24 hour susceptibility system, for both automated and manual read, compared against the Clinical Laboratory Standards Institute (CLSI) reference broth microdilution (BMD) method (M07A7 and M07A9) and the Sensititre®-24 hour susceptibility system when testing non-fastidious Gram-positive clinical and challenge isolates. This study suggests that this is an acceptable method for accurate testing of Delafloxacin.

REFERENCES


The “NOA (New Drug Application) for Delafloxacin” is under FDA review.

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