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


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**ABSTRACT**

Omadacycline (OMC) (Paratek Pharmaceuticals, King of Prussia, PA), is an antibiotic belonging to the oxazolidinone subclass of lactam-bacil that is in phase 3 development for the treatment of acute bacterial skin and skin structure infections (ABSSSIs) and community-acquired bacterial pneumonia (CABP). OMC is active against non-fastidious gram-positive pathogens including Staphylococcus aureus (MSSA and MRSA), and Enterococcus spp. (VSE and VRE). A site evaluation was determined to improve the accuracy and reproducibility of OMC susceptibility testing using the Sensititre® dried MIC susceptibility system (Thermo Fisher Scientific, Cleveland, OH) compared with the CLSI (M07) and ISO 20776-1 reference broth microdilution method (BMD). Both auto and manual read methodologies were employed.

**MATERIALS and METHODS**

Omadacycline was tested against: (Table 1.)

- Enterococcus spp.
- Staphylococcus spp.
- Staphylococcus saprophyticus
- Staphylococcus aureus
- Coagulase-negative Staphylococcus spp.
- *Streptococcus* spp.
- *Lactococcus* spp.

**RESULTS**

**Continuous Comparisons of OMC MICs for non-fastidious gram-positive Organisms**

**Clinical and Challenge Isolates Using the Auto Read Method**

<table>
<thead>
<tr>
<th>Isolates</th>
<th>603</th>
<th>Reproducibility Isolates (4) (3 x day for 3 days)</th>
<th>15 (540)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality Control</strong></td>
<td><strong>CLSI Quality Control Strains (20 replicates of each strain at 4 sites)</strong></td>
<td><strong>2 (106)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1248</strong></td>
<td></td>
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</table>

**Quality Control**

Recommended CLSI quality control (QC) organisms were tested daily and all results were within the acceptable range.

**DISCUSSION**

This study validates that the Sensititre Susceptibility System (both auto and manual read) demonstrated an equivalent level of performance compared to the CLSI BMD using automated and manual read methods that were 99.8% and 99.4%, respectively.

**CONCLUSIONS**

This study validates that the Sensititre 18–24 hour susceptibility system (both auto read and manual read) demonstrated an equivalent level of performance compared to the CLSI BMD for automated and manual reads.

**REFERENCES**

- **Omadacycline**
  - Auto Read Manual
  - Between-site isolates tested 440 440
  - Between-site isolates within ±1 log dilution 430 437
  - Between-site reproducibility 430 437
  - Between-site reproducibility % 99.8% 99.4%
  - Total essential agreement 636/640 637/640
  - Essential agreement % 99.8% 99.4%

**CONCLUSIONS**

This study validates that the Sensititre 18–24 hour susceptibility system (both auto read and manual read) demonstrated an equivalent level of performance compared to the CLSI BMD for automated and manual reads. The overall essential agreement for Omadacycline within ±1 log, dilution was 97.3% for the auto read method and 97.7% for the manual read method.

**RESULTS Cont.**

The overall essential agreement for Omadacycline within ±1 log, dilution was 97.7% for the auto read method.

**Table 5. Summary Data and % Essential Agreement of Non-Fastidious Gram-Positive Organisms**

**Clinical Isolates Only**

**Table 4. Summary Data and % Essential Agreement of Non-Fastidious Gram-Positive Clinical and Challenge Isolates Using the Auto Read Method**

**RESULTS Cont.**

**Figure 1. Chemical Structure of Omadacycline**

**RESULTS**

**Essential agreement for Omadacycline on the Sensititre susceptibility plate compared to the reference microdilution plate was calculated for each read method (Auto and Manual) using the ±1 log, dilution standard. Essential agreement rates are shown for non-fastidious gram-positive isolates in Tables 3 and 4.**

**Table 1. Organisms Tested**

**Table 3. Summary Data and % Essential Agreement of Non-Fastidious Gram-Positive Organisms**

**Table 6. Summary Data and % Essential Agreement of Non-Fastidious Gram-Positive Clinical and Challenge Isolates Using the Auto Read Method**

**RESULTS**

**Essential agreement for Omadacycline on the Sensititre susceptibility plate compared to the reference microdilution plate was calculated for each read method (Auto and Manual) using the ±1 log, dilution standard. Essential agreement rates are shown for non-fastidious gram-positive isolates in Tables 3 and 4.**

**Table 2. Quality Control Strains**

- **Staphylococcus aureus ATCC 29213**
  - 0.12-1
- **Enterococcus faecalis ATCC 29212**
  - 0.06-0.5

**RESULTS**

**Clinical and Challenge Organisms**

**Table 4. Summary Data and % Essential Agreement of Non-Fastidious Gram-Positive Clinical and Challenge Isolates Using the Auto Read Method**

**RESULTS**

The overall essential agreement for Omadacycline within ±1 log, dilution was 97.7% for the auto read method.