**BACKGROUND AND IMPORTANCE**

Vancomycin eye-drops (VED) are unavailable in Europe and are usually extemporaneously compounded in hospital pharmacies.

**AIM AND OBJECTIVES**

To collect data on VED physico-chemical stability in three different containers stored either refrigerated or frozen.

**MATERIALS AND METHODS**

**PRODUCTION OF VED AT 50 MG/ML**

Vancomycin 1g (Mylan®) + 20 mL of sterile water for injection (Baxter®) → Homogenized empty bag (Macopharma®) → 1000 mL of Vancomycin 50 mg/mL solution → 10 mL by container with 0.2µm filtration → 28 vials or 26 vials

**STABILITY STUDY DESIGN**

- Using methodological guidelines for stability studies (GERPAC-SFPC 2013)
- At each time of the study (Dx), using the same vials:
  - Vancomycin concentration (stability indicating HPLC method)
  - pH
  - Osmolality
  - Visual aspect
- At D1 and D90:
  - Sterility
  - Non-visible particle count (by light obscuration particle count test)
- Non-parametric tests were used to compare containers and storage conditions (α=5%).

**STORAGE CONDITIONS**

<table>
<thead>
<tr>
<th>MONTH 1</th>
<th>MONTH 2</th>
<th>MONTH 3</th>
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<tbody>
<tr>
<td>D0</td>
<td>D3 D7</td>
<td>D15 D40 D60 D90</td>
</tr>
<tr>
<td>2-8°C</td>
<td></td>
<td>-20°C</td>
</tr>
<tr>
<td>D1 D3 D7 D20</td>
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</tbody>
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2 vials per container type thawed at room temperature (RT)
2 vials per container type thawed at 2-8°C

**RESULTS**

- No significant difference between packaging (p=0.323) or thawing method (p=0.736)
- pH and osmolality stable with no difference between containers (p=0.242 and p=0.414) or thawing method (p=0.287 and p=0.999).
- Sterility preserved

**CONCLUSION AND RELEVANCE**

VED remained stable for two months refrigerated or frozen, and for seven days after thawing (RT or 2-8°C). These results will allow the preparation of a stock of VED available immediately. A microbiological stability study in real conditions of use should complete this work.

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