**BACKGROUND**

Bacterial keratitis is an infectious ocular disease that can cause a severe visual impairment. Commercial eye drops are not effective in many cases.

**OBJECTIVE**

To develop and characterize imipenem eye drops through release and stability studies of three possible formulations for the treatment of resistant bacterial keratitis.

**METHODS**

**Imipenem 5 mg/ml**

- Balanced Salt Solution (BSS)
- 0.4% hyaluronic acid (HA)
- 0.84% ion-sensitive hydrogel (gellan gum and kappa carrageenan) (ISH)

**Stability study**

- All formulations were stored protected from light.
- Transparency, pH and concentration were determined daily.

**RESULTS**

**Release assays**

- Imipenem diffusion was studied with vertical Franz cells and artificial tears as receptor medium:
  - 37°C, 24 hours
  - 100 rpm orbital shaker
  - 12-14 kD dialysis membrane
- The drug release was determined with a spectrophotometer (298 nm).

**Imipenem initial dose (%)**

<table>
<thead>
<tr>
<th>Day</th>
<th>ROOM TEMPERATURE</th>
<th>4-8°C (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>BSS</td>
<td>0.4% HA</td>
</tr>
<tr>
<td>6</td>
<td>66.13</td>
<td>70.20</td>
</tr>
<tr>
<td>10</td>
<td>49.35</td>
<td>49.20</td>
</tr>
<tr>
<td>10</td>
<td>39.33</td>
<td>36.36</td>
</tr>
</tbody>
</table>

**Stability study**

- No significant pH variation were shown at both storing conditions.

**CONCLUSION**

- The ISH vehicle shows the best release characteristics, but its poor physicochemical-stability (<3 days) would difficult its use in clinical practice.
- The optimal vehicles for the elaboration in clinical practice are BSS and hyaluronic acid.
- It is recommended to store these eye drops at 4-8°C protected from light for a validity period of 5 days.