INDIGO CARMINE SOLUTION AND ADRENALINE IN SUBMUCOSAL CHROMOENDOSCOPY
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OBJETIVES
✓ Description and galenic validation of a solution of indigo carmine (IC) and adrenaline in colloid plasma expander derived from gelatin for use in submucosal chromoendoscopy.
✓ Establishing the period of validity according to the Guide to Good Preparation Practices (GPP).

MATERIALS AND METHODS
Development of the composition of the formula and review of its pharmacological and physicochemical characteristics.

ELABORATION
- 1 mg/1 mL adrenalin
- 4 mL (32 mg) indigo carmine 0.8%
- c.s.p. 100 mL Gelafundina®

CONSERVATION
- FRIDGE: 2-8 °C
- 14 days.

OBTAINING RESULTS
- Trypticase Soy Agar
- pH

RESULTS
- There was no color change in any sample except at t45.
- There was no microbiological growth in any sample.
- A medium risk level and a validity period of 14 days between 2-8°C were established according to the GPP.
- After its use, the endoscopists consider that the preparation meets the demanded requirements, and it has not been necessary to vary the formulation composition.

<table>
<thead>
<tr>
<th>Time</th>
<th>Color Change</th>
<th>pH (potentiometry)</th>
<th>Microbiology Trypticase Soy Agar</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>(-)</td>
<td>6.65 ± 0.02</td>
<td>(-)</td>
</tr>
<tr>
<td>T15</td>
<td>(-)</td>
<td>6.83 ± 0.02</td>
<td>(-)</td>
</tr>
<tr>
<td>T30</td>
<td>(-)</td>
<td>6.57 ± 0.03</td>
<td>(-)</td>
</tr>
<tr>
<td>T45</td>
<td>(+)</td>
<td>6.70 ± 0.02</td>
<td>(-)</td>
</tr>
</tbody>
</table>

CONCLUSION
✓ The IC solution is physically, chemically, and microbiologically stable for 14 days at 2-8°C.
✓ The final concentration of IC used and the association with adrenaline allow, in the opinion of the endoscopists, the adequate differentiation and distinction of the areas susceptible to endoscopic resection.