BACKGROUND

Defects in the urea cycle are genetic diseases in which ammonia is accumulated. Sodium benzoate (SB) is conjugated with glycine giving rise to hippurate, excreted in the urine. Currently, no oral sodium benzoate preparation is commercialized.

METHODS

10% Sodium benzoate in water

All formulations were stored protected from light during 30 days.

Refrigerated 2-8 °C

Room temperature (<25°C)

Measurements

- Colour
- Opacity
- Precipitation
- pH
- Absorbance

All absorbance measurements were obtained with a Shimadzu® spectrophotometer model UVmini-1240 UV-Vis at 223 nm.

RESULTS

10% Sodium Benzoate at 2-8°C

10% Sodium Benzoate at room temperature

Average degradation (%)

<table>
<thead>
<tr>
<th>Day</th>
<th>Refrigerated (2-8 °C)</th>
<th>Room temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>2.82</td>
<td>1.49</td>
</tr>
<tr>
<td>30</td>
<td>3.48</td>
<td>2.55</td>
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</tbody>
</table>

After 30 days, no colour change, opacity or precipitation were observed. In all test solutions, pH values remained unchanged.

CONCLUSION

The 10% Sodium benzoate oral solution, used in urea cycle defects in pediatric patients, is physically and chemically stable when stored protected from light at room temperature or refrigerated (5°C±3°C) for at least 30 days.