STABILITY STUDY OF A 10% SODIUM BENZOATE ORAL SOLUTION

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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.

OBJECTIVE

To evaluate the stability of an **oral solution of 10% sodium benzoate** at two different storage conditions for the treatment of urea cycle disorders.

METHODS

10% Sodium benzoate in water

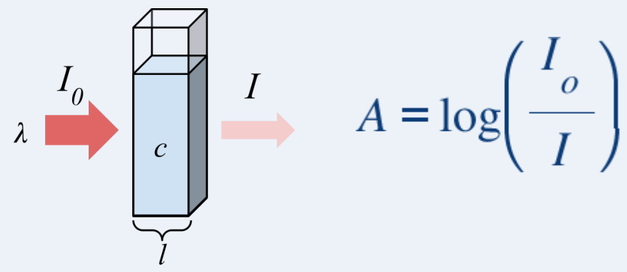
Room temperature (<25ºC)

All formulations were stored protected from **light** during **30 days**.

Refrigerated 2-8 ºC

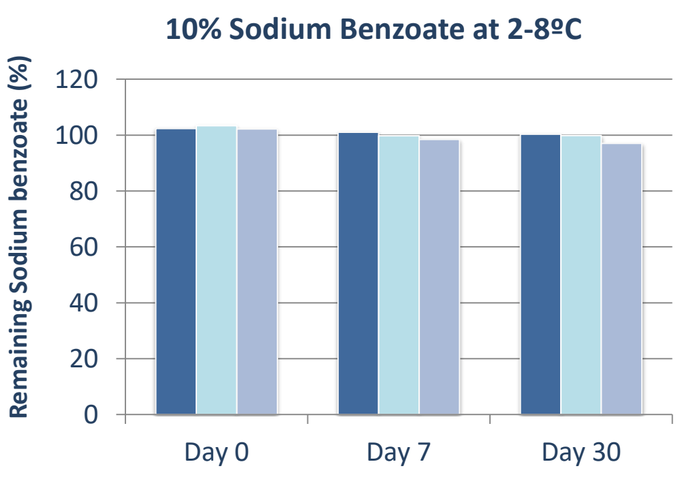
Measurements

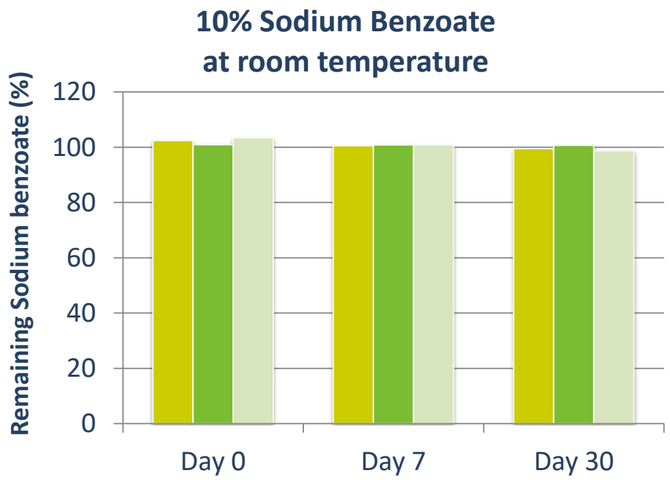
- ✓Colour
- ✓Opacity
- ✓Precipitation
- ✓pH
- ✓**Absorbance**



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

RESULTS





Average degradation (%)		
Day	Refrigerated (2-8 ºC)	Room temperature
7	2.82	1.49
30	3.48	2.55

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**.