

BACKGROUND & OBJECTIVE

Used in **oral onco-paediatric** therapy for the treatment of Ewing's sarcoma or rhabdomyosarcoma, only cyclophosphamide tablets are marketed.

⇒ **Difficult to adapt** for paediatric use

⇒ Manufacture of oral liquid magistral preparations, often made with syrup containing **excipients with known effects** (EKE), for which few stability data are available



To perform a **stability study** of a 10 mg/mL oral solution of cyclophosphamide without EKE, in order to establish a shelf life

MATERIAL & METHOD

Formulation :

30 mL of cyclophosphamide solution
Endoxan® 1000 mg/50 mL (reconstituted
with water for injection) + 30 mL

d'Inorpha®

3 batches packaged in amber glass bottles



Storage at 2-8°C



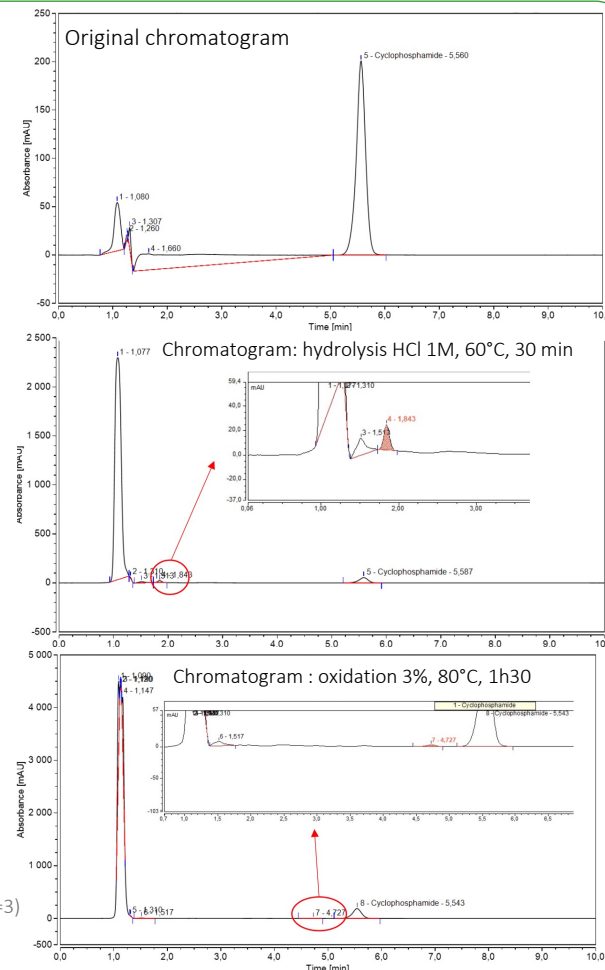
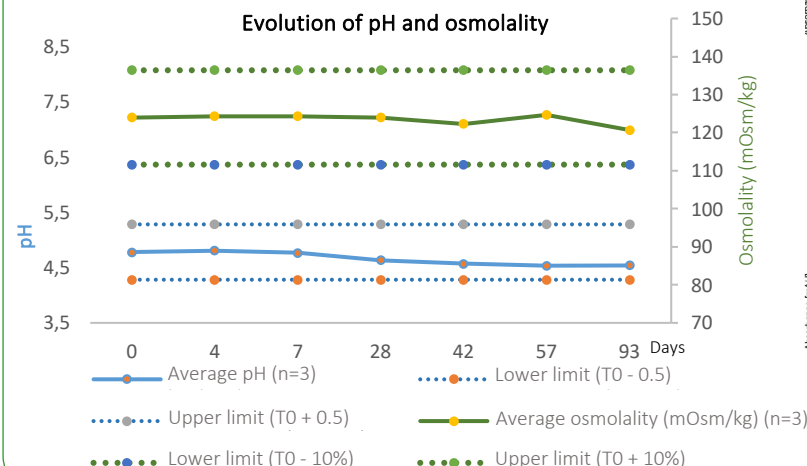
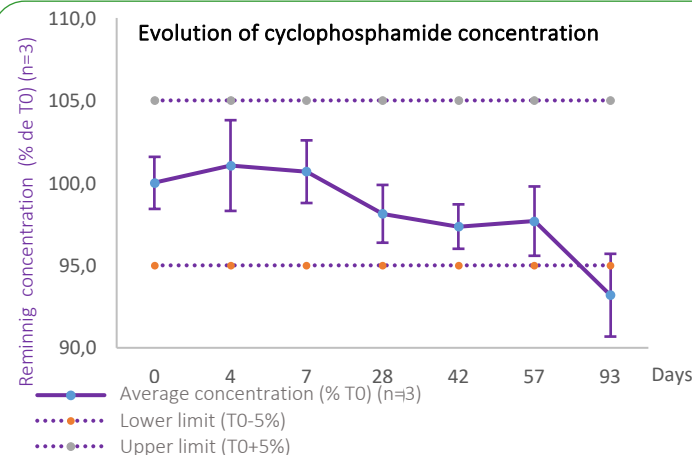
Stability study :

D0, D4, D7, D28, D42, D57, D93

CONCLUSION

An **EKE-free** oral solution of cyclophosphamide 10 mg/mL was developed using the **neutral formulation** of Inorpha®. In addition to **flavouring**, this vehicle contains a **bitterness-masking agent** of particular interest for this active substance. The physicochemical properties of this preparation appear to be stable for **57 days** when stored in **amber glass bottles** at **2-8°C**.

RESULTS



- Remaining cyclophosphamide concentration : **> 95 %** of the initial concentration for **57 days**, no degradation product was observed
- pH** and **osmolality** : **constant** throughout the study.
- Organoleptic** properties : **unchanged**.