

1. BACKGROUND & OBJECTIVE

- **Vinorelbine** → paediatric use + patients with swallowing difficulties
- **Available forms are unsuitable for paediatric use** → a liquid oral formulation is required.

- **Objective:** To develop a 5 mg/mL oral solution of vinorelbine in InOrpha® and to evaluate its physicochemical and microbiological stability.

2. MATERIALS & METHODS

Analytical development (HPLC-UV)

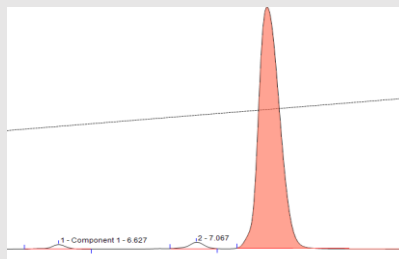
Forced degradation

- HCl 0,1N
- NaOH 0,05N
- H₂O₂ 3%

Specificity

Method validation

- ICH Q2R1 criteria



Formulation development

- Vinorelbine (10mg/mL) + InOrpha® QSP 50 mL → 5 mg/ml

- 3 amber glass bottles



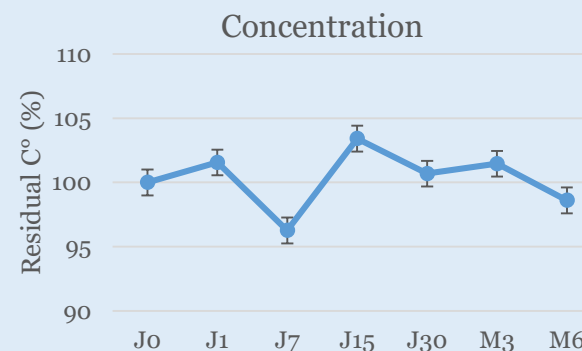
Stability studies

- Between +2 and 8°C
- Store away from light

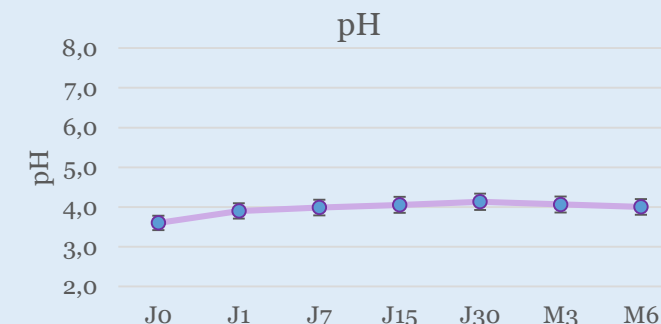
- Appearance
- Vinorelbine concentration (HPLC-UV)
- pH
- Microbiology

J0 J1 J7 J15 J30 M3 M6

3. RÉSULTS



- Loss in M6 content of the 3 batches: 6%, 4%, 2%
- C° > 95% of the initial C°
- No degradation products observed



- Average pH of the three batches: 3.51 (± 0.01) at J0 compared with 3.97 (± 0.10) at M6

+ No change in appearance
+ 3 sterile batches at 6 months

4. CONCLUSION



Stability: 180 days at between +2 and +8 °C, protected from light, for the 5 mg/mL oral formulation of vinorelbine in InOrpha® liquid (pH 4).