

# PHYSICOCHEMICAL AND MICROBIOLOGICAL STABILITY OF A NEW PAEDIATRIC ORAL SOLUTION OF CLONIDINE

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## INTRODUCTION

As many drugs are unavailable for paediatric use, hospital pharmacies often requested to develop suitable formulation.

→ Clonidine used in paediatrics (in severe hypertension or in anaesthetic premedication) without appropriate formulation.

→ We developed an oral solution of clonidine dedicated to children and assessed its physicochemical and microbiological stability.

## MATERIALS & METHODS

### FORMULATION

- Oral solution of clonidine hydrochloride
- Excipients suitable for neonates and paediatrics

### FORCED DEGRADATION

- 3 conditions: acidic, basic and oxydative
- 6 degradation products (DP)

### PHYSICOCHEMICAL STABILITY

- GERPAC-SFPC guidelines
- Analysed parameters :
  - Clonidine concentration up to 90% and no formation of DP, using a HPLC-UV-DAD method
  - Limpidity, pH and osmolality

### MICROBIOLOGICAL STABILITY

- European Pharmacopeia
- Inhibition of the preservative agent
- Membrane filtration

Solutions were stored in amber glass bottles with an oral adapter up to 3 months under two different conditions: between 2 and 8°C and at 25°C with 60% residual humidity.

## RESULTS

### Formulation

Oral solution of clonidine hydrochloride

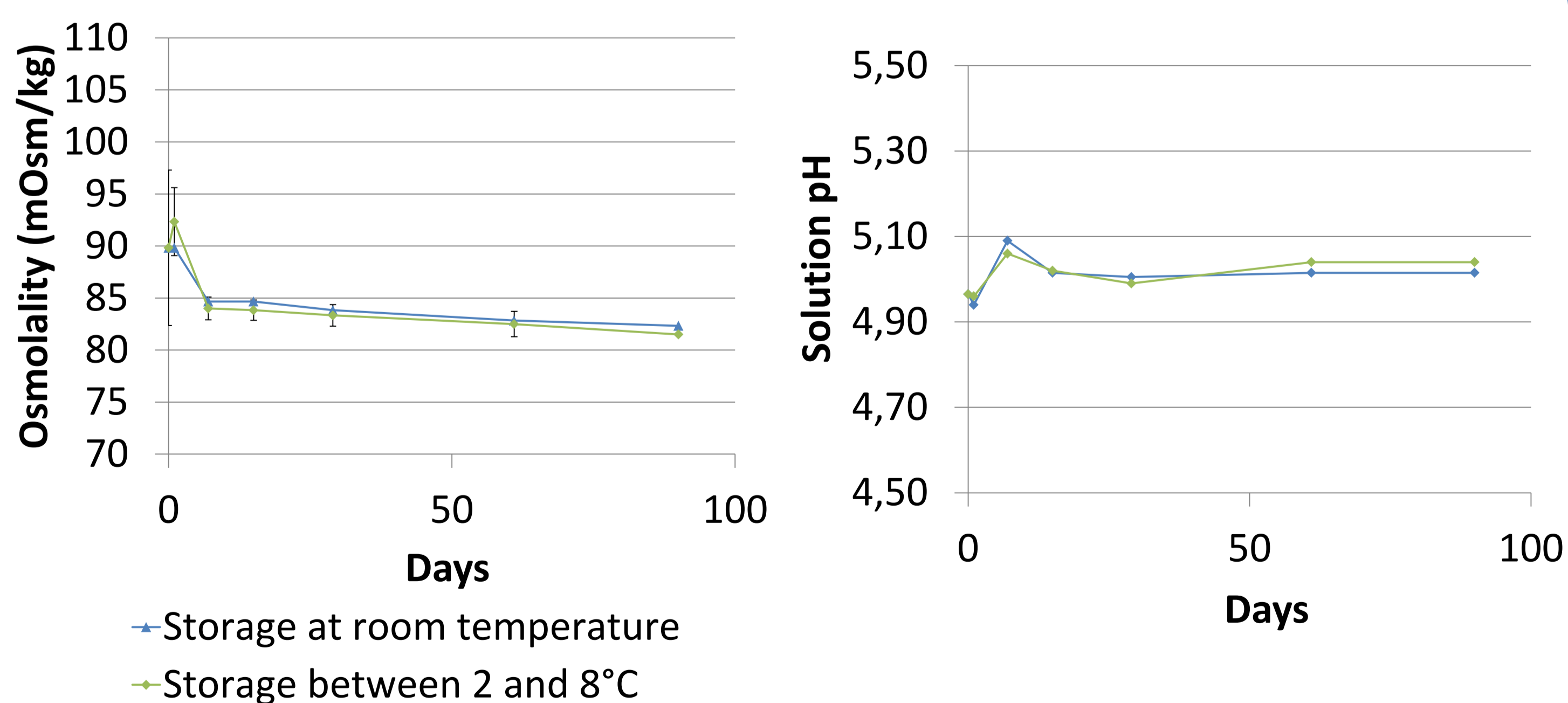
Concentration: 10µg/mL

Excipients:

- potassium sorbate (0.3%),
- citric acid and potassium citrate,
- sodium saccharine.



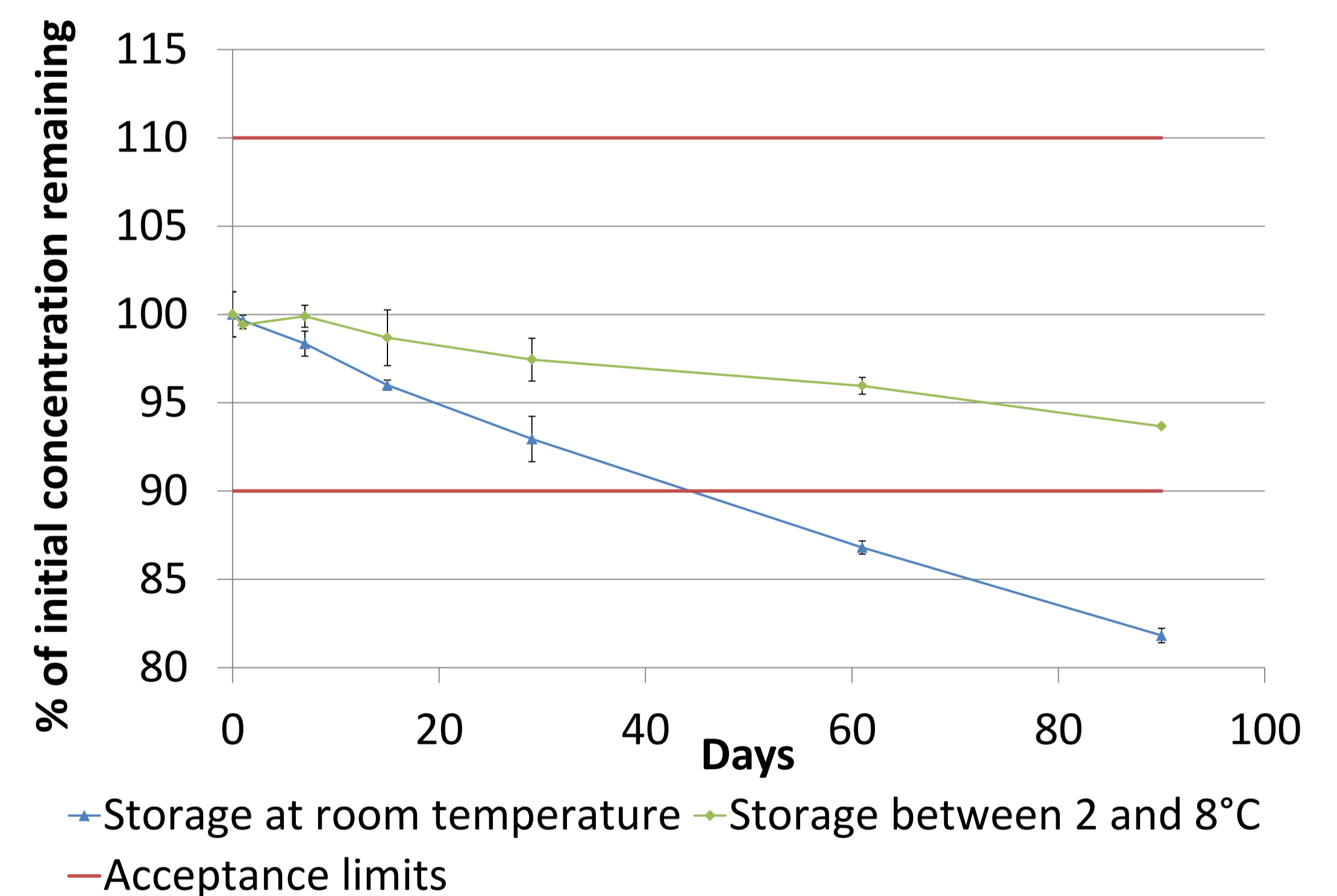
### Physical Stability



➤ No visual change observed

➤ No variation of pH and osmolality during the study

### Chemical Stability



➤ The solution is stable one month at room temperature and 3 months between 2 and 8°C.

### Microbiological Stability

- <1 micro-organism/mL
- No detected E.coli
- Only environmental micro-organisms were identified (*Micrococcus*, coagulase-negative *Staphylococcus*, *Methylobacterium* and *Bacillus*)

## CONCLUSION

Formulation in amber glass bottles stable 3 months between 2 and 8°C and one month when stored at room temperature.

Microbiological stability proven in accordance with the European Pharmacopeia monograph.