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 oxidative
- 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

- Storage at room temperature
- Storage between 2 and 8°C
- 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.

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