STABILITY OF CHLORHEXIDINE 0.05% EYE DROPS COMPOUNDING DRUG

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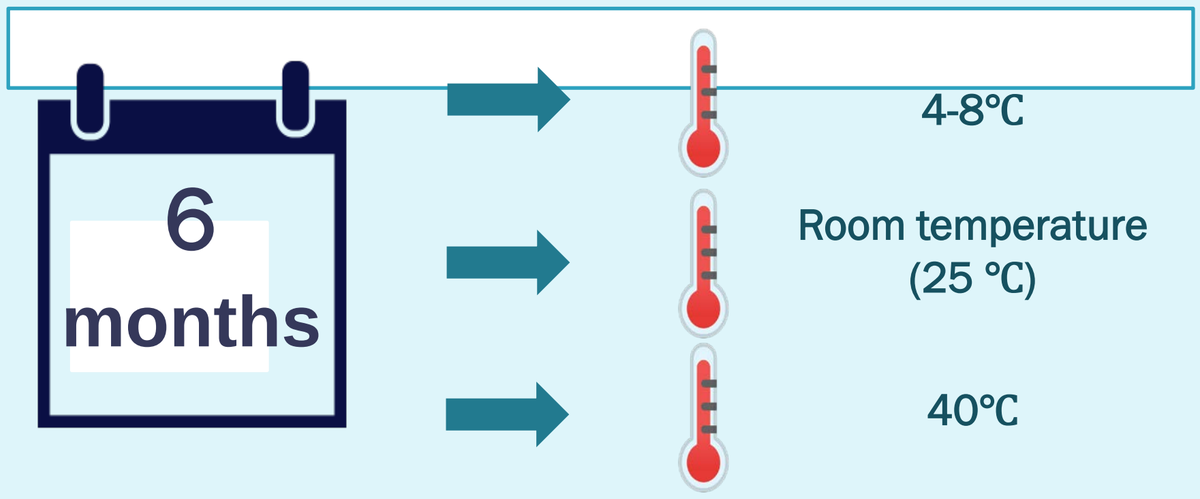
OBJECTIVE

The development of a 0.05% Chlorhexidine eye drops and the subsequently stability study in different storage conditions: refrigerated (4-8ºC), room temperature (25ºC) and accelerated (40ºC).

METHODS

Clorhexidine digluconate 20% (Acofarma)
Glacial acetic acid (Fagron)
Water for injection (Braun)

→ **Clorhexidine 0.05% eye drops**
(High density poliethylene eye dropper)



pH
pHmeter Hanna HI5221

Osmolarity Fiske Model 210

Concentration
HPLC, Agilent 1260series HPLC System with a PAD detector

RESULTS

- The **organoleptic properties** of the three formulations were acceptable.
- The **pH** and **osmolarity** results minimally differed between 0 and 6 months, less than a 5% difference in pH and less than a 10% difference in osmolarity.
- The **concentration** fell down below than a 10% at month 6.

Temperature conditions	Refrigerated (4-8ºC)	Room temperature (25ºC)	Accelerated (40ºC)
pH	5.66	5.67	5.66
Osmolality (mOsm/Kg)	198.35	198.54	200.45

CONCLUSIONS

- 0.05% Chlorhexidine eye drops could be formulated in the Pharmacy Service for allergic surgical patients.
- The drug fulfill the galenic requirements for ophthalmic preparations.
- It could be **stored** both at **room temperature** and **refrigerated.**
- Valid for a period of **three months unopened in high density polyethylene eye dropper**.

1. Merani R, McPherson ZE, Luckie AP, Gilhotra JS, Runciman J, Durkin S, et al. Aqueous Chlorhexidine for Intravitreal Injection Antisepsis: A Case Series and Review of the Literature. Ophthalmology. 2016;123(12):2588-94.

http://www.eahp.eu/24-3PC-010