



# Stability of preservative-free losartan potassium 0.8 mg/mL eye drops compounded in hospital pharmacy practice

García Aguilera AM, Romero Carreño E, Gázquez Pérez R, Gómez Sánchez MT, Molina Cuadrado E, Verdejo Reche F. Hospital Universitario Torrecárdenas. Pharmacy. Almería (Spain)



## Background and importance

Topical losartan 0.8 mg/mL has shown antifibrotic effects that reduces subretinal inflammation and protect the optic nerve in diseases such as glaucoma and AMD



In hospital settings, LP eye drops are compounded extemporaneously but, without standardised stability or sterility data, they are often assigned short beyond-use dates.

No commercial ophthalmic formulations are available.



Given the strict requirements for ophthalmic preparations (pH, osmolality, clarity, and sterility) it is essential to have stability evidence to ensure safety.



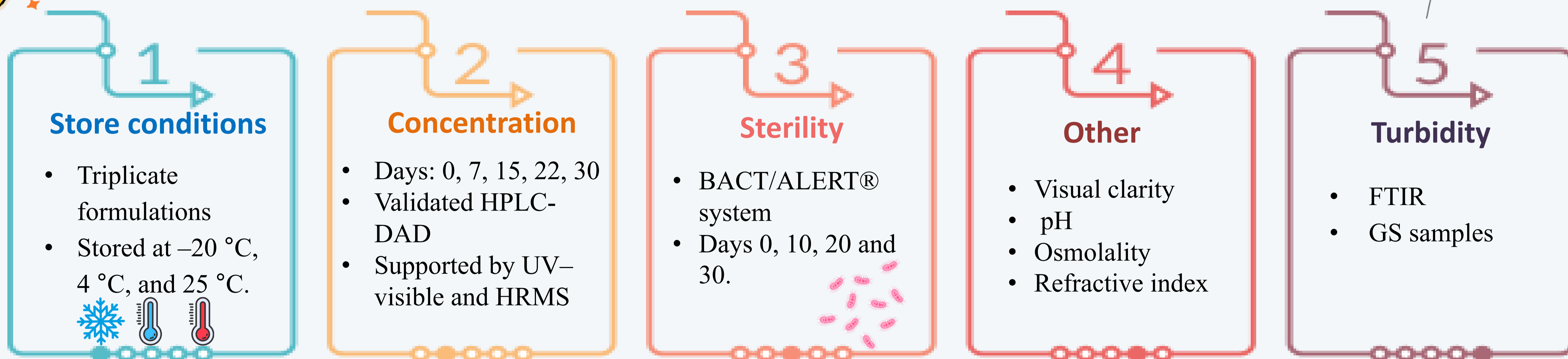
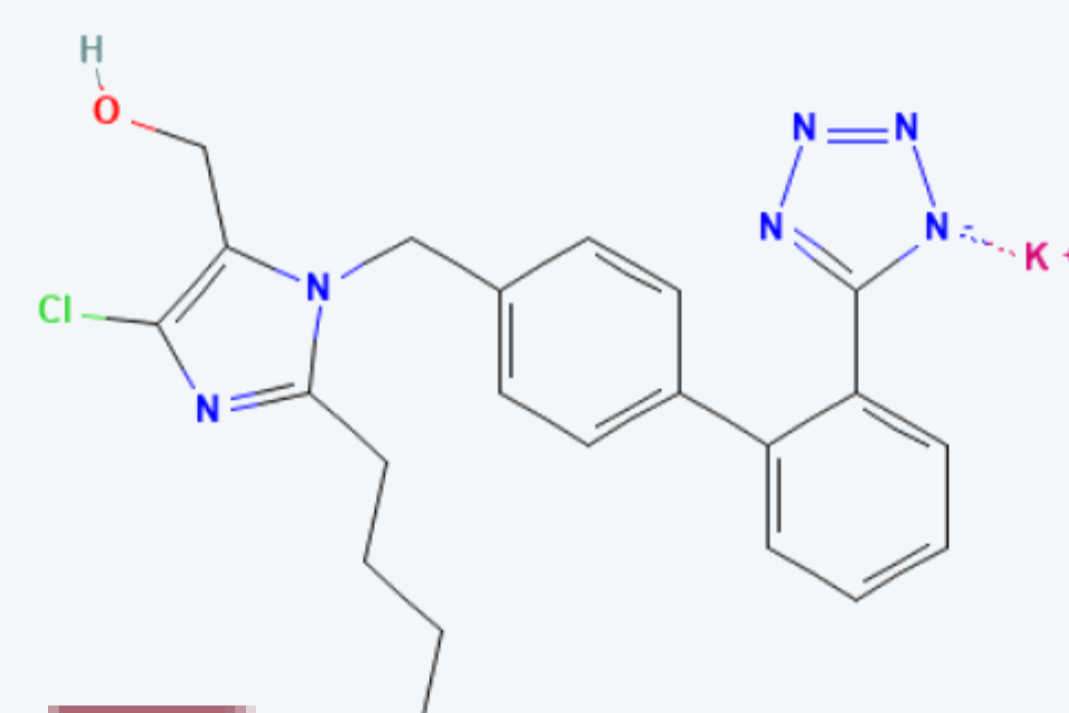
## Aim and objectives



To evaluate the 30 day physicochemical and microbiological stability of preservative-free losartan potassium 0.8 mg/mL eye drops prepared with balanced salt solution (BSS), normal saline (NS), or glucose saline (GS), and stored in sterile bottles at different conditions: room temperature, refrigerated, and frozen.



## Materials and methods



## Results

All tested samples remained sterile throughout the days of the study.

**Formulations based in BSS and NS**  
Retained  $\geq 96\%$  of  $[\text{LP}]_i$

- HRMS: no degradation products detected
- pH: (6.5–7.3)
- Osmolality:  $\sim 300$  mOsm/kg
- Refractive index: stable
- Clarity: no changes

### Formulations based in GS

Stable  $5 \pm 3^{\circ}\text{C}$  /  $25^{\circ}\text{C}$  → Turbidity at 15 and 20 days.  $[\text{LP}]_i < 50\%$

FTIR suggested reversible losartan-glucose aggregation



## Conclusion

BSS and NS are suitable vehicles for extemporaneous losartan eye drops, supporting 30-day refrigerated or frozen storage. GS should be avoided at room temperature. These findings provide validated evidence to safely extend expiration dates and improve ophthalmic care delivery.

