

VANCOMYCIN EYE DROPS AT 50 MG/ML : PHYSICO-CHEMICAL STABILITY, IMPACT OF PACKAGING AND STORAGE CONDITIONS

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BACKGROUND AND IMPORTANCE

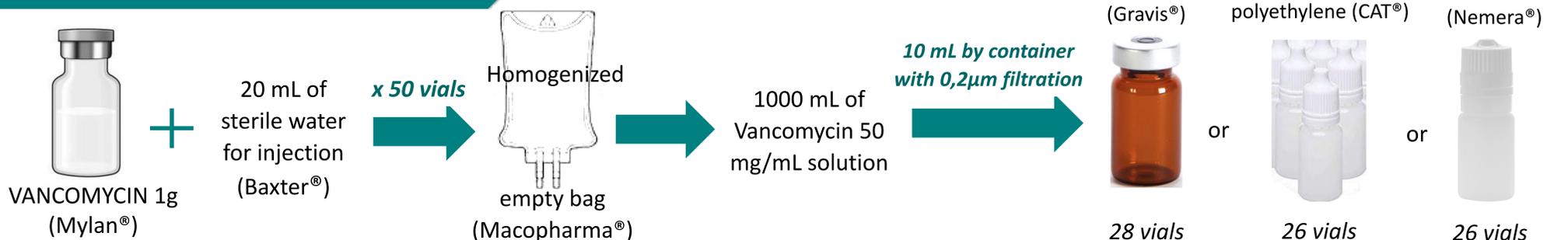
Vancomycin eye-drops (VED) are unavailable in Europe and are usually extemporaneously compounded in hospital pharmacies.

AIM AND OBJECTIVES

To collect data on VED physico-chemical stability in three different containers stored either refrigerated or frozen.

MATERIALS AND METHODS

PRODUCTION OF VED AT 50 MG/ML



STABILITY STUDY DESIGN

✓ Using methodological guidelines for stability studies (GERPAC-SFPC 2013)

At each time of the study (Dx), using the same vials :

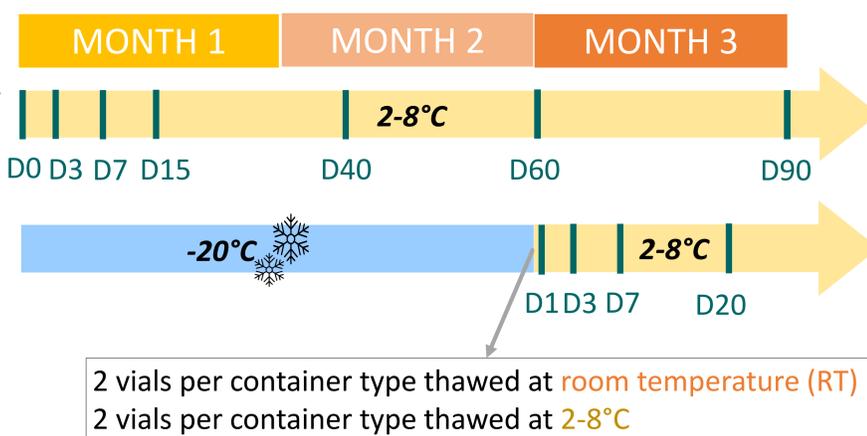
- Vancomycin concentration (stability indicating HPLC method) 12 vials per container type stored at 2-8°C
- pH
- Osmolality
- Visual aspect

At D1 and D90 :

- Sterility
- Non-visible particle count (by light obscuration particle count test) 4 vials per container type stored at -20°C

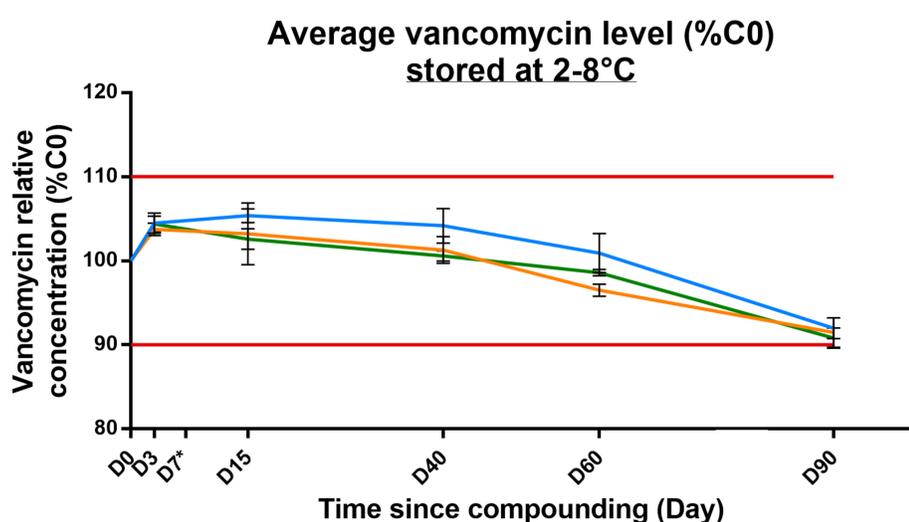
Non-parametric tests were used to compare containers and storage conditions ($\alpha=5\%$).

STORAGE CONDITIONS



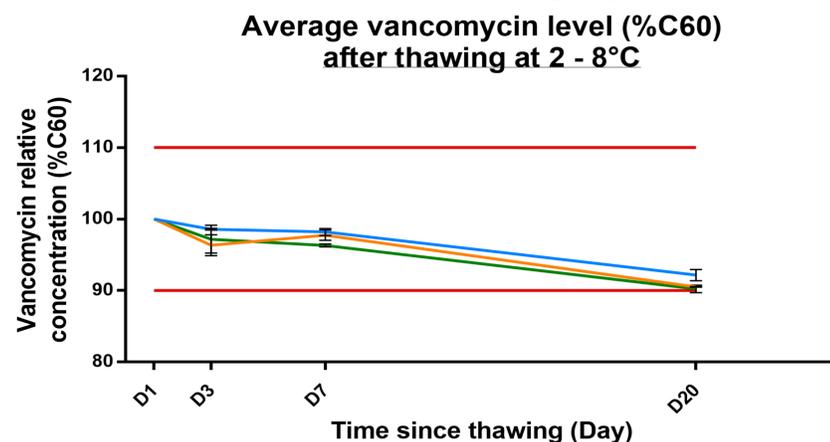
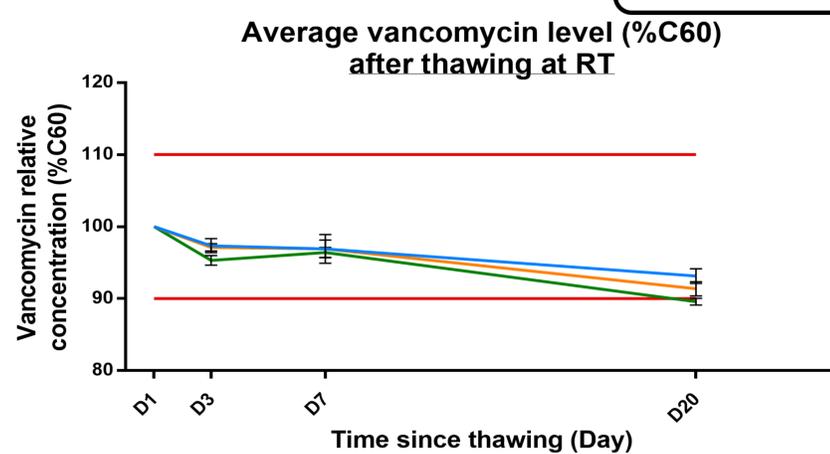
RESULTS

- ✓ No significant difference between packaging ($p=0.323$) or thawing method ($p=0.736$)
- ✓ pH and osmolality stable with no difference between containers ($p=0.242$ and $p=0.414$) or thawing method ($p=0.287$ and $p=0.999$).
- ✓ Sterility preserved



* Values excluded due to a material bias

- Visual aspect : A slight yellow coloration of VED (2-8°C) was perceived after D60
- A slight increase in non-visible particles count was observed between D1 and D90 in glass and classic LDPE but values complied with USP threshold : [< 50 particles ($>10\mu\text{m}$) / mL] and [< 5 particles ($> 25\mu\text{m}$) / mL]



CONCLUSION AND RELEVANCE

VED remained stable for two months refrigerated or frozen, and for seven days after thawing (RT or 2-8°C). These results will allow the preparation of a stock of VED available immediately. A microbiological stability study in real conditions of use should complete this work.