

Sterility assay by membrane filtration method : Suitability test for 0.1% EDTA eye drops

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INTRODUCTION

Eye drops edetate disodium (EDTA): hospital preparation

- Indications: removal of calcareous concretions in strip keratopathy
- Final checks according to Good Preparation Practices: physicochemical and **microbiological (sterility)**



Aim: validate suitability test for sterility assay of 0.1% EDTA eye drops

MATERIALS & METHOD

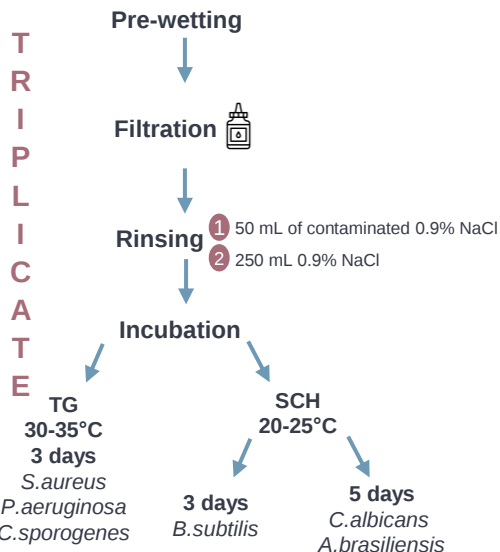
Materials

- 0.1% EDTA eye drops
- Steritest™ Symbio LFH pump (Merck-Millipore)
- Canisters fitted with a 0.45 µm cellulose ester membrane (Merck-Millipore)
- Bioball® SingleShot calibrated to 30 CFU (Biomérieux)
- Culture media:
 - Thioglycolate (TG) for *Staphylococcus aureus**, *Pseudomonas aeruginosa**, *Clostridium sporogenes**
 - Soy Casein Hydrolysate (SCH) for *Bacillus subtilis**, *Candida albicans**, *Aspergillus brasiliensis**



Method

- Reference method: membrane filtration according to EP 11th Ed. (2.6.1)



RESULTS

- Visual signs of growth:

NC : Not concerned

Pathogen	Medium	D1	D2	D3	D4	D5
<i>C.sporogenes</i>	TG	-	+	+	NC	NC
<i>P.aeruginosa</i>	TG	-	+	+	NC	NC
<i>S.aureus</i>	TG	-	+	+	NC	NC
<i>B.subtilis</i>	SCH	-	-	+	NC	NC
<i>A.brasiliensis</i>	SCH	-	+	+	+	+
<i>C.albicans</i>	SCH	-	-	-	+	+
Témoins négatifs	TG and SCH	-	-	-	-	-

- Identification reports: **monomorphic culture in each canister**

DISCUSSION - CONCLUSION

- Confirmation of inhibition of bacteriostatic activity of EDTA eye drops linked to polymerase inhibition by chelation of magnesium (Mg²⁺), by simple rinsing
- Validation of the applicability test for these eye drops

→ Sterility test suitable for routine use