

INTRODUCTION

- Request for the production of a new hospital preparation of ropivacaine 1mg/mL in 100mL bags to replace the commercial form at 2mg/mL $\Rightarrow$ hemodynamic effects +++
- Indication: analgesia in major visceral and urological surgery via epidural route

- Sterile injectable preparation $\Rightarrow$ need for sterility control



Objective: to develop and validate the sterility testing method by membrane filtration for a new 1mg/mL ropivacaine preparation

MATERIAL AND METHODS

$\Rightarrow$ Membrane filtration method performed in accordance with the European Pharmacopoeia 11th édition (2.6.1)

MATERIAL:

- Steritest® Equinox pump (Merck-Millipore)
- Canisters equipped with a 0,45µm cellulose ester membrane (Merck-Millipore)
- BioBall® Multi-shot 550 beads (Biomérieux)



- Growing medium
- Ropivacaine bags 1mg/mL 100mL
- Incubator



METHOD: fertility test (positive controls) combined with a sterility test



Staphylococcus aureus
Clostridium sporogenes
Pseudomonas aeruginosa

Thioglycolate 3 days at 37°C

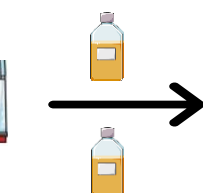
Bacillus subtilis
Candida albicans
Aspergillus brasiliensis



FILTRATION



Casein and soybean hydrolysate 5 days at 22°C



RESULTS

POSITIVE CONTROLS	D5
<i>Staphylococcus aureus</i>	✓
<i>Clostridium sporogenes</i>	✓
<i>Pseudomonas aeruginosa</i>	✓
<i>Bacillus subtilis</i>	✓
<i>Candida albicans</i>	✓
<i>Aspergillus brasiliensis</i>	✓

- Monomorphic growth
- Clear negative controls: absence of microbial contamination

STERILITY TEST	D5
<i>Staphylococcus aureus</i>	✓
<i>Clostridium sporogenes</i>	✓
<i>Pseudomonas aeruginosa</i>	✓
<i>Bacillus subtilis</i>	✓
<i>Candida albicans</i>	✓
<i>Aspergillus brasiliensis</i>	✓
Negative controls	✗

$\Rightarrow$ Conformity testing for fertility and sterility

DISCUSSION/CONCLUSION

- Validation of the membrane filtration sterility test method for this preparation
- No inhibitor effect of ropivacaine 1mg/mL on the growth of pathogens

$\Rightarrow$ Sterility test suitable for routine use