

CENTRALIZATION OF VITAMIN-LIPID BLEND PRODUCTION: VALIDATION OF MEMBRANE FILTRATION FOR STERILITY TESTING

A. Ressel, B. Mathat, E. Olivier, C. Baguet, N. Cormier

Pharmacie, CHU de Nantes site Hôtel-Dieu, 5 Allée de l'Île Gloriette, 44000 Nantes

COM26-29334

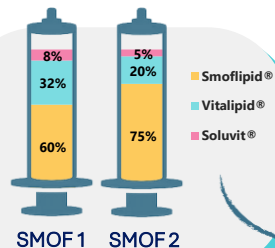
CONTEXT

Vitamin-Lipid Blend (VLB) are sterile preparations used for nutritional supplementation for premature newborns

As part of an effort to improve their safety and their quality, the Pharmaceutical Technology department was asked to centralize the production of these syringes.

Given the needs of clinical care units, 2 standardized formulas were established, with a limited stability (7 days)

This standardization requires the implementation of an appropriate microbiological control: a sterility test is required by the European Pharmacopoeia (EP)



OBJECTIVE

To validate a membrane filtration sterility test method in conformity with the European Pharmacopoeia

CONCLUSION

Validation of membrane filtration for sterility testing of VLB syringe

METHOD

MANIPULATIONS

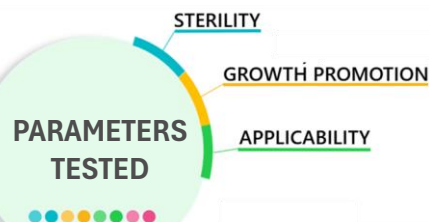
6 microbial strains, defined by the PE, obtained by rehydration of BioBall®

50 CFU per strain

2 culture media: casein soy broth (CSB) and thioglycolate broth (TB)

3 repetitions, different operators, and different days

C. sporogenes • *P. aeruginosa* • *S. aureus* • *A. brasiliensis* • *B. subtilis* • *C. albicans*



VLB contamination: reconstitution and insertion of the BioBall® into the syringes

Membrane filtration and inoculation: using a peristaltic pump

Positive (PC) and negative (NC) controls

Incubation for 14 days at 25°C and 35°C depending on the medium used

Canister readings on Days 1, 3, 5, 7 and 14

Technique limitations:

- Prolonged incubation time (14 days)
- Limited stability of VLBs (7 days)

→ Early release for daily use

RESULTS

	<i>Staphylococcus aureus</i>		<i>Pseudomonas aeruginosa</i>		<i>Clostridium sporogenes</i>	
	PC	VLB	PC	VLB	PC	VLB
D1	Turbid	Turbid	Turbid	Turbid	Turbid	Turbid
D3	Positive	Positive	Positive	Positive	Positive	Positive
D5	Positive	Positive	Positive	Positive	Positive	Positive
Identification	<i>Staphylococcus aureus</i>		<i>Pseudomonas aeruginosa</i>		<i>Clostridium sporogenes</i>	

	<i>Bacillus subtilis</i>		<i>Aspergillus brasiliensis</i>		<i>Candida albicans</i>	
	PC	VLB	PC	VLB	PC	VLB
D1	Negative	Negative	Negative	Negative	Negative	Negative
D3	Positive	Positive	Positive	Positive	Turbid	Turbid
D5	Positive	Positive	Positive	Positive	Positive	Positive
Identification	<i>Bacillus subtilis</i>		<i>Aspergillus brasiliensis</i>		<i>Candida albicans</i>	

Mean time to **positivity** = 3 days

Microorganism **identification**: **consistent**

No microbial contamination of négatives controls after 14 days

Equivalent growth between VLB canisters and positive controls: **growth promotion test** validated

Perspectives :

Use of **faster alternatives methods** for daily VLBs testing ?

→ BACTEC® alternative method

COM26-47513