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Title / *Titre*:

Validation Report of Sterility Testing of Medical Devices for:
C-CIT

Report no.: 27468
Rev: 0
Date: 30th September 2020
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SOP ref. 7.5.1-5
Copy: Medistri SA

1.0 General Information

Medistri Address	Route de l'industrie 96 CH – 1564 Domdidier	Tel : 0041 26 676 90 80 Fax : 0041 26 676 90 85
Customer name	**C-CIT**	
Customer's address	**Einsiedlerstrasse 29** **CH – 8820 Wädenswil**	
Customer's reference (Delivery note # ; order #...)	Offer n° 2200333	
Date of reception of the product	25th September 2020	
Product identification (name and reference)	**BIO / MeMo Flowcell**	
Manufacturing batch	GoD / Lod200903	
Packaging conditions	☐ Under vaccum packaging ☒ Standard packaging	
Sterilization conditions	☒ Sterile : ☐ *EtO* ☐ *Steam* ☒ *Gamma* ☐ *Medistri SA : Ste batch # n.a.* ☒ *Other: Data available at customer*	☐ Non sterile
Quantity of samples	6 samples	
Quantity of analysis	**1 validation**	
Date of analysis	From 25th September 2020 to 29th September 2020	

2.0 Method

The present document reports on the validation of the method used to test the sterility of medical devices, according to EN ISO 11737-2 and Medistri internal procedure WI 33.

3.0 Results

Germ	Strain	cfu inoculated*	Growth in presence of product (yes/no)	Verification of growth (passed/failed)**	Conform (yes/no
S. aureus	NCTC 10788	21	Yes	Passed	Yes
P. aeruginosa	NCTC 12924	36	Yes	Passed	Yes
C. sporogenes	NCTC 12935	21	Yes	Passed	Yes
B. subtilis	NCTC 10400	18	Yes	Passed	Yes
C. albicans	NCPF 3179	30	Yes	Passed	Yes
A. brasiliensis	NCPF 2275	18	Yes	Passed	Yes

* quantitative verification by culturing of the inoculated suspension on TSA. Tolerance limits range between 10 and 100 cfu.

** qualitative verification of growth by subculturing of the medium in presence of the product.

The sterility testing is validated for BIO / MeMo Flowcell in 200ml of medium.

4.0 Introduction

Validation. The aim is to evaluate the inhibitive properties of the product potentially leading to false negative results using the method of direct immersion of the product in the culture medium. Inhibitive properties are evaluated by inoculating small amount of microorganisms to the culture medium in presence of the product. A growth signifies that the product is not inhibitive to microbial growth and can be tested for sterility test of medical devices after sterilization. Growth must be detectable and countable within the time indicated in chap 6.3, otherwise the validation is considered as non-conform and further investigation may be required.

Routine. The sterility test is performed under aseptic conditions, in a clean room under a microbiological safety cabinet. The working precautions taken do not affect the microorganism searched for. The operatory conditions when performing the tests are monitored by microbiological control of air and working surfaces.

5.0 Materiel

5 - 1 Product tested: BIO / MeMo Flowcell

Part of the product used for the test: ☒ Entire product
☐ Other : *n.a.*

Volume of medium used: 200 ml

5 - 2 Microorganisms used for validation

- *Staphylococcus aureus*
- *Clostridium sporogenes*
- *Bacillus subtilis*
- *Pseudomonas aeruginosa*
- *Candida albicans*
- *Aspergillus brasiliensis*

5 - 3 Culture media

- Liquid thyoglycolate medium (THIO): for the detection of aerobic and anaerobic germs

- Liquid trypcase soja medium (TSB): for the detection of aerobic germs, yeasts and moulds

5 - 4 Material and equipment

- Clean room and microbiological safety cabinet
- Sterile containers
- Sterile instruments for handling

6.0 Method

6 - 1 Preparation of the inoculum for validation

The microbial suspensions are prepared and adjusted to 10 - 100 cfu.

6 - 2 Validation

For each type of microorganism specified under 5.2, transfer the device to test into the culture medium. Inoculate with an inoculum containing 10 - 100 cfu from each strain. Incubate according to section 6.3

In parallel, perform a count by transferring the same inoculum of suspension onto a TSA plate, and incubate 5 days at 33°C (min 30°C; max 35°C). The *C. sporogenes* strain needs to be incubated under anaerobic conditions.

After growth in the broth culture media and in presence of the product, perform a subculturing to confirm that growth corresponds to the germ inoculated.

6 - 3 Overview

Germ	Strains	Medium	Temperature	Limit*
S. aureus	NCTC 10788	THIO	30 - 35°C	3 days
P. aeruginosa	NCTC 12924	THIO	30 - 35°C	3 days
C. sporogenes	NCTC 12935	THIO	30 - 35°C	3 days
B. subtilis	NCTC 10400	TSB	20 - 25°C	3 days
C. albicans	NCPF 3179	TSB	20 - 25°C	5 days
A. brasiliensis	NCPF 2275	TSB	20 - 25°C	5 days

** growth must be detectable within the time indicated, otherwise the validation is considered as non-conform*

6 - 4 Routine

- Aseptically remove the samples from their package and transfer one of them into TSB and the second one into THIO in 200ml of medium.
- Hermetically close the containers.
- Prepare the respective negative controls.
- Incubate 14 days at 30-35°C for THIO and 20-25°C for TSB.
- Examine the media to check for macroscopic development of microbial growth.
- If there is no growth at the end of incubation, the batch of the product satisfies sterility testing.

7.0 Validation acceptance criteria

If after incubation a microbial growth is clearly visible, visually comparable to the positive control, the product does not have any antimicrobial activity in the conditions of testing, or its antimicrobial activity has been removed in a satisfying way. The sterility testing can then be performed without further modifications.

8.0 Conclusions

The testing method used to perform the medical devices' sterility testing on the product is validated and the results are evaluated as conform according to EN ISO 11737-2

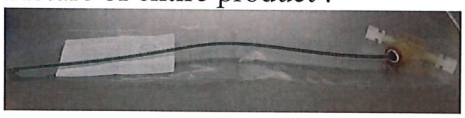
9.0 Approvals

Date: 30th September 2020
Laboratory Department:

Date: 30th September 2020
Quality Department:

10.0 Attachments

Picture of entire product :



Picture of the product in medium :