TEST REPORT

TUBERCULOCIDAL ACTIVITY OF THE F1031V2 PRODUCT ACCORDING TO THE EN 14348 STANDARD

Delivered to **Ms CHAKCHOUK**

For: **FRANKLAB**
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78180 MONTIGNY LE BRETONNEUX

Date of request: 10/18/2018

Study number: n°268D25-2018-24

MYCOBACTERICIDAL TESTS:

According to the European standard NF EN 14348 (June 2005) – Chemical disinfectants and antiseptics - Test suspension for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area -
Test method and requirements (phase 2, step 2)

Tests using the F1031V2 LINGETTES product against 1 reference strain: *Mycobacterium terrae.*

This test report included 7 pages.

Study completion date: 01/25/2019

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1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
4, rue des Grandes Pièces
Zone EURESPACE
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FRANCE

2 PRODUCT IDENTITY

Product	Batch N°
F1031V2 lingettes	701301

Expiration date: non communicated

Manufacturer : FRANKLAB

Manufacturing date: non communicated

Storage conditions: room temperature

Active substances : ethanol, isopropanol, tertiary amine

Appearance of the product: non-woven wipes, VH 23g/m2, 280% impregnation

Product diluent recommended by the manufacturer for use: none, ready-to-use product

Date of delivery of the product: 11/09/2018

Date of tests: from 10/29/2018 to 12/30/2018

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80% - Extraction of the product by manual spinning.

Appearance of the product and its dilutions: clear.

Method: dilution-neutralization.

Exposure time: 5 min, 10 min and 60 min

Temperature using during the assays: 20°C ± 1°C

Diluent used for the assays: distilled water.

Diluent used for the mycobacterial suspensions: sterile trypton salt solution.

Organic soil load: dirty conditions, BSA 3 g/L + sheep erythrocytes 3 mL/L

Product stability: limpid solution with organic soil load

Neutralizer: tween 80 and egg yolk

Strains*: Mycobacterium terrae* CIP 104321, batch n°16308 (Institut Pasteur).

Media: Middlebrook 7H9 ADC 10% broth, Middlebrook 7H10 OADC 10% media, 37°C ± 1°C.

4 VALIDATIONS AND ASSAYS

See results sheets.

The tuberculocidal activity is demonstrated if the reduction of the population is ≥ 4 log.

– *Mycobacterium terrae*, R = 4,89 (10 min)

5 CONCLUSION

According to the EN 14348 standard (June 2005), the F1031V2 lingettes product:

- demonstrated a tuberculocidal activity against *Mycobacterium terrae* strain in 10 min at 20°C, under dirty conditions, when used pure

6 SHEETS OF RESULTS

See below.

Methodology controls:
- 1,5 x 10^9 UFC/ml≤ N ≤ 5,0 x 10^9 UFC/ml
- 3 x 10^2 UFC/ml≤ Nv 1,6 x 10^3
- 30≤ Nv0 ≤160 UFC/ml
- A, B and C ≥0,5 x Nv0

Vc = number of colonies on Petri dish
Nv 0= number of colonies / ml in A, B and C solutions
N = number of CFU/ml of the test suspension
Na = number of survivor per ml after time exposure with the product
A = number of CFU/ml in validation assay of experimental conditions
B = number of CFU/ml in validation assay of non-toxicity of the Neutralizer
C = number of CFU/ml in validation assay of the dilution-neutralization method
$\bar{x}$ = average of Vc1 and Vc2
LOG R = reduction (lg R = lg N0 – lg Na)

7 *Mycobacterium terrae* - trial

Standard: EN 14348 Product : **F1031V2 LINGETTES** Batch N° : 701301 Study N° : 268D25-2018-24 Date of trials : 11/19/2018	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : tween 80 + egg yolk 5% Temperature of trials : 20°C Organic soil load : 3 g/L BSA + 3 mL/L SE Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

	Suspension of validation		Validation A		Validation B		Validation C		Trial suspension			Concentrations (v/v)					
												5 min		10 min		60 min	
	VC1	VC2	VC1	VC2	VC1	VC2	VC1	VC2		VC1	VC2		VC1	VC2	VC1	VC2	VC1	VC2
Mycobacterium terrae	66	57	61	66	53	58	50	47	1.10^{-7}	227	217	1.10^{0}	>660	>660	301	298	46	35
	$\bar{x}$	**61,5**	$\bar{x}$	**64,0**	$\bar{x}$	**55,5**	$\bar{x}$	**48,5**	1.10^{-8}	25	22	1.10^{-1}	266	248	34	30	8	5
	30 ≤ Nv0 ≤ 160		A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0					1.10^{-2}	30	28	5	4	2	0
	× yes □ no		× oui □ non		× oui □ non		× oui □ non					1.10^{-3}	4	3	0	1	0	0
									Log N	9,35		Na	$2,60.10^{4}$		$3,01.10^{3}$		$4,05.10^{2}$	
									Log N0	8,35		Log Na	4,41		3,48		2,61	
									8,17 ≤ log N0 ≤ 8,70?			Log R	**3,94**		**4,87**		**5,74**	
									x yes □ no									

8 *Mycobacterium terrae* - repetition

Standard: EN 14348 Product : **F1031V2 LINGETTES** Batch N° : 701301 Study N° : 268D25-2018-24 Date of trials : 11/20/2018	Method: ☒ Pour plating ☐ Spread plating ☒ Number of petri dishes: 2 petri dish / ml	Neutralizer : tween 80 + egg yolk 5% Temperature of trials : 20°C Organic soil load : 3 g/L BSA + 3 mL/L SE Incubation temperature : 37°C ± 1°C Diluent : sterile distilled water

	Suspension of validation		Validation A		Validation B		Validation C		Trial suspension			Concentrations (v/v)						
													5 min		10 min		60 min	
	VC1	VC2	VC1	VC2	VC1	VC2	VC1	VC2		VC1	VC2		VC1	VC2	VC1	VC2	VC1	VC2
Mycobacterium terrae	48	53	56	63	61	60	34	41	1.10^{-7}	165	171	1.10^{0}	662	662	223	191	49	50
	$\bar{x}$	**50,5**	$\bar{x}$	**59,5**	$\bar{x}$	**60,5**	$\bar{x}$	**37,5**	1.10^{-8}	19	20	1.10^{-1}	401	389	26	31	6	6
	30 ≤ Nv0 ≤ 160		A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0					1.10^{-2}	55	46	2	0	1	1
	× yes □ no		× yes □ no		× yes □ no		× yes □ no					1.10^{-3}	6	10	0	0	0	0
									Log N	9,23		Na	$4,05.10^{4}$		$2,14.10^{3}$		$4,95.10^{2}$	
									Log N0	8,23		Log Na	4,61		3,33		2,69	
									8,17 ≤ log N0 ≤ 8,70?			Log R	**3,62**		**4,90**		**5,54**	
									x yes □ no									

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9 TECHNICAL APPENDIX

MEDIA

- Middlebrook broth 7H9, FLUKA, ref. 100957898, batch n° BCBC4788
- ADC 10%, FLUKA, ref. 101007527, batch n° BCBD4192
- Middlebrook media and Cohn 7H10 SIGMA-ALDRICH, ref. M0303, batch n°1405662
- OADC 10%, FLUKA, ref. 100962567, batch n° BCBC5497

DILUENT

Trypton-Salt Solution _ Per liter of distilled water:

- Trypton, Dominique Dutscher, ref. 777472, batch n° 090633 1,00 g
- Sodium Chloride, Grosseron, ref. 9020401, batch n° FR08 085 793 8,50 g

Final pH at 25°C : 7,0 ± 0,2

NEUTRALIZER

Ingredients per liter of distilled water:

- Tween 80, Sigma Aldrich, ref 59924, batch BCBJ6978V 30 g
- Egg yolk 5 g

Sterilised by autoclaving

ORGANIC SOIL LOAD

Albumin Serum Bovine in powder, Fraction V, Dominique Dutscher, ref. P6154, batch D1304039