EAK
EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L236

EVS-EN 14348:2005
INTERFLO OÜ
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Quantitative suspension test for the evaluation of mycobactericidal activity in the medical area (phase 2, step 1)

TEST REPORT no 688

1. General information and material

Client:	MEDISEPT SP. ZOO Reg. 946001016
Dates of orders:	2021/08/25; 2021/09/21

2. Identification of sample

Name of the product:	VIRUTON PULVER
Batch number:	210526 4
Manufacturer:	MEDISEPT SP. ZOO
Date of delivery:	2021/08/24
Storage conditions:	room temperature and darkness

Apperance of the product:	white powder with blue granules
Recommended diluent:	water 30 °C, testing 15 min after dilution
Active substance and concentration:	Sodium percabonate – 44 %; TAED – 26 %

3. Test conditions

Test period:	2021/08/26 – 2021/10/13
Date of tests:	2021/08/26; 2021/09/22
Product test concentrations:	0,5 %; 1,0 % (testing 15 min after dilution in hard water 30 ºC)
Exposure time:	15 min, 30 min, 60 min
Test temperature:	19,5 ± 0,5ºC
Temperature of incubation	36,5 ± 0,5ºC
Organic load:	0,3 g/l bovine albumin for low-level soiling; 3,0 g/l bovine albumin and 3,0 ml/l sheep erythrocytes for high-level soiling
Neutralizer:	Polysorbate 80, 30 g/l, Sodium thiosulphate, 5 g/l, Lecithin, 3 g/l
Test organisms:	Mycobacterium terrae ATCC 15755, Mycobacterium avium ATCC 15769

4. Methods

Test method and its validation:	dilution neutralisation

5. Results see annex

6. Conclusion

In accordance with EN 14348:2005, product VIRUTON PULVER (batch 210526 4) with concentration 0,5 % in 15 min possesses tuberculocidal activity in suspension test at 20 ºC under dirty conditions for reference strain Mycobacterium terrae ATCC 15755.
In accordance with EN 14348:2005, product VIRUTON PULVER (batch 210526 4) with concentration 0,5 % at 15 min possesses mycobactericidal activity in suspension test at 20 ºC under dirty and clean conditions for referenced strain Mycobacterium avium ATCC 15769.

The product VIRUTON PULVER (batch 210526 4) demonstrates at least a 4 lg reduction in all aforementioned cases.

The conclusion is true only for the studied sample of the product VIRUTON PULVER (batch 210526 4).

Total 10 pages
Annex on 7 pages
Tallinn, 2021/10/13

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Annex 1

VALIDATION AND CONTROLS

Test organisms	**Validation suspensions Nvo** Dilution range -1			**Experimental conditions control A**			**Neutralizer control B**			**Method validation C**		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
Mycobacterium terrae ATCC 15755 For the order 2021/08/25 With concentration 1,0 %	108	96	102	90	101	96	82	78	80	89	80	85
Mycobacterium terrae ATCC 15755 For the order 2021/09/21 With concentration 0,5 %	59	73	66	60	49	55	40	43	42	54	66	60
Mycobacterium avium ATCC 15769 For the order 2021/08/25 With concentration 1,0 %	55	49	52	60	47	54	40	38	39	45	40	43

Annex 2

TEST SUSPENSIONS

Test organisms	**Dilution range**	**Vc1**	**Vc2**	**N, No**
Mycobacterium terrae ATCC 15755 For the order 2021/08/25	-7 -8	>330 54	>330 46	N = 5,0 x 10 ^{9} = lg 9,7 **No 8,7** 8,17≤lg No≤8,70
Mycobacterium terrae ATCC 15755 For the order 2021/09/21	-7 -8	>300 50	>300 39	N = 4,45 x 10 ^{9} = lg 9,65 **No 8,65** 8,17≤lg No≤8,70
Mycobacterium avium ATCC 15769 For the order 2021/08/25	-7 -8	>330 44	>330 50	N = 4,7 x 10 ^{9} = lg 9,67 **No 8,67** 8,17≤lg No≤8,70

Annex 3

TEST 1 Dirty conditions
For the order 2021/08/25

Test organisms	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentration	Contact time
Mycobacterium terrae ATCC 15755	1	0	0	<140	<2,15	**6,55**	1,0 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
Mycobacterium avium ATCC 15769	1	0	0	<140	<2,15	**>6,52**	1,0 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 4

TEST 2 Dirty conditions
For the order 2021/08/25

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentration	Contact time
Mycobacterium avium ATCC 15769	1	12	18	159	2,2	**6,47**	0,5 %	15 min
	-1	2	3					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>6,52**	0,5 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	4	8	<140	<2,15	**>6,52**	1,0 %	15 min
	-1	2	3					
	-2	1	0					
	-3	0	0					

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Annex 5

TEST 3 Clean conditions
For the order 2021/08/25

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Concentration	Contact time
Mycobacterium avium ATCC 15769	1	0	0	<140	<2,15	**>6,52**	0,5 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 6

TEST 4 Dirty conditions
For the order 2021/09/21

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentration	Contact time
Mycobacterium terrae ATCC 15755	1	16	12	140,9	2,15	**6,5**	0,5 %	15 min
	-1	2	1					
	-2	1	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>6.5**	0,5 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>6.5**	0,5 %	60 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 7

$N = c / (n1 + 0,1\ n2) \times 10\ -z$

$No = N / 10$

$Na = c \times 10 / n$

$R = lg\ No – lg\ Na$

N – is the number of colonies for 1 ml test suspension
Vc1, Vc2 - is the is number of colonies for 1 ml sample
n – is the number of Vc-values taken into account
z – is the dilution factor corresponding to the lower dilution
R – reduction