BALTIACHEMI

VIRUTON PULVER
EN 14563:2009

Akrediteeritud L236

EVS-EN 14563:2009
OÜ BALTIACHEMI
LABORATORY
Tel.. +372 6214 694
e-mail: info@baltiachemi.ee

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Quantitative carrier test for the evaluation of mycobactericidal and tuberculocidal activity for instruments used in the medical area (phase 2, step 2)

TEST REPORT no 315

1. General information and material

1.1 Client:	Medi-Sept Sp. z.o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order:	2016/11/24
1.2 Identification of sample	
Name of the product:	VIRUTON PULVER
Batch number:	LOT: 160819_55
Manufacturer:	Medi-Sept Sp. z.o.o.
Date of delivery:	2016/12/01
Storage conditions:	room temperature and darkness
Apperance of the product:	powder
Active substance:	44 % Sodium percarbonate, 26 % TAED (PAA)
1.3 Test conditions	

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory

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Test period:	2017/01/24 – 2017/02/15
Date of test:	2017/01/24
Product test concentrations:	1,0 %; 2,0 %
Exposure time:	10 min; 30 min
Test temperature:	19,5 ± 0,5°C
Organic load:	for clean conditions is bovine albumine 0,3 g/l; for dirty conditions are bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l
Neutralizer:	Polysorbate 80, 30 g/l; Lecithin, 3 g/l; Sodium thiosulphate, 5 g/l
Temperature of incubation	36,5°C ± 0,5°C
Test organisms:	Mycobacterium terrae ATCC 1575; Mycobacterium avium ATCC 15769

2. Methods

2.1. Test method and its validation: dilution neutralisation

3. Results see annex

4. Conclusion

In accordance with EN 14563:2009, product VIRUTON PULVER (LOT: 160819_55) for instrument disinfection with concentration 1,0 % in 10 min and 30 min and 2,0 % in 10 min possesses mycobactericidal and tuberculocidal activity in carrier test at 20 °C under clean and dirty conditions for referenced strains Mycobacterium avium ATCC 15769 and Mycobacterium terrae ATCC 1575 respectively.

The product VIRUTON PULVER demonstrates at least a 4 lg reduction.

Total 8 pages
Annex on 6 pages

Maardu, 2017/02/15

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory

EESTI VABARIIK
OÜ Baltiachemi
REG. KOOD 10965891

Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension Nv			Experimental conditions control A			Neutralizer control B			Method validation C Concentr. 2,0 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
Mycobacterium terrae ATCC 1575	70	63	67	54	61	58	57	50	54	61	49	55
Mycobacterium avium ATCC 15769	37	42	40	40	38	39	35	31	33	36	30	33

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Annex 2

TEST SUSPENSION

Test organisms	Dilution step	Vc1	Vc2	N
Mycobacterium terrae ATCC 1575	-7	>200	>200	N= 2,6 x 10^9 = lg 9,41
	-8	31	21	9,17≤lg N ≤ 9,77
Mycobacterium avium ATCC 15769	-7	>300	>300	N= 3,7 x 10^9 = lg 9,57
	-8	40	34	9,17≤lg N ≤ 9,77

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Annex 3

WATER CONTROL

Test organisms	Dilution step	Vc1	Vc2	Nw
Mycobacterium terrae ATCC 1575	-4	>300	>300	N= 1,9 x 10^8 = **lg 8,28**
	-5	>100	>100	7,15≤lg Nw ≤ lgN-1,3
	-6	18	20	
Mycobacterium avium ATCC 15769	-4	>300	>300	N= 8,5 x 10^7 = **lg 7,93**
	-5	100	70	7,15≤lg Nw ≤ lgN-1,3
	-6	7	9	

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Head of the Laboratory

EESTI VABARIIK
OÜ
Baltiachemi
REG. KOOD 10965891

Annex 4
TEST 1 Mycobacterium terrae

Test organism	Conditions	Concentration	Dilution	Vc1	Vc2	Na x 10	lg Na	lg R	Cont. time
Mycobacterium terrae ATCC 1575	Clean	1,0 %	1	3	3	< 140	< 2,15	**>6,13**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
			1	0	0	< 140	< 2,15	**>6,13**	30 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
		2,0 %	1	0	0	< 140	< 2,15	**>6,13**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
	Dirty	1,0 %	1	18	11	145	2,16	**6,12**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
			1	0	0	< 140	< 2.15	**>6,13**	30 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
		2,0 %	1	1	0	< 140	< 2,15	**>6,13**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory

EESTI VABARIIK
OÜ Baltiachemi
REG. KOOD 10965891

Annex 5
TEST 2 Mycobacterium avium

Test organism	Conditions	Concentration	Dilution	Vc1	Vc2	Na x 10	lg Na	lg R	Cont. time
Mycobacterium avium ATCC 15769	Clean	1,0 %	1	17	11	140	2,15	**5,78**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
			1	4	3	< 140	< 2,15	**>5,78**	30 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
		2,0 %	1	10	6	< 140	< 2,15	**>5,78**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
	Dirty	1,0 %	1	15	19	170	2,23	**5,7**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
			1	0	0	< 140	< 2,15	**>5,78**	30 min
			-1	8	8				
			-2	0	0				
			-3	0	0				
		2,0 %	1	10	12	< 140	< 2,15	**>5,78**	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory

EESTI VABARIIK
OÜ Baltiachemi
REG. KOOD 10965391

Annex 7

$$N = \frac{C}{(n1 + 0.1\ n2) \times 10^{-7}}$$

$Na = c \times 10 / n$

$Nw = c \times 10 / n^{-5}$

$R = \lg Nw - \lg Na$

N – is the number of cfu (colony forming unit) for 1 ml test suspension
Vc1, Vc2 - is the is number of cfu for 1 ml sample
n – is the number of Vc-values taken into account
Nw – water control
R – reduction

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory

EESTI VABARIIK
CO
Baltiachemi
REG. K