



Akrediteeritud L236

EVS-EN 14563:2009
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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:

Date of order:
Medi-Sept Sp. z.o.o., Konopnica 159 c, 21-030 Motycz, Poland
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
Appearance of the product:
powder
Active substance:
44 % Sodium percarbonate, 26 % TAED (PAA)

1.3 Test conditions

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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

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VALIDATION AND CONTROLS

Test organisms	Validation suspension N _v			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

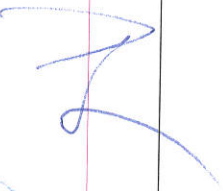
Test organisms	Dilution step	Vc1	Vc2	N
Mycobacterium terrae ATCC 1575	-7	>200	>200	$N = 2,6 \times 10^9 = \lg 9,41$
	-8	31	21	$9,17 \leq \lg N \leq 9,77$
Mycobacterium avium ATCC 15769	-7	>300	>300	$N = 3,7 \times 10^9 = \lg 9,57$
	-8	40	34	$9,17 \leq \lg N \leq 9,77$

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WATER CONTROL

Test organisms	Dilution step	Vc1	Vc2	N _w
Mycobacterium terrae ATCC 1575	-4	>300	>300	$N = 1,9 \times 10^8 = \lg 8,28$
	-5	>100	>100	$7,15 \leq \lg N_w \leq \lg N-1,3$
	-6	18	20	
Mycobacterium avium ATCC 15769	-4	>300	>300	$N = 8,5 \times 10^7 = \lg 7,93$
	-5	100	70	$7,15 \leq \lg N_w \leq \lg N-1,3$
	-6	7	9	

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Annex 4
TEST 1 Mycobacterium terrae

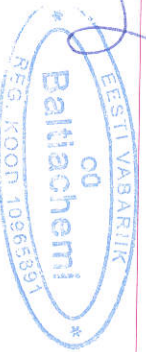
Test organism	Conditions	Concentration	Dilution	Vc1	Vc2	Na x 10	lg Na	lg R	Cont. time
Mycobacterium terrae ATCC 1575	Clean	1,0 %	1	3	3	< 140	< 2,15	> 6,13	10 min
			-1	0	0				
			-2	0	0				
			-3	0	0				
			1	0	0				
			-1	0	0				
		-2	0	0					
		-3	0	0					
		1	0	0					
		-1	0	0					
		-2	0	0					
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

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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							
			-1	0	0							
		-2	0	0								
		-3	0	0								
		1	10	6	< 140	< 2,15	> 5,78	30 min				
		-1	0	0								
		-2	0	0								
		-3	0	0								
	1	15	19									
	-1	0	0									
	-2	0	0	170	2,23	5,7	10 min					
	-3	0	0									
	1	0	0									
	-1	8	8									
	-2	0	0									
	-3	0	0									
	Dirty	1,0 %	1	10	12	< 140	< 2,15	> 5,78	30 min			
			-1	0	0							
			-2	0	0							
			-3	0	0							
1			2,0 %	0	< 140					< 2,15	> 5,78	10 min
-1			0	0								
-2		0	0									
-3		0	0									
1		0	0									
-1		0	0									

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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 number of cfu for 1 ml sample

n – is the number of V-c-values taken into account

Nw – water control

R – reduction

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