



EVS-EN 14561:2006
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Quantitative carrier test for the evaluation of bactericidal activity in the medical area (phase 2, step 2)

TEST REPORT no 386

1. General information and material

- 1.1 Client: Medi-Sept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
- Date of order: 2018/06/04
- 1.2 Identification of sample: VIRUTON PULVER
- Name of the product: 180222_5
- Batch number: Medi-Sept Sp. z.o.o.
- Manufacturer: 2018/06/11
- Date of delivery: room temperature and darkness
- Storage conditions: white powder
- Appearance of the product: white powder
- Recommended diluent: water

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Active substance:

1.3 Test conditions

44 % Sodium percarbonate, 26 % TEAD

Test period:

2018/06/21 – 2018/06/28

Date of test:

2018/06/21, 2018/06/26

Product test concentrations:

0,5 %

Diluent:

hard water (45°C)

Exposure time:

30 min

Test temperature:

19,5 ± 0,5°C

Organic load:

for clean conditions (bovine albumine 0,3 g/l)

for dirty conditions (bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l)

Polysorbate 80, 30 g/l; Sodium thiosulphate, 5 g/l; Lecithin, 3 g/l

Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541,

Pseudomonas aeruginosa ATCC 15442

Neutralizer:

Test organisms:

2. Methods

2.1. Test method and its validation:

dilution neutralisation

see annex

3. Results

4. Conclusion

In accordance with EN 14561:2006, product VIRUTON PULVER (batch number 180222_5) with concentration 0,5 % possesses bactericidal activity in carrier test in 30 min at 20 °C under clean and dirty conditions for strain Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Pseudomonas aeruginosa ATCC 15442. The product VIRUTON PULVER demonstrates at least a 5 lg reduction.

Total 9 pages

Annex on 7 pages

Maardu, 2018/07/16

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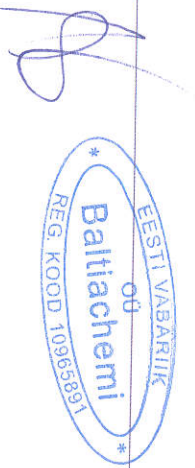
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VALIDATION AND CONTROLS

Test organisms	Validation suspension N _v Dilution step -1			Experimental conditions control A Dilution step 1			Neutralizer control B Dilution step 1			Method validation C 0,5 % Dilution step 1		
	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}
Staphylococcus aureus ATCC 6538	66	52	59	48	50	49	38	47	43	39	35	37
Pseudomonas aeruginosa ATCC 15442	95	112	104	88	93	91	69	80	75	75	79	77
Enterococcus hirae ATCC 10541	71	64	68	60	57	59	67	69	68	59	71	65

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Annex 2

TEST SUSPENSIONS

Test organism	Dilution step	Vc1	Vc2	N
Staphylococcus aureus ATCC 6538	-7 -8	>300 41	>300 59	$N = 5,0 \times 10^9 = 1g\ 9,7$
Pseudomonas aeruginosa ATCC 15442	-7 -8	>300 48	>300 36	$N = 4,2 \times 10^9 = 1g\ 9,62$
Enterococcus hirae ATCC 10541	-7 -8	>300 25	>300 39	$N = 3,2 \times 10^9 = 1g\ 9,5$

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Annex 3

WATER CONTROL

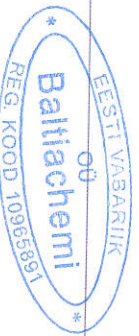
Water control Nw	Test organisms	Dilution step	Vc1	Vc2	
	Staphylococcus aureus ATCC 6538	-4	>300	>300	$N_w 4,65 \times 10^7$ $Ig N_w 7,67$
		-5	38	55	
		-4	>300	300	
		-4	>300	300	
		-5	40	29	
		-5	>200	>200	
	Pseudomonas aeruginosa ATCC 15442	-4	>200	>200	$N_w 3,45 \times 10^7$ $Ig N_w 7,54$
		-5	40	29	
		-4	>200	>200	
	Enterococcus hirae ATCC 10541	-4	>200	>200	$N_w 2,35 \times 10^7$ $Ig N_w 7,37$
		-5	21	26	

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Annex 4

TEST 1

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Staphylococcus aureus ATCC 6538	Clean	1	0	0	<140	<2,15	>5,52	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				
		1	0	0				
	Dirty	-1	0	0	<140	<2,15	>5,52	30 min
		-2	0	0				
		-3	0	0				
		1	0	0				
		-3	0	0				

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Annex 5

TEST 2

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Pseudomonas aeruginosa ATCC 15442	Clean	1	0	0	<140	<2,15	>5,39	30 min
			0	0				
			0	0				
		-2	0	0				
			0	0				
			0	0				
	Dirty	1	0	0	<140	<2,15	>5,39	30 min
			0	0				
			0	0				
			0	0				

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Annex 6

TEST 3

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Enterococcus hirae ATCC 10541	Clean	1	0	0	<140	< 2,15	> 5,22	30 min
			0	0				
			0	0				
		-2	0	0				
			0	0				
			0	0				
	Dirty	1	0	0	<140	< 2,15	> 5,22	30 min
			0	0				
			0	0				
		-1	0	0				
			0	0				
			0	0				
-2	0	0						
	0	0						
	0	0						
-3	0	0						
	0	0						
	0	0						

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Annex 7

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

$$Na = c \times 10 / n$$

$$R = \lg Nw - \lg Na$$

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
R – reduction

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