



EVS-EN 13727:2012+A2:2015  
OÜ INTERFLO  
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**Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1)**

TEST REPORT no 716

**1. General information and material**

Client: MEDISEPT SP. ZOO, Konopnica 159 c, 21-030 Motycz, Poland  
NIP. 9460010016  
Date of order: 2022/02/21

**2. Identification of sample**

Name of the product: VIRUTON PULVER  
Batch number: 16022022-2  
Manufacturer: MEDISEPT SP. ZOO  
Date of delivery: 2022/02/21  
Storage conditions: room temperature and darkness  
Apperance of the product: white powder with blue granules

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Recommended diluent: hard water  
Active substance: Peracetic acid (44 % Sodium percarbonate; 26 % TAED)

### 3. Test conditions

Test period: 2022/03/14 – 2022/03/16  
Date of test: 2022/03/14  
Product test concentrations: 0,5 %; 1,0 %  
Exposure time: 15 min  
Test temperature:  $19,5 \pm 0,5^{\circ}\text{C}$   
Incubation temperature:  $36,5 \pm 0,5^{\circ}\text{C}$   
Organic load: bovine albumine 3,0 g/l and sheep erythrocytes 3,0 ml/l for high-level soiling  
Neutralizer: Polysorbate 80, 30 g/l; Sodium thiosulphate, 5 g/l; Lecithin, 3 g/l  
Test organisms: Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Enterococcus hirae ATCC 10541

### 4. Methods

Test method and its validation: dilution neutralisation

### 5. Results

see annex

### 6. Conclusion

In accordance with EN 13727:2015, product VIRUTON PULVER (batch number 16022022-2) with concentration 0,5 % and 1,0% possesses bactericidal activity in suspension test in 15 min at 20 °C under dirty conditions for referenced strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541. The product VIRUTON PULVER (batch number 16022022-2) demonstrates at least a 5 lg reduction.

*The conclusion is true only for the studied sample of the product VIRUTON PULVER (batch number 16022022-2).*

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Annex on 6 pages

Tallinn, 2022/03/04

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N <sub>vo</sub> -1			Validation suspension N <sub>vbo</sub> -3			Experimental conditions control A			Neutralizer control B -2			Method validation C Concentration 1,0 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
Staphylococcus aureus ATCC 6538	132	120	126	88	75	82	116	123	120	68	71	70	105	100	103
Pseudomonas aeruginosa ATCC15442	112	122	117	55	40	48	95	90	93	38	48	43	98	111	105
Enterococcus hirae ATCC 10541	60	74	67	85	70	78	55	49	52	69	73	70	50	53	52

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Annex 2

TEST SUSPENSIONS

Test organisms	Dilution step	Vc1	Vc2	N No
Staphylococcus aureus ATCC 6538	10 <sup>-6</sup>	>100	>100	N= 1,6 x 10 <sup>8</sup> = lg 8,2 No = N / 10 = <b>lg 7,2</b> 7,17 ≤ lg No ≤ 7,70
	10 <sup>-7</sup>	14	18	
Pseudomonas aeruginosa ATCC 15442	10 <sup>-6</sup>	159	144	N= 1,52 x 10 <sup>8</sup> = lg 8,18 No = N / 10 = <b>lg 7,18</b> 7,17 ≤ lg No ≤ 7,70
	10 <sup>-7</sup>	18	14	
Enterococcus hirae ATCC 10541	10 <sup>-6</sup>	150	162	N= 1,57 x 10 <sup>8</sup> = lg 8,2 No = N / 10 = <b>lg 7,2</b> 7,17 ≤ lg No ≤ 7,70
	10 <sup>-7</sup>	15	19	

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Annex 3

TEST 1

Test organism	Concentration	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Staphylococcus aureus ATCC 6538	0,5%	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,05	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				
	1,0 %	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,05	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				

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Annex 4

TEST 2

Test organism	Concentration	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Pseudomonas aeruginosa ATCC 15442	0,5%	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,03	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				
	1,0 %	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,03	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				

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Annex 5

TEST 3

Test organism	Concentration	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Enterococcus hirae ATCC 10541	0,5%	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,05	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				
	1,0 %	10 <sup>0</sup>	0	0	< 140	< 2,15	>5,05	15 min
		10 <sup>-1</sup>	0	0				
		10 <sup>-2</sup>	0	0				
		10 <sup>-3</sup>	0	0				

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Annex 6

$$N = c / (n_1 + 0.1 n_2) \times 10^{-7} / -6$$

$$N_0 = N / 10$$

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

$$R = \lg N_0 - \lg N_a$$

N – is the number of colonies for 1 ml test suspension  
Vc<sub>1</sub>, Vc<sub>2</sub> - 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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