

EN ISO/IEC 17025
L236

EVS-EN 13727:2012+A2:2015
OÜ BALTIACHEMI
LABORATORY
Tel. +372 6214 694
e-mail: info@baltiachemi.ee

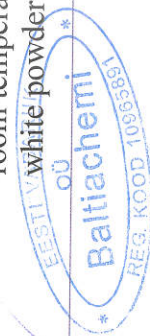
Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1)

TEST REPORT no 384

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
Name of the product: VIRUTON PULVER
Batch number: 180222_5
Manufacturer: Medi-Sept Sp. z.o.o.
Date of delivery: 2018/06/11
Storage conditions: room temperature and darkness
Appearance of the product: white powder

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



Recommended diluent:

water

44 % Sodium percarbonate, 26 % TEAD

1.3 Test conditions

Test period:

2018/06/21 – 2018/06/28

Date of test:

2018/06/21, 2018/06/26

Product test concentrations:

0,5 %

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)

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**2. Methods**

2.1. Test method and its validation:

dilution neutralisation

3. Results

see annex

4. Conclusion

In accordance with EN 13727:2013, product VIRUTON PULVER (batch number 180222_5) with concentration 0,5 % possesses bactericidal activity in suspension test in 30 min at 20 °C under clean and dirty conditions for referenced strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541. The product VIRUTON PULVER demonstrates at least a 5 lg reduction.

Total 8 pages

Annex on 6 pages

Maardu, 2018/07/16

Microbiologist

Ljudmila Shljapnikova

Biol.Ph.D.


Head of the Laboratory



Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension NV Dilution step -1			Validation suspension NVB Dilution step -3			Experimental conditions control A Dilution step 1			Neutralizer control B Dilution step -2			Method validation C 0,5 % Dilution step 1		
	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}
Staphylococcus aureus ATCC 6538	66	52	59	45	40	43	48	50	49	35	37	36	39	35	37
Pseudomonas aeruginosa ATCC 15442	95	112	104	48	55	52	88	93	91	44	46	45	75	79	77
Enterococcus hirae ATCC 10541	71	64	68	52	42	47	60	57	59	38	40	39	59	71	65



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 Biol.Ph.D.
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Annex 2

TEST SUSPENSION

Test organisms	N	Vc1	Vc2	No
Staphylococcus aureus ATCC 6538	-7	>300	>300	$N = 5,0 \times 10^8 = \lg 8,7$
	-8	41	59	$No = N / 10 = \lg 7,7$ $7,17 \leq \lg No \leq 7,70$
Pseudomonas aeruginosa ATCC 15442	-7	>300	>300	$N = 4,2 \times 10^8 = \lg 8,62$
	-8	36	48	$No = N / 10 = \lg 7,62$ $7,17 \leq \lg No \leq 7,70$
Enterococcus hirae ATCC 10541	-7	>300	>300	$N = 3,2 \times 10^8 = \lg 8,5$
	-8	25	39	$No = N / 10 = \lg 7,5$ $7,17 \leq \lg No \leq 7,70$

Microbiologist

Ljudmila Shljapnikova

Biol.Ph.D.

Head of the Laboratory



Annex 3

TEST 1 Staphylococcus aureus

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Staphylococcus aureus ATCC 6538	Clean	1	0	0	< 140	< 2.15	> 5,55	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				
	Dirty	1	0	0	< 140	< 2.15	> 5,55	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				

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



Annex 4

 TEST 2 *Pseudomonas aeruginosa*

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
<i>Pseudomonas aeruginosa</i> ATCC 15442	Clean	1	0	0	< 140	< 2.15	> 5,47	30 min
		-1	0	0				
		-2	0	0				
	Dirty	-3	0	0	< 140	< 2.15	> 5,47	30 min
		1	0	0				
		-1	0	0				
		-2	0	0				
		-3	0	0				

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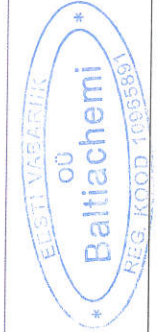


Annex 5

TEST 3 Enterococcus hirae

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Enterococcus hirae ATCC 10541	Clean	1	0	0	< 140	< 2.15	> 5,35	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				
	Dirty	1	0	0	< 140	< 2.15	> 5,35	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				

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Annex 6

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

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

$$R = \lg N_0 - \lg Na$$

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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