BALTIACHEMI

MEDI-SPRAY
EN 13727:2013

Akrediteeritud L236

EVS-EN 13727:2012+A1:2013
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 244

1. General information and material

1.1 Client:	Medi-Sept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order:	06.11.2015
1.2 Identification of sample	
Name of the product:	MEDI-SPRAY
Batch number:	151030_50
Manufacturer:	Medi-Sept Sp. z.o.o.
Date of delivery:	09.11.2015
Storage conditions:	room temperature and darkness
Apperance of the product:	liquid, clear, without color
Recommended diluent:	product is ready for use
Active substance:	55-65 % Ethanol and 5-10 % Propan-2-ol

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

Digitally signed by Palii Nina
Date: 2023.01.05 09:38:43 EET
Reason: MoldSign Signature
Location: Moldova

OÜ Baltiachemi REG. KOOD 10965891

1.3 Test conditions

Test period:	11.11.2015 – 13.11.2015
Date of test:	11.11.2015
Product test concentrations:	97 %
Exposure time:	15 s.,30 s., 60 s.
Test temperature:	19,5 ± 0,5°C
Organic load:	dirty conditions (bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l) clean conditions (bovine albumine 0,3 g/l)
Neutralizer:	Polysorbate 80, 30 g/l; Saponin 30 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 MEDI-SPRAY with concentration 97 % possesses bactericidal activity in suspension test in 30 s. and 60 s. at 20 °C under dirty and clean conditions for referenced strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541, and in 15 s. under clean conditions for referenced strains Staphylococcus aureus ATCC 6538 and Enterococcus hirae ATCC 10541. The product MEDI-SPRAY demonstrates at least a 5 lg reduction.

Total 11 pages
Annex on 9 pages

Maardu, 13.11.2015

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

Baltiachemi OÜ

Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension Nv Dilution step -1			Validation suspension NvB Dilution step -2			Experimental conditions control A Dilution step 1			Neutralizer control B Dilution step -2			Method validation C Dilution step 1		
	Vc1	Vc2	X^-	Vc1	Vc2	X^-	Vc1	Vc2	X^-	Vc1	Vc2	X^-	Vc1	Vc2	X^-
Staphylococcus aureus ATCC 6538	75	63	69	44	35	40	88	71	80	50	39	45	60	79	70
Pseudomonas aeruginosa ATCC 15442	60	52	56	35	37	36	53	44	49	40	34	37	48	43	46
Enterococcus hirae ATCC 10541	35	40	38	68	73	70	30	31	31	50	54	52	38	32	35

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

OÜ Baltiachemi REG KOOD 10965091

Annex 2

TEST SUSPENSION

Test organisms	N	Vc1	Vc2	No
Staphylococcus aureus ATCC 6538	-7	257	288	N= 2,8 x 10 9 = lg 9,45 No = N / 100 = **lg 7.45**
	-8	33	35	7.17≤lg No≥ 7.70
Pseudomonas aeruginosa ATCC 15442	-7	295	274	N= 2,83 x 10 9 = lg 9,45 No = N / 100 = **lg 7.45**
	-8	25	30	7.17≤lg No≥ 7.70
Enterococcus hirae ATCC 10541	-7	300	300	N= 3,01 x 10 9 = lg 9,47 No = N / 10 = **lg 7.47**
	-8	38	26	7.17≤lg No≥ 7.70

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

EESTI VABARIIK OÜ Baltiachemi REG. KOOD 10965891

Annex 3

TEST 1 Staphylococcus aureus
Clean conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Staphylococcus aureus ATCC 6538	1	0	0	< 140	< 2.15	>5.3	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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

Annex 4

TEST 2 Staphylococcus aureus
Dirty conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Staphylococcus aureus ATCC 6538	1	0	0	< 140	< 2.15	>5.3	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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

Baltiachemi

Annex 5

TEST 3 Pseudomonas aeruginosa
Clean conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Pseudomonas aeruginosa ATCC 15442	1	0	0	< 140	< 2.15	>5.3	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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

Baltiachemi

Annex 6

TEST 4 Pseudomonas aeruginosa
Dirty conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Pseudomonas aeruginosa ATCC 15442	1	97	84	910	2,96	4,49	15 s.
	-1	6	4				
	-2	0	0				
	-3	0	0				
	1	28	20	240	2,38	5,07	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.3	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

Annex 7

TEST 5 Enterococcus hirae
Clean conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Enterococcus hirae ATCC 10541	1	0	0	< 140	< 2.15	>5.32	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.32	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.32	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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

Annex 8

TEST 6 Enterococcus hirae
Dirty conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Enterococcus hirae ATCC 10541	1	0	0	< 140	< 2.15	>5.32	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.32	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>5.32	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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

Annex 9

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

$Na = c \times 10 / n$

$R = lgNo - lg\ Na$

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

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