

EN ISO/IEC 17025
L236

EVS- EN 13727:2012+A1:013+A2:2015
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Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1)

TEST REPORT no 511

1. General information and material

Client:

OY FINNSCO
Reg. 2387841-4
Peltosaarekatu 19 FI-11130 Riihimäki, Finland

2. Identification of sample

Name of the product: PRO-10® PINTADESI
Batch number: 23.04.2020
Manufacturer: OY FINNSCO
Date of delivery: 2020/05/05

Microbiologist
Ljudmila Shljapnikova
Ph.D.
Head of the Laboratory

Storage conditions: room temperature and darkness
Apperance of the product: clear colorless liquid
Recommended diluent: product is ready for use
Active substance: Ethanol 73,5 %

3. Test conditions

Test period: 2020/05/12 – 2020/05/14
Date of test: 2020/05/12
Product test concentrations: 98 %
Exposure time: 30 sec.
Test temperature: 19,5 ± 0,5°C
Organic load: clean conditions (bovine albumine 0,3 g/l)
Neutralizer: Polysorbate 80, 30 g/l, Lecithin, 3 g/l, Saponin, 30 g/l
Test organisms: Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442,
Enterococcus hirae ATCC 10541

4. Methods

Test method and its validation: modified method dilution neutralization

5. Results

see annex

6. Conclusion

In accordance with EVS- EN 13727:2012+A1:013+A2:2015, product PRO-10® PINTADESI (the batch number 23.04.2020) with concentration 98 % possesses bactericidal activity in suspension test in 30 sec. at 20 °C under clean conditions for reference strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541. The product PRO-10® PINTADESI (the batch number 23.04.2020) demonstrates at least a 5 lg reduction.

Total 6 pages

Annex on 4 pages

2020/05/14

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _{vo}			Validation suspension N _{vBo}			Experimental conditions control A			Neutralizer control B			Method validation C 98 %		
	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}
Staphylococcus aureus ATCC 6538	79	92	86	50	64	57	80	71	76	44	46	45	65	69	67
Pseudomonas aeruginosa ATCC15442	66	70	68	70	84	77	59	62	61	60	58	59	54	61	58
Enterococcus hirae ATCC 10541	109	117	113	46	53	50	90	94	92	38	40	39	92	84	88

Annex 2

TEST SUSPENSIONS

Test organisms	Dilution step	Vc ₁	Vc ₂	N No
Staphylococcus aureus ATCC 6538	10 ⁻⁷	>200	>100	N= 1,9 x 10 ⁹ = lg 9,28 No = N / 100 = lg 7,28 7,17 ≤ lg No ≤ 7,70
	10 ⁻⁸	12	26	
Pseudomonas aeruginosa ATCC 15442	10 ⁻⁷	163	140	N= 1,53 x 10 ⁹ = lg 9,18 No = N / 100 = lg 7,18 7,17 ≤ lg No ≤ 7,70
	10 ⁻⁸	14	21	
Enterococcus hirae ATCC 10541	10 ⁻⁷	193	169	N= 1,8 x 10 ⁹ = lg 9,26 No = N / 100 = lg 7,26 7,17 ≤ lg No ≤ 7,70
	10 ⁻⁸	12	22	

Annex 3

TESTS

Test organism	Conditions	Dilution step	Vc ₁	Vc ₂	Na x 10	Ig Na	Ig R	Contact time
Staphylococcus aureus ATCC 6538	Clean	1	11	6	85	1,93	5,35	30 sec.
		-1	0	0				
		-2	0	0				
		-3	0	0				
Pseudomonas aeruginosa ATCC 15442	Clean	1	9	10	95	1,98	5,2	30 sec.
		-1	0	0				
		-2	0	0				
		-3	0	0				
Enterococcus hirae ATCC 10541	Clean	1	0	0	< 140	< 2,15	>5,08	30 sec.
		-1	0	0				
		-2	0	0				
		-3	0	0				

Annex 4

$$N = c / (n_1 + 0,1 n_2) \times 10^{-7}$$

$$N_0 = N / 100$$

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

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

N – is the number of colonies for 1 ml test suspension

V_{c1} , V_{c2} - is the is number of colonies for 1 ml sample

n – is the number of Vc-values taken into account

R – reduction