



Akrediteeritud L236

EVS-EN 14348:2005
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Quantitative suspension test for the evaluation of tuberculocidal activity in the medical area (phase 2, step 1)

TEST REPORT no 253

1. General information and material

1.1 Client: Medi-Sept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order: 23.11.2015

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

1.3 Test conditions

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Test period: 25.11.2015 –16.12.2015
Date of test: 25.11.2015
Product test concentrations: 98 %
Exposure time: 30 s., 60 s.
Test temperature: 19,5 ± 0,5°C
Organic load: clean conditions (bovine albumine 0,3 g/l)
dirty conditions (bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l)
Neutralizer: Polysorbate 80, 30 g/l; Saponin 30 g/l, Lecithin, 3 g/l
Test organism: Mycobacterium terrae ATCC 15755

2. Methods

2.1. Test method and its validation: dilution neutralisation

3. Results

see annex

4. Conclusion

In accordance with EN 14348:2005, product MEDI SPRAY (batch number 151030_50) with concentration 98 % possesses tuberculocidal activity in suspension test in 30 s. and 60 s. at 20 °C under clean and dirty conditions for referenced strain Mycobacterium terrae ATCC 15755. The product MEDI SPRAY demonstrates at least a 4 lg reduction.

Total 6 pages
Annex on 4 pages

Maardu, 16.12.2015

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension Nv Dilution step -1			Experimental conditions control A			Neutralizer control B			Method validation C 98 % 60 s.		
	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻
Mycobacterium terrae ATCC 15755	80	75	78	55	48	52	50	57	54	47	50	49

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Annex 2

TEST SUSPENSION

Test organisms	N	Vc1	Vc2	No
Mycobacterium terrae ATCC 15755	-8	195	179	N= $1.85 \times 10^{10} = \lg 10,26$ No = N / 100 = lg 8,26 $8.17 \leq \lg \text{No} \leq 8.70$
	-9	18	15	

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Annex 3
TEST

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Mycobacterium terrae ATCC 15755	Clean conditions	1	250	250	2500	3,39	4,87	30 s.
		-1	28	22				
		-2	0	0				
		-3	0	0				
	Dirty conditions	-4	>300	>300	3950	3,59	4,67	
		-1	48	31				
		-2	1	0				
		-3	0	0				
	Clean conditions	1	0	0	<140	<2,15	>6.11	60 s.
		-1	0	0				
		-2	0	0				
		-3	0	0				
	Dirty conditions	1	52	40	460	2,66	5,6	
		-1	7	4				
		-2	0	0				
		-3	0	0				
		-4	0	0				

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Annex 4

$$N = \frac{C}{(n1 + 0.1 n2) \times 10^{-8}}$$

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

$$R = \lg No - \lg Na$$

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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