



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 N _v 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 | -4 | 0 | 0 | <140 | <2,15 | >6.11 | |
| | | 1 | 0 | 0 | | | | |
| | | -1 | 0 | 0 | | | | |
| | | -2 | 0 | 0 | | | | |
| | Dirty conditions | -3 | 0 | 0 | 460 | 2,66 | 5,6 | |
| | | -4 | 0 | 0 | | | | |
| | | 1 | 52 | 40 | | | | |
| | | -1 | 7 | 4 | | | | |
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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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