



EVIS-EN 14348:2005
INTERFLO OÜ
LABORATORY
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Quantitative suspension test for the evaluation of mycobactericidal and tuberculocidal activity in the medical area (phase 2, step 1)

TEST REPORT no 914

1. General information and material

Client:

Date of orders:

2. Identification of sample

Name of the product:

Batch number:

Manufacturer:

Date of delivery:

Storage conditions:

Appearance of the product:

Recommended diluent:

Active substance and concentration:

3. Test conditions

Microbiologist
Ljudmila Shljapnikova
Ph.D.
Head of the Laboratory

ELADUM PHARMA SRL
Reg. 1016600024547, Strasenii, Cojuzna, str. Centenarului, no. 2C, Rep. Moldova
2025/01/20, 2025/02/14

PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 %
Lot 391224, DD 10.12.24
ELADUM PHARMA SRL
2025/01/17
room temperature and darkness
transparent liquid
the product is ready to use
Hydrogen Peroxide – 6,0 %



Test period:

2025/01/23 – 2025/03/11

Date of test:

2025/01/23, 2025/02/18

Product test concentrations:

80,0 %

Exposure time:

30 min, 60 min, 120 min

Test temperature:

19,5 ± 0,5°C

Temperature of incubation

36,5 ± 0,5°C

Organic load:

0,3 g/l bovine albumin for low-level soiling

Neutralizer:

Polysorbate 80, 30 g/l, Sodium thiosulfate, 5 g/l, Lecithin, 3 g/l

Test organisms:

Mycobacterium terrae ATCC 15755, Mycobacterium avium ATCC 15769

4. Methods

Test method and its validation:

dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 14348:2005, product PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 % (Lot 391224, DD 10.12.24) with concentration 80 % possesses mycobactericidal and tuberculocidal activity in suspension test in 120 min at 20 °C under clean conditions for referenced strains Mycobacterium terrae ATCC 15755 and Mycobacterium avium ATCC 15769.

The product PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 % (Lot 391224, DD 10.12.24) demonstrates at least a 4 lg reduction.

The conclusion is true only for the studied sample of the product PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 % (Lot 391224, DD 10.12.24).

Total 7 pages

Annex on 5 pages

Maardu, 2025/03/25

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspensions N _{yo} Dilution range -1			Experimental conditions control A			Neutralizer control B			Method validation C Concentration 80 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
<i>Mycobacterium terrae</i> ATCC 15755	50	62	56	60	55	58	51	53	52	60	53	57
<i>Mycobacterium avium</i> ATCC 15769	62	70	66	59	65	62	55	58	57	60	53	56

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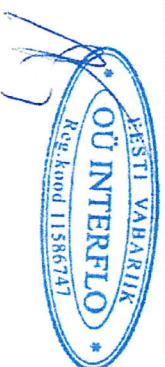


Annex 2

TEST SUSPENSIONS

Test organisms	Dilution step	Vc1	Vc2	N, No
Mycobacterium terrae ATCC 15755	-7 -8	178 19	184 20	182,27x10 ⁷ = lg 9,26 No 8,26 8,17 ≤ lg No ≤ 8,70
Mycobacterium avium ATCC 15769	-7 -8	>300 35	>300 41	N = 3,8 x 10 ⁹ = lg 9,58 No 8,58 8,17 ≤ lg No ≤ 8,70

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Annex 3

TEST 1

Test organism	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Concentration	Contact time
Mycobacterium terrae ATCC 15755	1	>300	>300	1250000	6,1	2,16	80 %	30 min
	-1	>300	>300					
	-2	>300	>300					
	-3	120	130					
	1	>300	>300					
	-1	>300	>300	108180	5,03	3,23	80 %	60 min
	-2	91	99					
	-3	20	28					
	1	>300	>300					
	-1	161	149	18182	4,26	4,0	80 %	120 min
	-2	40	50					
	-3	5	5					

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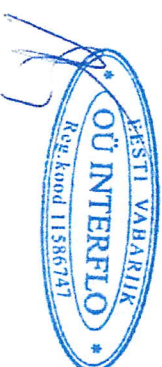


Annex 4

TEST 2

Test organism	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Concentration	Contact time
Mycobacterium avium ATCC 15769	1	>300	>300	920000	5,96	2,62	80 %	30 min
	-1	>300	>300					
	-2	>300	>300					
	-3	88	96					
	1	270	282					
	-1	38	27	2804,5	3,45	5,13	80 %	60 min
	-2	6	4					
	-3	0	1					
	1	0	0					
	-1	0	0	<140	<2,15	>6,04	80 %	120 min
	-2	0	0					
	-3	0	0					

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Annex 5

$$N = c / (n1 + 0,1 n2) \times 10^{-z}$$

$$N_0 = N / 10$$

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

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

N – is the number of colonies for 1 ml test suspension
Vc1, Vc2 - is the number of colonies for 1 ml sample
n – is the number of Vc-values taken into account
z – is the dilution factor corresponding to the lower dilution
R – reduction

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