



EN 13624:2021
INTERFLO OÜ
LABORATORY
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Quantitative suspension test for the evaluation of fungicidal activity in the medical area (phase 2, step 1)

TEST REPORT no 962

1. Client:

ELADUM PHARMA SRL
Reg. 1016600024547, Straseni, Cojuszna, str. Centenarului, no. 2C, Rep.
Moldova

Date of order:

2025/05/05

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2. Identification of the sample:

Name of the product:	PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 %
Batch number:	Lot 391224, DD 10.12.24
Manufacturer:	ELADUM PHARMA SRL
Date of delivery:	2025/01/17
Storage conditions:	Room temperature and darkness
Appearance of the product:	Transparent colorless liquid
Product diluent:	ready-to-use
Test period:	2025/05/27 – 2025/05/30,
Date of tests:	2025/05/27,
Active substance:	Hydrogen Peroxide - 6,0%

3. Test conditions:

Neutralizer:	Polysorbate 80, 30 g/l; Lecithin, 3 g/l; Saponin, 30 g/l; Sodium thiosulphate, 20 g/l.
Product test concentrations:	80%.
Organic load:	0,3 g/l bovine albumin for low-level soiling.
Test temperature:	19,5 ± 0,5°C.
Temperature of incubation:	29,5 ± 0,5°C.
Contact time:	15 min., 30 min., 60 min.
Identification of the strain:	Candida albicans ATCC 10231, Aspergillus brasiliensis ATCC 16404

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4. Method:

Test method and its validation:

Dilution-neutralization, modified for ready-to-use products.

5. Test results:

See annex.

6. Conclusion:

In accordance with EN 13624:2021, product PEROXID DE HIDROGEN-ELADUM, SOLUTIE DESINFECTANTA 6 % Lot 391224, DD 10.12.24 possesses fungicidal activity in suspension test with concentration 80% in 60 min. at 20 °C under clean conditions with 0,3 g/l bovine albumin for referenced strains *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404, reduction > 4 lg.

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 8 pages

Annex on 5 pages

Maardu, 2025/06/06

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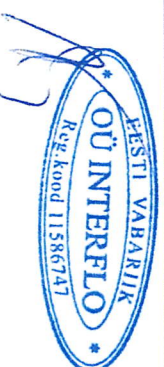


Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension NV Dilution range E-2			Validation suspension NVB Dilution range E-3			Experimental conditions control A			Neutralizer control B Dilution range E-2			Method validation C Concentration 80,0 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
<i>Aspergillus brasiliensis</i> ATCC 16404	82	90	86	79	84	82	59	67	63	60	61	61	49	51	50
<i>Candida albicans</i> ATCC 10231	84	92	88	69	77	73	73	79	76	64	72	68	67	75	71

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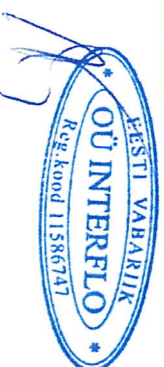


Annex 2

TEST SUSPENSIONS

Test organisms	Dilution step	Vc1	Vc2	No
Aspergillus brasiliensis ATCC 16404	-5 -6	>165 20	>165 26	$N = 2,3 \times 10^7 = \lg 7,36$ $N_0 = N / 10 = 6,36$ $6,17 \leq \lg N_0 \leq 6,70$
Candida albicans ATCC 10231	-5 -6	>300 39	>300 43	$N = 4,1 \times 10^7 = \lg 7,61$ $N_0 = N / 10 = 6,61$ $6,17 \leq \lg N_0 \leq 6,70$

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Annex 3

TEST 1

Test organisms	Product concentration	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Aspergillus brasiliensis ATCC 16404	80,0%	1	>165	>165	>100000	>5,00	<1,36	15 min
		-1	>165	>165				
		-2	>100	>100				
		1	>165	>165	3750	3,57	2,79	30 min
		-1	36	39				
		-2	4	4				
		1	0	0				
		-1	0	0	<140	<2,15	>4,21	60 min
		-2	0	0				

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Annex 4

TEST 2

Test organisms	Product concentration	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Candida albicans ATCC 10231	80,0%	1	112	118	1191	3,08	3,53	15 min
		-1	14	18				
		-2	2	2				
		1	9	11	<140	<2,15	>4.46	30 min
		-1	0	0				
		-2	0	0				
		1	0	0	<140	<2,15	>4.46	60 min
		-1	0	0				
		-2	0	0				
		1	0	0				

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Annex 5

$$N = c / (n1 + 0,1 n2) \times 10^{-6}$$

$$No = N / 10$$

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

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

N – is the number of colonies in 1 ml of the test suspension;
No – is the number of colonies in 1 ml of the test mixture;
c - is the sum of Vc-values taken into account;
Vc1, Vc2 - is the number of colonies in 1 ml of the sample;
n – is the number of Vc-values taken into account;
R – is the reduction factor.

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