



EVS-EN 13624:2019
OÜ INTERFLO
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Quantitative suspension test for the evaluation of yeasticidal activity in the medical area (phase 2, step 1)

TEST REPORT no 759

1. General information and material

Client: Medisept Sp. z o.o., ul. Ludwika Spiessa 4, 20 270 Lublin, Poland
Date of order: 2022/11/28

2. Identification of sample

Name of the product: VIRUTON PULVER
Batch number: 220902_4
Manufacturer: Medsept Sp. z.o.o.
Date of delivery: 2022/11/21
Storage conditions: room temperature and darkness
Apperance of the product: white and blue powder
Recommended diluent: water

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Active substance:	44 % Sodium percarbonate, 26 % TEAD
2. Test conditions	
Test period:	2022/11/30 – 202/12/05
Date of test:	2022/11/30
Product test concentrations:	0,5 %
Diluent:	hard water
Exposure time:	60 min
Test temperature:	19,5 ± 0,5°C
Organic load:	for clean conditions (bovine albumine 0,3 g/l) for dirty conditions (bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l)
Neutralizer:	Polysorbate 80, 30 g/l; Sodium thiosulphate, 5 g/l; Lecithin, 3 g/l
Test organisms:	Aspergillus brasiliensis ATCC 16404, Candida albicans ATCC 10231
3. Methods	
2.1. Test method and its validation:	dilution neutralisation
4. Results	see annex
5. Conclusion	

In accordance with EN 13624:2013, product VIRUTON PULVER (batch number 220902_4) with concentration 0,5 % possesses in suspension test fungicidal activity under clean and dirty conditions in 60 min at 20 °C for strains Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404. The product VIRUTON PULVER demonstrates at least a 4 lg reduction.

Total 7 pages
Annex on 5 pages

Tallinn, 2022/12/05

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _{vo} -1			Validation suspension N _{vBo} -3			Experimental conditions control A			Neutralizer control B -2			Method validation C Concentration 0,5 %		
	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}
Candida albicans ATCC 10231	59	65	62	46	50	48	55	61	58	75	79	77	54	62	58
Aspergillus brasiliensis ATCC 16404	66	79	73	59	67	63	55	57	56	41	35	38	66	79	73

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Annex 2

TEST SUSPENSIONS

Test organisms	Dilution range	Vc1	Vc2	N No
Candida albicans ATCC 10231	-5	>330	>330	$N = 2,3 \times 10^7 = \lg 7,36$ $No = N / 10 = \mathbf{6,36}$ $6,17 \leq \lg No \leq 6,70$
	-6	21	25	
Aspergillus brasiliensis ATCC 16404	-5	>165	>165	$N = 4,5 \times 10^7 = \lg 7,65$ $No = N / 10 = \mathbf{\lg 6,65}$ $6,17 \leq \lg No \leq 6,70$
	-6	39	51	

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Annex 3

TEST 1

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Candida albicans ATCC 10231	Clean	10 ⁰	0	0	< 140	< 2,15	>4,21	60 min
		10 ⁻¹	0	0				
		10 ⁻²	0	0				
		10 ⁻³	0	0				
	Dirty	10 ⁰	0	0	< 140	< 2,15	>4,21	60 min
		10 ⁻¹	0	0				
		10 ⁻²	0	0				
		10 ⁻³	0	0				

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Annex 4

TEST 2

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	Ig Na	Ig R	Contact time
Aspergillus brasiliensis ATCC 16404	Clean	10 ⁰	0	0	<140	< 2,15	> 4,5	60 min
		10 ⁻¹	0	0				
		10 ⁻²	0	0				
		10 ⁻³	0	0				
	Dirty	10 ⁰	0	0	<140	< 2,15	> 4,5	60 min
		10 ⁻¹	0	0				
		10 ⁻²	0	0				
		10 ⁻³	0	0				

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Annex 5

$$N = c / (n1 + 0.1 n2) \times 10^{-6}$$

$$N_0 = N / 10$$

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

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

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

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