



EVS-EN 14562:2006
INTERFLO OÜ
LABORATORY
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Quantitative carrier test for the evaluation of yeasacidal and fungicidal activity for instruments used in the medical area (phase 2, step 2)

TEST REPORT no 715

1. General information and material

Client: MEDISEPT SP. ZOO, Konopnica 159 c, 21-030 Motycz, Poland
NIP. 9460010016
Date of order: 2022/02/21

2. Identification of sample

Name of the product: VIRUTON PULVER
Batch number: LOT: 16022022-2
Manufacturer: MEDISEPT SP. ZOO
Date of delivery: 2022/02/21
Storage conditions: room temperature and darkness
Apperance of the product: white powder with blue granules
Diluent: hard water

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Active substance:

Peracetic acid (44 % Sodium percarbonate, 26 % TAED)

3. Test conditions

Test period:

2022/03/10– 2022/03/14

Date of test:

2022/03/10

Product test concentrations:

1,0 %; 1,5 %

Exposure time:

15 min; 30 min; 60 min

Test temperature:

19,5 ± 0,5°C

Organic load:

dirty conditions (3,0 g/l bovine albumine and 3 ml/ sheep erythrocytes)

Neutralizer:

Polysorbate 80, 30 g/l; Lecithin, 3 g/l; Sodium thiosulphate, 5 g/l

Temperature of incubation

29,5°C ± 0,5°C

Test organisms:

Candida albicans ATCC10231; Aspergillus brasiliensis ATCC 16404

4. Methods

2.1. Test method and its validation:

dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 14562:2006, product VIRUTON PULVER (LOT: 16022022-2) for instrument disinfection with concentration 1,5 % in 15 min and with concentration 1,0 % in 30 min and 60 min possesses yeasticidal and fungicidal activity in carrier test at 20 °C under dirty conditions for reference strains Candida albicans ATCC10231 and Aspergillus brasiliensis ATCC 16404.

The product VIRUTON PULVER (LOT: 16022022-2) demonstrates at least a 4 lg reduction.

The conclusion is true only for the studied sample of the product VIRUTON PULVER (batch 16022022-2).

Total 8 pages

Annex on 6 pages

Maardu, 2022/03/14

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _{vo}			Experimental conditions control A			Neutralizer control B			Method validation C Concentration 1,5 %		
	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}
Candida albicans ATCC10231	70	86	78	68	65	67	60	59	60	71	63	67
Aspergillus brasiliensis ATCC 16404	48	53	51	50	42	46	40	37	39	41	36	39

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Annex 2

TEST SUSPENSION

Test organisms	Dilution step	Vc1	Vc2	N
Candida albicans ATCC10231	10 ⁻⁶	>100	>100	N = 1,55 x 10 ⁸ = lg 8,19
	10 ⁻⁷	14	17	8,17 ≤ lg N ≤ 8,77
Aspergillus brasiliensis ATCC 16404	10 ⁻⁶	142	157	N = 1,5 x 10 ⁸ = lg 8,18
	10 ⁻⁷	13	18	8,17 ≤ lg N ≤ 8,77

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Annex 3

WATER CONTROL

Test organisms	Dilution step	Vc1	Vc2	Nw
Candida albicans ATCC10231	10 ⁻⁴	14	16	Nw = 1,91 x 10 ⁶ = lg 6,28
	10 ⁻⁵	5	7	6,15 ≤ lg Nw ≤ lgN-1,3
Aspergillus brasiliensis ATCC 16404	10 ⁻⁴	12	15	Nw = 1,41 x 10 ⁶ = lg 6,15
	10 ⁻⁵	1	3	6,15 ≤ lg Nw ≤ lgN-1,3

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Annex 4

TEST 1

Test organisms	Concentration	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Candida albicans ATCC10231	1,0 %	Dirty	10 ⁰	0	0	< 140	< 2,15	> 4,13	30 min
			10 ⁻¹	0	0				
			10 ⁻²	0	0				
			10 ⁻³	0	0	< 140	< 2,15	> 4,13	
			10 ⁰	0	0				
			10 ⁻¹	0	0				
	1,5 %	Dirty	10 ⁻²	0	0	< 140	< 2,15	> 4,13	15 min
			10 ⁻³	0	0				
			10 ⁰	0	0				
			10 ⁻¹	0	0	< 140	< 2,15	> 4,13	
			10 ⁻²	0	0				
			10 ⁻³	0	0				

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Annex 5

TEST 2

Test organism	Concentration	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time	
Aspergillus brasiliensis ATCC 16404	1,0 %	Dirty	10 ⁰	0	0	< 140	< 2,15	>4,0	30 min	
			10 ⁻¹	0	0					
			10 ⁻²	0	0					
			10 ⁻³	0	0					
			10 ⁰	0	0					
			10 ⁻¹	0	0					
	1,5 %	Dirty	Dirty	10 ⁰	0	0	< 140	< 2,15	>4,0	15 min
				10 ⁻¹	0	0				
				10 ⁻²	0	0				
				10 ⁻³	0	0				
				10 ⁰	0	0				
				10 ⁻¹	0	0				

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Annex 6

$$N = C / (n_1 + 0.1 n_2) \times 10^{-6 \text{ or } -5}$$

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

$$N_w = c \times 10 / n - 4$$

$$R = \lg N_w - \lg N_a$$

N – is the number of cfu (colony forming unit) for 1 ml test suspension

Vc1, Vc2 - is the is number of cfu for 1 ml sample

n – is the number of Vc-values taken into account

Nw – water control

R – reduction

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