



EVS-EN 13624:2013
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Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity in the medical area (phase 2, step 1)

TEST REPORT no 382

1. General information and material

- 1.1 Client: Medi-Sept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order: 2018/06/04
- 1.2 Identification of sample
Name of the product: VIRUTON PULVER
Batch number: 180222_5
Manufacturer: Medi-Sept Sp. z.o.o.
Date of delivery: 2018/06/11
Storage conditions: room temperature and darkness
Apperance of the product: white powder
Recommended diluent: water

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Active substance:

44 % Sodium percarbonate, 26 % TEAD

1.3 Test conditions

Test period:

2018/06/13 – 2018/07/09

Date of test:

2018/06/13, 2018/07/04

Product test concentrations:

0,5 %

Diluent:

hard water (45°C)

Exposure time:

30 min, 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)

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

Aspergillus brasiliensis ATCC 16404, Candida albicans ATCC 10231

Neutralizer:

Test organisms:

dilution neutralisation

see annex

2. Methods

2.1. Test method and its validation:

3. Results

4. Conclusion

In accordance with EN 137624:2013, product VIRUTON PULVER (batch number 180222_5) with concentration 0,5 % possesses yeasticidal activity in suspension test in 30 min at 20 °C under clean and dirty conditions for strain Candida albicans ATCC 10231 and in 60 min for strain Aspergillus brasiliensis ATCC 16404. The product VIRUTON PULVER demonstrates at least a 4 lg reduction.

Total 7 pages

Annex on 5 pages

Maardu, 2018/07/16

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _v Dilution step -1			Experimental conditions control A Dilution step 1			Neutralizer control B Dilution step 1			Method validation C Concentration 0,5% Dilution step 1		
	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}
Aspergillus brasiliensis ATCC 16404	66	79	73	59	67	63	55	57	56	41	35	38
Candida albicans ATCC 10231	60	72	66	54	50	52	49	55	52	41	57	49

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Annex 2

TEST SUSPENSIONS

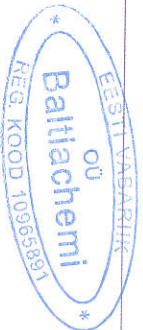
Test organisms	N	Vc1	Vc2	No
Aspergillus brasiliensis ATCC 16404	-5 -6	>165 39	>165 51	$N = 4,5 \times 10^7 = \lg 7,65$ $No = N / 10 = \lg 6,65$ $6,17 \leq \lg No \leq 6,70$
Candida albicans ATCC 10231	-5 -6	>200 24	>200 34	$N = 2,9 \times 10^7 = \lg 7,46$ $No = N / 10 = \lg 6,46$ $6,17 \leq \lg No \leq 6,70$

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Annex 3

TEST 1

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Aspergillus brasiliensis ATCC 16404	Clean	1	>165	>165	1900	3,28	3,37	30 min
		-1	20	18				
		-2	0	0				
		-3	0	0				
		1	0	0				
		-1	0	0				
	-2	0	0					
	-3	0	0					
	1	>165	>165	3700	3,57	3,08	30 min	
	-1	44	30					
	-2	4	0					
	-3	0	0					
1	0	0						
-1	0	0						
-2	0	0						
-3	0	0	<140	< 2,15	> 4,5	60 min		
1	0	0						
-1	0	0						
-2	0	0						
-3	0	0						
Dirty	1	>165	>165	3700	3,57	3,08	30 min	
	-1	44	30					
	-2	4	0					
-3	0	0						
1	0	0						
-1	0	0						
-2	0	0						
-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
Candida albicans ATCC 10231	Clean	1	0	0	<140	< 2,15	> 4,31	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				
		1	0	0				
		-1	0	0				
	Dirty	-2	0	0	<140	< 2,15	> 4,31	30 min
		-3	0	0				
		1	0	0				
		-1	0	0				

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Annex 4

$$N = \frac{C}{(n1 + 0.1 n2) \times 10^{-7}}$$

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

$$R = \lg N_0 - \lg Na$$

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
R – reduction

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