EN ISO/IEC 17025
L236

EVS-EN 14562:2006
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Quantitative carrier test for the evaluation of yeasticidal and fungicidal activity in the medical area (phase 2, step 2)

TEST REPORT no 383

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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Location: Moldova

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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)
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
2. Methods	
2.1. Test method and its validation:	dilution neutralisation
3. Results	see annex
4. Conclusion	

In accordance with EN 14562:2006, product VIRUTON PULVER (batch number 180222_5) with concentration 0,5 % possesses yasticidal activity in carrier test in 30 min at 20 °C under clean and dirty conditions for strain Candida albicans ATCC 10231. The product VIRUTON PULVER demonstrates at least a 4 lg reduction.

Total 8 pages
Annex on 6 pages

Maardu, 2018/07/16

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Annex 1

VALIDATION AND CONTROLS

Test organism	Validation suspension Nv 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 organism	Dilution step	Vc1	Vc2	N
Aspergillus brasiliensis ATCC 16404	-6	>165	>165	N= 4,5 x 10 8 = lg 8,65
	-7	39	51	
Candida albicans ATCC 10231	-6	>200	>200	N= 2,9 x 10 8 = lg 8,46
	-7	24	34	

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Annex 3

WATER CONTROL

Water control Nw	Test organisms	Dilution step	Vc1	Vc2	Nw 1500000 lg Nw **6,18**
	Aspergillus brasiliensis ATCC 16404	-4	14	16	
		-5	1	0	
	Candida albicans ATCC 10231	-3	>300	>300	Nw 3650000 lg Nw **6,56**
		-4	40	33	

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Annex 4

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	2800	3,45	**2,73**	30 min
		-1	25	31				
		-2	6	8				
		-3	0	0				
		1	68	82	1600	3,2	**2,98**	60 min
		-1	14	18				
		-2	3	2				
		-3	0	0				
	Dirty	1	>165	>165	44500	4,65	**1,53**	30 min
		-1	>165	>165				
		-2	51	38				
		-3	0	0				
		1	80	86	2200	3,34	**2,84**	60 min
		-1	21	23				
		-2	0	1				
		-3	0	0				

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Annex 5

TEST 2

Test organism	Conditions	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Candida albicans ATCC 10231	Clean	1	0	0	<140	< 2,15	> 4,03	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				
	Dirty	1	0	0	<140	< 2,15	> 4,03	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				

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Annex 6

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

$Na = c \times 10 / n$

$R = \lg Nw - \lg Na$

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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