BALTIACHEMI

VIRUTON PULVER
EN 13624:2013

EESTI AKREDITEERIMISKESKUS
EAK
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L236

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)
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 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 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 organisms	N	Vc1	Vc2	No
Aspergillus brasiliensis ATCC 16404	-5 -6	>165 39	>165 51	N= 4,5 x 10 7 = lg 7,65 No = N / 10 = **lg 6,65** 6,17≤lg No≥ 6,70
Candida albicans ATCC 10231	-5 -6	>200 24	>200 34	N= 2,9 x 10 7 = lg 7,46 No = N / 10 = **lg 6,46** 6,17≤lg No≥ 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	<140	< 2,15	> 4,5	60 min
		-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	<140	< 2,15	> 4,5	60 min
		-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	lg Na	lg 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				
	Dirty	1	0	0	<140	< 2,15	**> 4,31**	30 min
		-1	0	0				
		-2	0	0				
		-3	0	0				

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Annex 4

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

$Na = c \times 10 / n$

$R = lgNo - lg\ Na$

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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