



Akrediteeritud L236

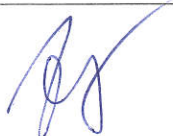
EVS-EN 13624:2013
OÜ BALTIACHEMI
LABORATORY
Tel.. +372 6214 694
e-mail: info@baltiachemi.ee**Quantitative suspension test for the evaluation of yeasticidal activity in the medical area (phase 2, step 1)**

TEST REPORT no 245

1. General information and material

1.1 Client:	Medi-Sept Sp. z.o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order:	06.11.2015
1.2 Identification of sample	
Name of the product:	MEDI-SPRAY
Batch number:	151030_50
Manufacturer:	Medi-Sept Sp. z.o.o.
Date of delivery:	09.11.2015
Storage conditions:	room temperature and darkness
Appearance of the product:	liquid, clear, without color
Recommended diluent:	product is ready for use
Active substance:	55-65 % Ethanol and 5-10 % Propan-2-ol

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1.3 Test conditions

Test period:	10.11.2015 – 14.11.2015
Date of test:	10.11.2015
Product test concentrations:	97 %
Exposure time:	15 s., 30 s., 60 s.
Test temperature:	19,5 ± 0,5°C
Organic load:	dirty conditions (bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l) clean conditions (bovine albumine 0,3 g/l)
Neutralizer:	Polysorbate 80, 30 g/l; Saponin 30 g/l, Lecithin, 3 g/l
Test organisms:	Candida albicans ATCC 10231

2. Methods

2.1. Test method and its validation: dilution neutralisation

3. Results

see annex

4. Conclusion

In accordance with EVS-EN 13624:2013, product MEDI-SPRAY with concentration 97 % possesses yeasticidal activity in suspension test in 15 s., 30 s. and 60 s. at 20 °C under dirty and clean conditions for referenced strain Candida albicans ATCC 10231. The product MEDI-SPRAY demonstrates at least a 4 lg reduction.

Total 7 pages
Annex on 5 pages

Maardu, 14.11.2015

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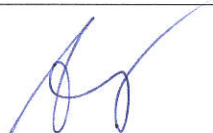


Annex 1

VALIDATION AND CONTROLS

Test organism	Validation suspension Nv Dilution step -1			Validation suspension NvB Dilution step -2			Experimental conditions control A Dilution step 1			Neutralizer control B Dilution step -2			Method validation C Dilution step 1		
	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻	Vc1	Vc2	X ⁻
Candida albicans ATCC 10231	39	38	39	40	51	45	30	32	31	37	45	39	36	30	33

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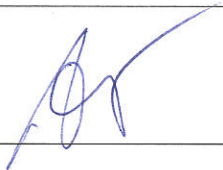



Annex 2

TEST SUSPENSION

Test organisms	N	Vc1	Vc2	No
Candida albicans ATCC 10231	-6	155	160	$N = 1,6 \times 10^8 = \lg 8,2$ $No = N / 100 = \lg 6,2$
	-7	13	15	$6.17 \leq \lg No \leq 6.70$

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Annex 3

 TEST 1 Candida albicans
 Clean conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Candida albicans ATCC 10231	1	0	0	< 140	< 2.15	>4,05	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>4,05	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>4,05	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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Annex 4

 TEST 2 Candida albicans
 Dirty conditions

Test organism	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Candida albicans ATCC 10231	1	0	0	< 140	< 2.15	>4,05	15 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>4,05	30 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				
	1	0	0	< 140	< 2.15	>4,05	60 s.
	-1	0	0				
	-2	0	0				
	-3	0	0				

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Annex 5

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

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

$$R = \lg No - \lg Na$$

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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