



**Test report No. 10619hd**

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA (EN 13624)

**Name of the product:** CHEMISEPT GEL

Batch number: 198030619

Date of test report: 24.07.2019

Client, representative:

Chemi-Pharm Ltd.

Tänassilma tee 11

Tänassilma küla

Saku vald, 76406

ESTONIA

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EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA  
(EN 13624)

Name of the product: CHEMISEPT GEL  
Batch number: 198030619  
Order number: 19023  
Manufacturer: Chemi-Pharm Ltd.  
Client, representative: Chemi-Pharm Ltd., Tännassilma tee 11, Tännassilma küla, Saku vald,  
76406, ESTONIA  
Maris Millner, +372-51-77-090  
Date of delivery: 03.07.2019  
Test material conditions: No specific features, sample in the manufacturers tare  
Storage conditions: In room temperature, dark  
Active substance – conc.: Ethyl alcohol 72.5 (w/w) %; isopropyl alcohol (w/w) 7.5%  
Appearance of the product: Transparent gel  
Test concentration: Ready to use  
Contact time: 60s  
Interfering substance: 3.0 g/l bovine albumin = clean conditions  
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l  
Neutralizer: -  
Test organisms: *Aspergillus brasiliensis* ATCC 16404  
Testing method: EVS-EN 13624:2013  
Quantitative suspension test for the evaluation of fungicidal or  
yeastcidal activity in the medical area.  
Testing date: 16.07.2019 – 18.07.2019  
Results: look appendix 1-2



Allar Laaneleht  
Chief specialist

Date of test report: 24.07.2019

## Appendix 1

### TEST RESULTS (fungicidal suspension test)

EVS-EN 13624:2013; Phase 2, step 1;  
Membrane filtration method;  
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l;  
Test organism: *Aspergillus brasiliensis* ATCC 16404;  
Test temperature: +20° C; Incubation temperature: +30° C  
Interfering substance: 3.0 g/l bovine albumin = clean conditions;  
Nordic Tersus Laboratory LLC.; Date of test: 16.07.2019  
Responsible person: Allar Laaneleht

### Validation and controls

#### Clean conditions

Validation suspension $N_{vo}$			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
$V_{C1}$	$V_{C2}$	$\bar{x}$	$V_{C1}$	$V_{C2}$	$\bar{x}$	$V_{C1}$	$V_{C2}$	$\bar{x}$	$V_{C1}$	$V_{C2}$	$\bar{x}$
61	74	67.5	33	39	36	42	30	36	41	49	45
$30 \leq \bar{x} N_{vo} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x} A \geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} B \geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} C \geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>		

### Test suspension and test

Testsuspension: $N$ and $N_0$	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 1.79 \times 10^8$ ; $\log N = 8.25$ $N_0 = N/100$ ; $\log N_0 = 6.25$ $6.17 \leq \log N_0 \leq 6.70$ ; yes X; no <input type="checkbox"/>
	$10^{-6}$	194	164	
	$10^{-7}$	21	15	

### Experimental results

Concentration of the product	Dilution step	$V_{C1}$	$V_{C2}$	$Na$ ( $=\bar{x} \cdot 10$ )	$\log Na$	$\log R$	Contact time	Conditions
Ready to use	-	17	15	160	2.20	4.05	60 s	Clean

#### Explanations:

$V_C$  = count per ml (one plate or more)  
 $\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$  (1. + 2. duplicate)  
 $N$  = cfu/ml microbes in testsuspension  
 $N_0$  = cfu/ml at the start of the contact time ( $t=0$ )  
 $N_{vo}$  = cfu/ml in the validation suspension ( $t=0$ )  
 $Na$  = surviving microbes after the test  
 $R$  = reduction factor ( $R = N_0 / Na$ ;  $\log R = \log N_0 - \log Na$ )

Appendix 2

Interpretation:

The ready to use product CHEMISEPT GEL (batch no. 198030619) was tested according to the test method EVS-EN 13624:2013. The test was performed at  $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ , under clean conditions during contact time of 60s. The membrane filtration method was used for testing the product's effectiveness against the reference strain: *Aspergillus brasiliensis* ATCC 16404. Under clean conditions the tested product was effective against the reference strain within 60 s.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that the ready to use product CHEMISEPT GEL has a fungicidal effect under clean conditions within 60 s.



Allar Laaneleht  
Chief specialist  
24.07.2019