Nordic Tersus
Laboratory

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

Digitally sig
Date: 2024.0
Reason: Mo
Location: M

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Laboratory

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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., Tänassilma tee 11, Tänassilma 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 yeasticidal activity in the medical area.**
Testing date:	16.07.2019 – 18.07.2019
Results:	look appendix 1-2

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Allar Laaneleht
Chief specialist
Date of test report: 24.07.2019

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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 □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$?yes X;no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.79 \times 10^8$; log$N$ = 8.25 $N_0 = N/100$; logN_0 = 6.25 $6.17 \leq \log N_0 \leq 6.70$; yesX; no □
N and N_0	10^{-6}	**194**	**164**	
	10^{-7}	**21**	**15**	

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	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; LogR=LogN_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 °C ± 1 °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.**

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Allar Laaneleht
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24.07.2019