Nordic Tersus
Laboratory

Test report No. sd0819

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

Name of the product:	STERISEPT WIPES
Batch number:	14300818W
Order number:	18014
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	04.10.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0.45%; Didecyl-Dimethyl-Ammonium Chloride (DDAC) 0.45%
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	60 s
Interfering substance:	15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes – dirty conditions
Rinsing liquid:	Tryptone 1 g/l + NaCl 9 g/l
Neutralizer:	-
Test organisms:	*Candida albicans* ATCC 10231
Testing method:	EVS-EN 13624:2013 Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.
Testing date:	17.10.2018 – 19.10.2018
Results:	look appendix 1-2

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ACCREDITED LABORATORY No L263. ISO/IEC 17025 NORDIC TERSUS LABORATORY OÜ REPUBLIC OF ESTONIA

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Allar Laaneleht
Chief specialist
Date of test report: 15.01.2019

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Appendix 1

TEST RESULTS (yeasticidal 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: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 17.10.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	73	$\bar{x}$ = 69	V_{C1}	53	$\bar{x}$ = 53.5	V_{C1}	47	$\bar{x}$ = 48.5	V_{C1}	58	$\bar{x}$ = 59.5
V_{C2}	65		V_{C2}	54		V_{C2}	50		V_{C2}	61	
30 ≤ $\bar{x}$ N_{vo} ≤160?yes X; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}?yes X; no □			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ N_{vo}?yesX; no□			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yesX; no□		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.82 \times 10^8$; log$N$ = 8.26
N and N_0	10^{-6}	193	172	$N_0 = N/100$; logN_0 = 6.26
	10^{-7}	16	19	6.17≤ logN_0≤6.70; yesX; no □

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	-	<14	<14	<140	<2.15	>4.11	60 s	dirty

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 **STERISEPT WIPES** (batch no. 14300818W) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C ± 1 °C, under dirty conditions during contact time of 60 s. The membrane filtration method was used for testing the produts effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty 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 STERISEPT WIPES has a yeasticidal effect under dirty conditions within 60 s.**

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