Nordic Tersus
Laboratory

Test report No. sd1119

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

Name of the product:	STERISEPT PLUS
Batch number:	212310518
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 12.5%; Didecyl-Dimethyl-Ammonium Chloride (DDAC) 12.5%
Appearance of the product:	Transparent liquid
Test concentration:	0.25%, 0.50%
Contact time:	15 min
Interfering substance:	3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes = dirty conditions; 0.3 g/l bovine albumin = clean 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:	28.10.2018 – 30.10.2018
Results:	look appendix 1-2

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Allar Laaneleht
Chief specialist
Date of test report: 15.01.2019

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: 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes = dirty conditions;
0.3g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.; Date of test: 28.10.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	48	$\bar{x}$ = 46	V_{C1}	41	$\bar{x}$ = 39	V_{C1}	33	$\bar{x}$ = 35	V_{C1}	42	$\bar{x}$ = 42
V_{C2}	44		V_{C2}	37		V_{C2}	37		V_{C2}	42	
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}	$\bar{x}_{wm}$ = 2.06 x 10^7; log$N$ = 7.22
N and N_0	10^{-5}	166	171	$N_0 = N/10$; logN_0 = 6.22
	10^{-6}	15	16	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
0.05%	-	>165	>165	>1650	>3.22	<3.00	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>4.07	15 min	Clean
0.50%	-	<14	<14	<140	<2.15	>4.07	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>4.07	15 min	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 product STERISEPT PLUS (batch no. 212310518) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C ± 1 °C, under clean and dirty conditions during contact time of 15 min, with the concentrations of 0.25% and 0.50%. 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 15 min for 0.50% and under clean conditions 0.25% within 15 min.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **the 0.25% solution of the product STERISEPT PLUS has a yeasticidal effect under clean conditions within 15 min and 0.50% under dirty conditions within 15 min.**

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15.01.2019