Nordic Tersus Laboratory

Test report No. shd0218

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

Name of the product:	Chemisept MED
Batch number:	196101017
Order number:	17028
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	15.12.2017
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Ethyl alcohol 72.5% wt, isopropyl alcohol 7.5% wt
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	15 sec
Interfering substance:	15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions; 3.0 g/l sheep blood erythrocytes = 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:	23.01.2018 – 25.01.2018
Results:	look appendix 1-2

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Diana Kaare, MSc

Head of laboratory, microbiologist

Date of test report: 26.01.2018

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Location: Moldova

Nordic Tersus Laboratory OÜ
Harjumaa, Tallinn, Serva tn 44a, 11618
Registrikood: 12561442
Tel: +372 503 0197
E-mail: info@ntl.ee

EESTI AKREDITEERIMISKESKUS EAK ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L263

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;
3.0g/l sheep blood erythrocytes = clean conditions;
Nordic Tersus Laboratory LLC.; Date of test: 23.01.2018 – 25.01.2018.
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	45	$\bar{x}$ = 43.5	V_{C1}	38	$\bar{x}$ = 35	V_{C1}	41	$\bar{x}$ = 37	V_{C1}	39	$\bar{x}$ = 41.5
V_{C2}	42		V_{C2}	32		V_{C2}	33		V_{C2}	44	
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}	$\bar{x}_{wm}$ = 1.71 x 10^8; log$N$ = 8.23
	10^{-6}	172	164	N_0 = N/100; logN_0 = 6.23
N and N_0	10^{-7}	19	22	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	>4.08	15 s	dirty
Ready to use	-	<14	<14	<140	<2.15	>4.08	15 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 for surgical hand disinfection **CHEMISEPT MED** (batch no. 196101017) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C ± 1 °C, under dirty and clean conditions with the contact time of 15 s. The membrane filtration method was used for testing the produts effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty and clean conditions the tested product was effective against the reference strain within 15 s of contact time.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **under dirty and clean conditions the ready to use product CHEMISEPT MED has a yeasticidal effect in case of surgical hand disinfection within 15 s.**

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