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<br>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<br>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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Chief of laboratory, microbiologist

Digitally signed by Diana Kaare
Date: 2023.01.06 14:20:13 EET
Reason: MoldSign Signature
Location: Moldova

Date of test report: 25.01.2018

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EAK Eesti Akrediteerimiskeskus 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; log$N_0$ = 6.23 |
| *N and $N_0$* | $10^{-7}$ | 19 | 22 | 6.17≤ log$N_0$≤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=Log$N_0$ - 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.**

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

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