Nordic Tersus
Laboratory

# Test report No. 167024hd

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

**Name of the product: CHEMISEPT MED**

Batch number: 196161220
Date of test report: 11/06/2024

Digitally signed by Moraru Grigore
Date: 2024.10.14 11:27:06 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Client, representative:
Chemi-Pharm Ltd.
Tänassilma tee 11
Tänassilma küla
Saku vald 76406
ESTONIA

EAK
EN ISO/IEC 17025
L263

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Laboratory

# Test report No. 167024hd

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

| | |
|---|---|
| **Name of the product*:** | **CHEMISEPT MED** |
| **Batch number*:** | 196161220 |
| **Order number:** | 20049 |
| **Manufacturer*:** | Chemi-Pharm Ltd. |
| **Client, representative*:** | Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald 76406; ESTONIA; Siimu Rom, +37253604748 |
| **Date of delivery:** | 29.03.2022 |
| **Test material conditions:** | No specific features, sample in the manufacturers tare |
| **Storage conditions:** | At room temperature, darkness |
| **Active substance – conc.*:** | Ethyl alcohol 72.5% w/w, isopropyl alcohol 7.5% w/w |
| **Appearance of the product:** | Transparent, colourless liquid |
| **Test concentration:** | 80.0%, 50.0%, 5.0% |
| **Contact time:** | 15 s |
| **Interfering substance:** | 3.0 g/l bovine albumin + 3 ml/l sheep blood erythrocytes (dirty conditions) |
| **Neutralizer:** | - |
| **Rinsing liquid:** | Tryptone 1 g/l + NaCl, 9 g/l |
| **Test organisms:** | *Candida albicans* ATCC 10231 |
| **Testing method:** | **EVS-EN 13624:2021**<br>**Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)** |
| **Testing date:** | 30.03.2022 – 01.04.2022 |
| **Results:** | Look appendix 1 |
| **Interpretation and conclusion:** | Look appendix 2 |

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Nele Aas-Valleriani
Laboratory Manager
Date of issue: 11.06.2024

** - Data provided by the customer*

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## TEST RESULTS (suspension test)

EVS-EN 13624:2021; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-distilled water
Appearance of product solutions: Transparent, colourless liquid
Test organism: *Candida albicans* ATCC 10231
Test temperature: +20° C; Incubation temperature: +30 ± 1° C
Interfering substance: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 30.03.2022
Responsible person: Kerda Treksler

## Validation and controls

### Dirty conditions

| Validation suspension $N_{vo}$ | | | Experimental conditions (A) | | | Neutralizer control (B) | | | Method validation (C) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| $V_{C1}$ | $V_{C2}$ | $\bar{x}$ | $V_{C1}$ | $V_{C2}$ | $\bar{x}$ | $V_{C1}$ | $V_{C2}$ | $\bar{x}$ | $V_{C1}$ | $V_{C2}$ | $\bar{x}$ |
| 30 | 39 | 34.5 | 35 | 33 | 34 | 34 | 28 | 31 | 32 | 39 | 35.5 |
| $30 \leq \bar{x}\ N_{vo} \leq 160$? yes ☒; no ☐ | | | $\bar{x}$ **A** is $\geq 0.5\ \bar{x}\ N_{vo}$? yes ☒; no ☐ | | | $\bar{x}$ **B** is $\geq 0.0005\ \bar{x}\ N_{vB}$? yes ☒; no ☐ | | | $\bar{x}$ **C** is $\geq 0.5\ \bar{x}\ N_{vo}$? yes ☒; no ☐ | | |

### Test suspension and test

| Test suspension: | $N$ | $V_{C1}$ | $V_{C2}$ | $\bar{x}_{wm} = 1.55 \times 10^7$; $\log N = 7.19$ |
|---|---|---|---|---|
| *N and* $N_0$ | $10^{-5}$ | **147** | **167** | $N_0 = N/10$; $\log N_0 = 6.19$ |
| | $10^{-6}$ | **13** | **15** | $6.17 \leq \log N_0 \leq 6.70$; yes ☒; no ☐ |

### Experimental results

| Concentration of the product % | Dilution step | $V_{C1}$ | $V_{C2}$ | Na (=$\bar{x}$*10) | lg*Na* | *lg*R | Contact time | Conditions |
|---|---|---|---|---|---|---|---|---|
| 80.0% | - | <14 | <14 | <140 | <2.15 | >4.04 | 15 s | Dirty |
| 50.0% | - | <14 | <14 | <140 | <2.15 | >4.04 | 15 s | Dirty |
| 5.0% | - | >165 | >165 | >1650 | >3.22 | <2.97 | 15 s | Dirty |

**Explanations:**

$V_C$ = count per ml (one plate or more)
$N$ = cfu/ml microbes in test suspension
$N_{vo}$ = cfu/ml in the validation suspension (t=0)
R = reduction factor (R= $N_0$/ *Na;* LogR=Log$N_0$ - Log *Na*)
$\bar{x}$ = average of $V_{C1}$ and $V_{C2}$ (1. + 2. Duplicate)
$N_0$ = cfu/ml at the start of the contact time (t=0)
*Na* = surviving microbes after the test

**Interpretation:**

The ready to use disinfection product **CHEMISEPT MED** (batch no. 196161220) was tested according to the test method EVS-EN 13624:2021. The test was performed at 20 °C ± 1 °C, under dirty conditions during contact time of 15 s. The membrane filtration method was used for testing the product's effectiveness against the reference strain *Candida albicans* ATCC 10231. Under dirty conditions, the 80.0 % solution of the tested sample of the product was effective against the reference strain *Candida albicans* within contact time tested.

**Conclusion:**

The surviving count of the reference strain *Candida albicans* showed at least 4 lg reduction meaning that **according to EVS-EN 13624:2021 under dirty conditions the sample of the ready to use disinfection product CHEMISEPT MED is effective against *Candida albicans* within 15 seconds.**

The results apply exclusively to the tested sample of the product with batch no. 196161220.

*This is the corrected version of the test report no. 022022hd. The results of the previous test report remain valid.*

This is the end of the test report.

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Nele Aas-Valleriani
Laboratory Manager
Date of issue: 11.06.2024