



**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

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



**EAK**

**EN ISO/IEC 17025  
L263**

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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., Tännassilma tee 11; Tännassilma 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  
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



Nele Aas-Valleriani  
Laboratory Manager  
Date of issue: 11.06.2024

\* - Data provided by the customer

## 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 <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.0005 \bar{x} N_{VB}$ ? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>		

### Test suspension and test

Test suspension:	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 1.55 \times 10^7$ ; $\log N = 7.19$ $N_0 = N/10$ ; $\log N_0 = 6.19$ $6.17 \leq \log N_0 \leq 6.70$ ; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
$N$ and $N_0$	$10^{-5}$	<b>147</b>	<b>167</b>	
	$10^{-6}$	<b>13</b>	<b>15</b>	

## Experimental results

Concentration of the product %	Dilution step	$V_{C1}$	$V_{C2}$	$N_a$ ( $=\bar{x} \cdot 10$ )	$\lg N_a$	$\lg R$	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 ( $R = N_0 / N_a$ ;  $\log R = \log N_0 - \log N_a$ )

$\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$  (1. + 2. Duplicate)

$N_0$  = cfu/ml at the start of the contact time ( $t=0$ )

$N_a$  = 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  $20\text{ °C} \pm 1\text{ °C}$ , 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.

  
  
Nele Aas-Valleriani  
Laboratory Manager  
Date of issue: 11.06.2024