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

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

Digitally signed by Moraru Grigore
Date: 2025.11.12 14:03:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EAK
EN ISO/IEC 17025
L263

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
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** **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=LogN_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