



Test report No. 022022hd

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: 01/04/2022

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

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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; Maris Millner, +3725177090
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 13624:2013
Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.
Testing date: 30.03.2022 – 01.04.2022
Results: Look appendix 1
Interpretation and conclusion: Look appendix 2



Nele Aas-Valleriani
Microbiologist
Date of issue: 01.04.2022

* - Data provided by the customer

TEST RESULTS (suspension test)

EVS-EN 13624:2013; 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 ≤ $\bar{x} N_{vo}$ ≤ 160? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} A$ is ≥ 0.5 $\bar{x} N_{vo}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} B$ is ≥ 0.0005 $\bar{x} N_{vb}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} C$ is ≥ 0.5 $\bar{x} N_{vo}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>		

Test suspension and test

Test suspension: N and N_0	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"/>
	10^{-5}	147	167	
	10^{-6}	13	15	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a (= \bar{x} *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

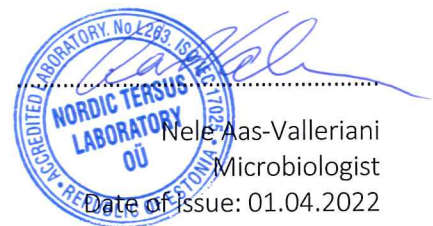
Interpretation:

The ready to use disinfection product **CHEMISEPT MED** (batch no. 196161220) was tested according to the test method EVS-EN 13624:2013. 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 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 13624:2013 under dirty conditions the sample of the ready to use disinfection product CHEMISEPT MED has yeasticidal activity within 15 seconds.**

This is the end of the test report.


Nele Aas-Valleriani
Microbiologist
Date of issue: 01.04.2022

