Nordic Tersus
Laboratory

Test report No. 24021sd

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

Name of the product*:	**BACTICID AF**
Batch number*:	197271120
Order number:	20037
Manufacturer*:	Chemi-Pharm Ltd.
Client, representative*:	Chemi-Pharm Ltd., Tänassilma tee 11, Tänassilma küla, Saku vald, 76406, ESTONIA, Maris Millner, +372 5177090
Date of delivery:	10.12.2020
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	At room temperature, darkness
Active substance – conc.*:	Ethyl alcohol 57.0% wt, isopropyl alcohol 6.0% wt
Appearance of the product:	Transparent liquid
Test concentration:	80.0%, 50.0%, 25.0%
Contact time:	2 min
Interfering substance:	3g/l bovine albumin + 3 ml/l sheep blood erythrocytes (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl 9 g/l
Test organisms:	*Aspergillus brasiliensis* ATCC 16404
Testing method:	**EVS-EN 13624:2013** **Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.**
Testing date:	17.02.2021 – 19.02.2021
Results:	Look appendix 1
Interpretation and conclusion:	Look appendix 2

Digitally sig
Date: 2023.
Reason: Mc
Location: M

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Allar Laaneleht
Chief specialist
Date of issue: 26.04.2021

* - *Data provided by the customer*

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TEST RESULTS (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: *Aspergillus brasiliensis* ATCC 16404
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: 17.02.2021
Responsible person: Melissa Ingela Bramanis, Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration 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}	$\bar{x}$
43	40	41.5	36	30	33	39	42	40.5	45	49	47
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}? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.64 \times 10^7$; log$N$ = 7.42
N and N_0	10^{-5}	**247**	**275**	$N_0 = N/10$; logN_0 = 6.42
	10^{-6}	**28**	**28**	6.17≤ logN_0≤6.70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lgNa	lg$R$	Contact time	Conditions
80.0%	-	19	21	200	2.30	4.12	2 min	Dirty
50.0%	-	>55	>55	>550	>2.74	<3.54	2 min	Dirty
25.0%	-	>55	>55	>550	>2.74	<3.54	2 min	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

Appendix 2

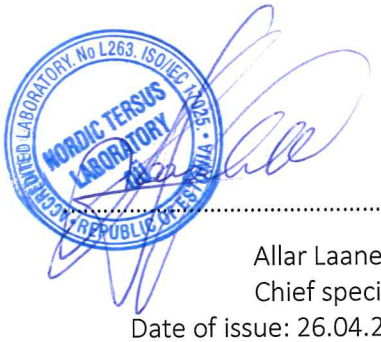
Interpretation:

The ready to use surface disinfection product **BACTICID AF** (batch no. 197271120) 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 times of 2 min. The membrane filtration method was used for testing the product's effectiveness against the reference strains *Aspergillus brasiliensis* ATCC 16404. Under dirty conditions, the 80.0% solution of the tested sample of the product was effective against *Aspergillus brasiliensis* within 2 minutes.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **according to EVS-EN 13624:2013 the sample of the ready to use surface disinfection product BACTICID AF is effective against *Aspergillus brasiliensis* within 2 minutes.**

This is the end of the test report



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Date of issue: 26.04.2021