
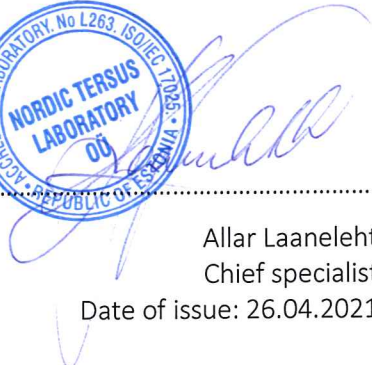


Test report No. 24021sd

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., Tännassilma tee 11, Tännassilma 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



Allar Laaneleht
Chief specialist
Date of issue: 26.04.2021

* - Data provided by the customer

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
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.64 \times 10^7$; $\log N = 7.42$ $N_0 = N/10$; $\log N_0 = 6.42$ $6.17 \leq \log N_0 \leq 6.70$; yes X; no <input type="checkbox"/>
N and N_0	10^{-5}	247	275	
	10^{-6}	28	28	

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%	-	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 ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

\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

Appendix 2

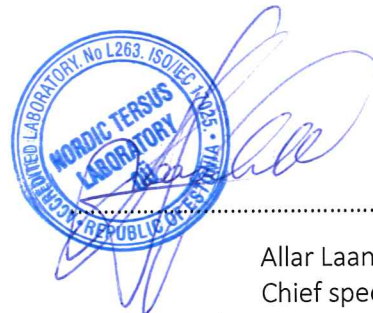
Interpretation:

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 $20\text{ °C} \pm 1\text{ °C}$, 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



Allar Laaneleht
Chief specialist

Date of issue: 26.04.2021