Nordic Tersus
Laboratory

Test report no. 035021sd

EVALUATION OF BACTERICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product: BACTICID AF
Batch number: 197020821/2
Date of test report: 19.09.2021

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

Nordic Tersus
Laboratory

Test report no.035021sd

EVALUATION OF BACTERICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product*:	**BACTICID AF**
Batch number*:	197020821/2
Order number:	20045
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:	06.08.2021
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	At room temperature, darkness
Active substance – conc.*:	Ethyl alcohol 57.0% w/w, isopropyl alcohol 6.0% w/w
Appearance of the product:	Transparent, colourless
Test concentration:	80.0%, 50.0%, 10.0%
Contact time:	15s
Interfering substance:	3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
Testing method:	**EVS-EN 13727:2012+A2:2015** **Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)**
Testing period:	10.08.2021 – 12.08.2021
Results:	look appendix 1-3
Interpretation and conclusion:	look appendix 4

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Melissa Ingela Bramanis
Microbiologist
Date of issue: 19.09.2021

** - Data provided by the customer*

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EN ISO/IEC 17025
L263

Appendix 1

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Staphylococcus aureus* ATCC 6538
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 10.08.2021
Responsible person: Melissa Ingela Bramanis

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}	$\bar{x}$
86	74	78.5	35	53	44	40	43	41.5	48	49	48.5
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

Test suspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 3.21 x 10^8; log$N$ = 8.50
N and N_0	10^{-6}	310	>330	$N_0 = N/10$; logN_0 =7.50
	10^{-7}	44	24	7.17≤ logN_0≤7.70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lgNa	lgR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.35	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.28	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.28	15s	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

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l;
Test organism: *Enterococcus hirae* ATCC 10541
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 10.08.2021
Responsible person: Melissa Ingela Bramanis

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}	$\bar{x}$
73	63	68	68	65	66.5	61	63	62	68	65	66.5
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

Test suspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.13 \times 10^8$; log$N$ = 8.50
N and N_0	10^{-6}	>330	298	$N_0 = N/10$; logN_0 =7.50
	10^{-7}	29	31	7.17≤ logN_0≤7.70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lgNa	lgR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.35	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.28	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.28	15s	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 3

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l
Test organism: *Pseudomonas aeruginosa* ATCC 15442
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC
Date of test: 10.08.2021
Responsible person: Melissa Ingela Bramanis

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}	$\bar{x}$
65	101	83	65	67	66	73	79	76	71	64	67.5
$30 \leq \bar{x}\ N_{vo} \leq 160$?yes X; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$?yes X;no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes X;no □		

Test suspension and test

Test suspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.33 \times 10^8$; log$N$ = 8.52
N and N_0	10^{-6}	>330	>330	$N_0 = N/10$; logN_0 =7.52
	10^{-7}	42	30	$7.17 \leq \log N_0 \leq 7.70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lgNa	lgR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.37	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.30	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	>4.30	15s	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 4

Interpretation:

The ready to use product **BACTICID AF** (batch no. 197020821/2) was tested according to the test method EVS-EN 13727:2012+A2:2015. The test was performed at 20 °C ± 1 °C, under dirty conditions with the contact time of 15 s. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541 and *Staphylococcus aureus* ATCC 6538. Under dirty conditions the tested product was effective against all the reference strains within the contact time tested.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **according to EVS-EN 13727:2012+A2:2015 under dirty conditions the sample ready to use surface disinfection product BACTICID AF has a bactericidal effect within 15 s.**

This is the end of the test report

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