Nordic Tersus
Laboratory

Test report No. 020022hd

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

Name of the product: CHEMISEPT GEL

Batch number: 198190821/3
Date of test report: 28/03/2022

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

EESTI AKREDITEERIMISKESKUS
EAK
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L263

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Test report No. 020022hd

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

Name of the product:	**CHEMISEPT GEL**
Batch number:	198190821/3
Order number:	20049
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald 76406; ESTONIA; Maris Millner, +3725177090.
Date of delivery:	14.03.2022
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Ethyl alcohol 72.5% w/w, isopropyl alcohol 7.5% w/w
Appearance of the product:	Transparent gel
Test concentration:	80%, 50%, 10%
Contact time:	15 s
Interfering substance:	3 g/l bovine albmin + 3 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 *Escherichia coli* ATCC 10536
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:	07.10.2021 - 13.10.2021
Results:	look appendix 1-4
Interpretation and conclusion:	look appendix 5

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Melissa Ingela Bramanis
Microbiologist
Date of test report: 28.03.2022

* - *Data provided by the customer*

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Appendix 1

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless gel
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 g/l bovine albmin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 07.10.2021
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}	$\bar{x}$
63	38	50.5	24	26	25	38	44	41	28	29	28.5
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.47 \times 10^8$; $\log N = 8.17$
N and N_0	10^{-6}	**156**	**138**	$N_0 = N/10$; $\log N_0 = 7.17$
	10^{-7}	**22**	**8**	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.02	15s	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.02	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<3.95	15s	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless gel
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 g/l bovine albmin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 11.10.2021
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}	$\bar{x}$
114	95	104.5	107	110	108.5	114	106	110	113	126	119.5
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}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 3.37 x 10^8; log$N$ = 8.53
N and N_0	10^{-6}	330	330	$N_0 = N/10$; logN_0 =7.53
	10^{-7}	37	45	7.17≤ logN_0≤7.70; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.38	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.31	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.31	15s	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 3

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless gel
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 g/l bovine albmin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 11.10.2021
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}	$\bar{x}$
151	213	182	116	110	113	127	101	114	154	118	136
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}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 3.61 x 10^8; log$N$ = 8.56
N and N_0	10^{-6}	330	330	$N_0 = N/10$; logN_0 =7.56
	10^{-7}	69	66	7.17≤ logN_0≤7.70; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.41	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.34	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.34	15s	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 4

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless gel
Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l
Test organism: *Escherichia coli NCTC 10538*
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albmin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 09.12.2021
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}	$\bar{x}$
78	70	74	39	39	39	64	63	63.5	55	55	55
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}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.48 \times 10^8$; log$N$ = 8.39
N and N_0	10^{-6}	**198**	**282**	$N_0 = N/10$; logN_0 =7.39
	10^{-7}	**27**	**38**	7.17≤ logN_0≤7.70; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.24	15s	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.24	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.17	15s	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 5

Interpretation:

The ready to use product **CHEMISEPT GEL** (batch no. 198190821/3) 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, *Staphylococcus aureus* ATCC 6538 and *Escherichia coli* NCTC 10538. Under the dirty conditions the tested product was effective against all the reference strains tested within 15 s.

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 of the ready to use product CHEMISEPT GEL has a bactericidal effect within 15 s.**

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Melissa Ingela Bramanis
Microbiologist
Date of test report: 28.03.2022