



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

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., Tännassilma tee 11; Tännassilma 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



Melissa Ingela Bramanis
Microbiologist
Date of test report: 28.03.2022

* - Data provided by the customer

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 albumin + 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 <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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)
 N_a = surviving microbes after the test
 R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

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

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.37 \times 10^8$; $\log N = 8.53$ $N_0 = N/10$; $\log N_0 = 7.53$ $7.17 \leq \log N_0 \leq 7.70$; yes x; no <input type="checkbox"/>
N and N_0	10^{-6}	330	330	
	10^{-7}	37	45	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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)
 N_a = surviving microbes after the test
 R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

N-7/29-V9

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

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.61 \times 10^8$; $\log N = 8.56$ $N_0 = N/10$; $\log N_0 = 7.56$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	330	330	
	10^{-7}	69	66	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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)

N_a = surviving microbes after the test

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

The test results apply to the tested sample only.

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N-7/29-V9

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 albumin + 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
$30 \leq \bar{x} N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 2.48 \times 10^8$; $\log N = 8.39$ $N_0 = N/10$; $\log N_0 = 7.39$ $7.17 \leq \log N_0 \leq 7.70$; yes x; no <input type="checkbox"/>
N and N_0	10^{-6}	198	282	
	10^{-7}	27	38	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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)

N_a = surviving microbes after the test

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

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N-7/29-V9

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.**





Melissa Ingela Bramanis
Microbiologist

Date of test report: 28.03.2022