



Test report No. 024022hd

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

Name of the product: CHEMISEPT MED

Batch number: 196161220

Date of test report: 05/04/2022

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

Test report No. 024022hd

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

Name of the product: CHEMISEPT MED
Batch number: 196161220
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: 29.03.2022
Test material conditions: No specific features, sample in the manufacturers tare
Storage conditions: In room temperature, darkness
Active substance – conc.: Ethyl alcohol 72.5% w/w, isopropyl alcohol 7.5% w/w
Appearance of the product: Transparent, colourless liquid
Test concentration: 80%, 50%, 10%
Contact time: 15 s
Interfering substance: 3 g/l bovine albumin + 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 K12 NCTC 10538
MRSA Staphylococcus aureus ATCC 33592
Acinetobacter baumannii ATCC 19606
Enterococcus Faecium VRE ATCC 700221
Salmonella enterica subsp. *Typhimurium* ATCC13311
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: 29.03.2022 - 05.04.2022
Results: look appendix 1-8
Interpretation and conclusion: look appendix 9




Nele Aas-Valleriani
Microbiologist

Date of test report: 05.04.2022

* - Data provided by the customer

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 liquid
 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: 29.03.2022
 Responsible person: Kerda Treksler

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}
76	59	67.5	45	36	40.5	42	49	45.5	46	47	46.5
$30 \leq \bar{x} N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 2.89 \times 10^8$; $\log N = 8.46$ $N_0 = N/10$; $\log N_0 = 7.46$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	271	309	
	10^{-7}	23	32	

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	>5.31	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.24	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.24	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 liquid
 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: 29.03.2022
 Responsible person: Kerda Treksler

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}
72	61	66.5	70	65	67.5	64	56	60	62	59	60.5
$30 \leq \bar{x} N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 2.84 \times 10^8$; $\log N = 8.45$ $N_0 = N/10$; $\log N_0 = 7.45$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	285	290	
	10^{-7}	19	31	

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	>5.30	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.23	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.23	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 liquid

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: 29.03.2022

Responsible person: Kerda Treksler

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}
130	120	125	109	126	117.5	95	125	110	94	117	105.5
$30 \leq \bar{x} N_{vo} \leq 160?$ 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}	$\bar{x}_{wm} = 3.43 \times 10^8$; $\log N = 8.54$ $N_0 = N/10$; $\log N_0 = 7.54$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	330	330	
	10^{-7}	54	41	

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	>5.39	15s	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.39	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.32	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 liquid

Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l

Test organism: *Escherichia coli* K12 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: 29.03.2022

Responsible person: Kerda Treksler

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}
90	66	78	51	46	48.5	32	42	37	39	62	50.5
$30 \leq \bar{x} N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 3.08 \times 10^8$; $\log N = 8.49$ $N_0 = N/10$; $\log N_0 = 7.49$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	324	283	
	10^{-7}	23	47	

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	>5.34	15s	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.34	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.27	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 liquid

Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l

Test organism: *MRSA Staphylococcus aureus ATCC 33592*

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: 04.04.2022

Responsible person: Kerda Treksler

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}
95	92	93.5	131	137	134	73	74	73.5	130	119	124.5
$30 \leq \bar{x} N_{vo} \leq 160?$ 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}	$\bar{x}_{wm} = 3.10 \times 10^8$; $\log N = 8.49$ $N_0 = N/10$; $\log N_0 = 7.49$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	280	322	
	10^{-7}	39	41	

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	>5.34	15s	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.27	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.27	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 liquid

Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l

Test organism: *Acinetobacter baumannii* ATCC 19606

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: 30.03.2022

Responsible person: Kerda Treksler

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}
157	179	168	107	134	120.5	106	111	108.5	132	152	142
$30 \leq \bar{x} N_{vo} \leq 160?$ 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}	$\bar{x}_{wm} = 1.77 \times 10^8$; $\log N = 8.25$ $N_0 = N/10$; $\log N_0 = 7.25$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	125	193	
	10^{-7}	33	38	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a (= $\bar{x} * 10$)	$\log N_a$	$\log R$	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.10	15s	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.10	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.03	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 liquid

Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l

Test organism: *Salmonella enterica subsp. Typhimurium* ATCC 13311

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: 30.03.2022

Responsible person: Kerda Treksler

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}
150	184	167	168	187	177.5	176	170	173	177	193	185
$30 \leq \bar{x} N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 3.60 \times 10^8$; $\log N = 8.56$ $N_0 = N/10$; $\log N_0 = 7.56$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	330	330	
	10^{-7}	77	54	

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%	-	<14	<14	<140	<2.15	>5.41	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.

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 liquid

Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l

Test organism: *Enterococcus Faecium* VRE ATCC 700221

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: 04.04.2022

Responsible person: Kerda Treksler

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}
44	57	50.5	41	38	39.5	36	39	37.5	36	44	40
$30 \leq \bar{x} N_{vo} \leq 160?$ 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}	$\bar{x}_{wm} = 1.75 \times 10^8$; $\log N = 8.24$ $N_0 = N/10$; $\log N_0 = 7.24$ $7.17 \leq \log N_0 \leq 7.70$; yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
N and N_0	10^{-6}	187	165	
	10^{-7}	18	15	

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	>5.09	15s	Dirty
50.0%	-	18	58	>380	>2.58	<4.66	15s	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.02	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.

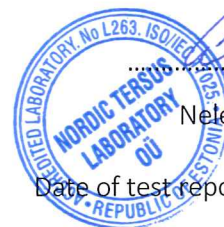
N-7/29-V9

Interpretation:

The ready to use product **CHEMISEPT MED** (batch no. 196161220) 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, *Escherichia coli* K12 NCTC 10538, *MRSA Staphylococcus aureus* ATCC 33592, *Acinetobacter baumannii* ATCC 19606, *Enterococcus Faecium* VRE ATCC 700221 and *Salmonella enterica subsp. Typhimurium* ATCC13311. Under the dirty conditions the 80.0 % solution of the tested sample of the 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 disinfection product CHEMISEPT MED has a bactericidal effect within 15 s.**




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Microbiologist

Date of test report: 05.04.2022