Nordic Tersus
Laboratory

Test report No. shd1018

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

Name of the product:	Chemisept MED
Batch number:	196101017
Order number:	17028
Manufacturer:	Chemi-Pharm Ltd
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	22.01.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Ethyl alcohol – 72.5 % wt; isopropyl alcohol – 7.5 % wt
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	15 sec, 30 sec
Interfering substance:	15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions; 1,5g/l bovine albumin = clean 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, NTCT 10538 *Staphylococcus aureus* MRSA ATCC 33592 *Enterococcus faecium* VRE ATCC 700221
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 date:	17.02.2018 – 19.02.2018
Results:	look appendix 1-7

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Diana Kaare, MSc
Head of laboratory, microbiologist
Date of test report: 21.02.2018

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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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	83	$\bar{x}$ = 86.5	V_{C1}	72	$\bar{x}$ = 68.5	V_{C1}	68	$\bar{x}$ = 71.5	V_{C1}	81	$\bar{x}$ = 77
V_{C2}	90		V_{C2}	65		V_{C2}	75		V_{C2}	73	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 2.45 x 10^9; log$N$ = 9.39
N and N_0	10^{-7}	257	224	N_0 = N/100; logN_0 = 7,39
	10^{-8}	28	30	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.24	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.24	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.24	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.24	30 sec	clean

Explanations:

V_C = count per ml (one plate or more)

x̄ = 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;
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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	62	$\bar{x}$ = 66	V_{C1}	47	$\bar{x}$ = 46	V_{C1}	52	$\bar{x}$ = 53.5	V_{C1}	59	$\bar{x}$ = 61
V_{C2}	70		V_{C2}	45		V_{C2}	55		V_{C2}	53	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 2.15 x 10^9; log$N$ = 9.33
N and N_0	10^{-7}	203	224	N_0 = N/100; logN_0 = 7,33
	10^{-8}	22	25	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.18	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.18	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.18	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.18	30 sec	clean

Explanations:

V_C = count per ml (one plate or more)

x̄ = 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;
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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	94	$\bar{x}$ = 87	V_{C1}	71	$\bar{x}$ = 72.5	V_{C1}	66	$\bar{x}$ = 68	V_{C1}	75	$\bar{x}$ = 78.5
V_{C2}	80		V_{C2}	74		V_{C2}	70		V_{C2}	82	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 2.74 x 10^9; log$N$ = 9.44
	10^{-7}	284	266	N_0 = N/100; logN_0 = 7,44
N and N_0	10^{-8}	24	29	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.29	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.29	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.29	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.29	30 sec	clean

Explanations:

V_C = count per ml (one plate or more)

x̄ = 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;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Escherichia coli* K12, NTCT 10538
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	82	$\bar{x}$ = 78.5	V_{C1}	68	$\bar{x}$ = 60	V_{C1}	69	$\bar{x}$ = 69.5	V_{C1}	70	$\bar{x}$ = 68.5
V_{C2}	75		V_{C2}	52		V_{C2}	73		V_{C2}	67	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 2.48 x 10^9; log$N$ = 9.39
	10^{-7}	241	257	N_0 = N/100; logN_0 = 7.39
N and N_0	10^{-8}	22	26	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.24	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.24	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.24	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.24	30 sec	clean

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

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* MRSA ATCC 33592
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	66	$\bar{x}$ = 61.5	V_{C1}	42	$\bar{x}$ = 45.5	V_{C1}	49	$\bar{x}$ = 47.5	V_{C1}	52	$\bar{x}$ = 53
V_{C2}	57		V_{C2}	49		V_{C2}	46		V_{C2}	54	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.99 x 10^9; log$N$ = 9.30
N and N_0	10^{-7}	204	191	N_0 = N/100; logN_0 = 7.30
	10^{-8}	18	24	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.15	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.15	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.15	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.15	30 sec	clean

Explanations:

V_C = count per ml (one plate or more)

x̄ = 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 6

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 faecium* VRE ATCC 700221
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
1,5g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 17.02.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	62	$\bar{x}$ = 64	V_{C1}	52	$\bar{x}$ = 54.5	V_{C1}	43	$\bar{x}$ = 47	V_{C1}	58	$\bar{x}$ = 59
V_{C2}	66		V_{C2}	57		V_{C2}	51		V_{C2}	60	
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

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.88 x 10^9; log$N$ = 9.27
	10^{-7}	181	195	N_0 = N/100; logN_0 = 7.27
N and N_0	10^{-8}	22	18	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>5.12	15 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.12	15 sec	clean
Ready to use	-	<14	<14	<140	<2.15	>5.12	30 sec	dirty
Ready to use	-	<14	<14	<140	<2.15	>5.12	30 sec	clean

Explanations:

V_C = count per ml (one plate or more)

x̄ = 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 7

Interpretation:

The product for surgical handrub **Chemisept MED** (batch no. 196101017) was tested according to the test method EVS-EN 13727:2012+A2:2015. The test was performed at 20 °C ± 1 °C, under clean and dirty conditions with the contact times of 15 sec and 30 sec. The membrane filtration method was used for testing the products' effectiveness against the reference strains: *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541, *Staphylococcus aureus* ATCC 6538, Escherichia coli K12 NTCT 10538, Staphylococcus aureus MRSA ATCC 33592 and *Enterococcus faecium* VRE ATCC 700221. Under clean and dirty conditions the tested product was effective against all the reference strains within 15 and 30 sec of contact times.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **under clean and dirty conditions the ready to use product Chemisept MED has a bactericidal effect in case of hand disinfection within 15 sec.**

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