Nordic Tersus
Laboratory

Test report No. id4019

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

Name of the product:	STERISEPT INSTRU
Batch number:	211310518
Order number:	18014
Manufacturer:	Chemi-Pharm Ltd
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	04.10.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 15%; Didecyl-Dimethyl-Ammonium Chloride (DDAC) 15%
Appearance of the product:	Transparent liquid
Test concentration:	0.25%; 0.50%
Contact time:	15 min for 0.25%; 5 min, 10 min and 15 min for 0.50%
Interfering substance:	3.0 g/l bovine albumin + 3ml/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 *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:	26.11.2018 – 27.11.2019
Results:	look appendix 1-6

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Allar Laaneleht
Chief specialist
Date of test report: 15.01.2019

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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: 3.0 g/l bovine albumin + 3ml/l sheepblood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 26.11.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	49	$\bar{x}$ = 45.5	V_{C1}	36	$\bar{x}$ = 34.5	V_{C1}	38	$\bar{x}$ = 36.5	V_{C1}	32	$\bar{x}$ = 31
V_{C2}	42		V_{C2}	33		V_{C2}	35		V_{C2}	30	
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}	$\bar{x}_{wm}$ = 1.60 x 10^8; log$N$ = 8.20
N and N_0	10^{-6}	155	163	N_0 = N/10; logN_0 =7.20
	10^{-7}	16	18	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
0.05%	-	>165	>165	>1650	>3.22	<3.98	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>5.05	15 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.05	5 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.05	10 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.05	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>5.05	5 min	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;
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 + 3ml/l sheepblood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 26.11.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	72	$\bar{x}$ = 67.5	V_{C1}	62	$\bar{x}$ = 58.5	V_{C1}	58	$\bar{x}$ = 54.5	V_{C1}	53	$\bar{x}$ = 49.5
V_{C2}	63		V_{C2}	55		V_{C2}	51		V_{C2}	46	
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}	$\bar{x}_{wm}$ = 1.87 x 10^8; log$N$ = 8.27
N and N_0	10^{-6}	179	193	N_0 = N/10; logN_0 =7.27
	10^{-7}	21	18	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
0.05%	-	>165	>165	>1650	>3.22	<4.05	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>5.12	15 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.12	5 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.12	10 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.12	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>5.12	5 min	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;
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 + 3ml/l sheepblood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 26.11.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	84	$\bar{x}$ = 79.5	V_{C1}	58	$\bar{x}$ = 61	V_{C1}	67	$\bar{x}$ = 69	V_{C1}	72	$\bar{x}$ = 70
V_{C2}	75		V_{C2}	64		V_{C2}	71		V_{C2}	68	
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}	$\bar{x}_{wm}$ = 2.09 x 10^8; log$N$ = 8.32
N and N_0	10^{-6}	204	215	N_0 = N/10; logN_0 =7.32
	10^{-7}	22	19	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
0.05%	-	>165	>165	>1650	>3.22	<4.10	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>5.17	15 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.17	5 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.17	10 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.17	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>5.17	5 min	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;
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: 3.0 g/l bovine albumin + 3ml/l sheepblood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 26.11.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	60	$\bar{x}$ = 57	V_{C1}	42	$\bar{x}$ = 45	V_{C1}	51	$\bar{x}$ = 46.5	V_{C1}	51	$\bar{x}$ = 55
V_{C2}	54		V_{C2}	48		V_{C2}	42		V_{C2}	59	
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}	$\bar{x}_{wm}$ = 1.79 x 10^8; log$N$ = 8.25
N and N_0	10^{-6}	184	175	N_0 = N/10; logN_0 =7.25
	10^{-7}	16	18	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
0.05%	-	>165	>165	>1650	>3.22	<4.03	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>5.10	15 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.10	5 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.10	10 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.10	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>5.10	5 min	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

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: 3.0 g/l bovine albumin + 3ml/l sheepblood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 26.11.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	58	$\bar{x}$ = 54.5	V_{C1}	40	$\bar{x}$ = 40	V_{C1}	36	$\bar{x}$ = 37.5	V_{C1}	41	$\bar{x}$ = 38.5
V_{C2}	51		V_{C2}	40		V_{C2}	39		V_{C2}	36	
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}	$\bar{x}_{wm}$ = 1.75 x 10^8; log$N$ = 8.24
N and N_0	10^{-6}	167	181	N_0 = N/10; logN_0 =7.24
	10^{-7}	17	20	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
0.05%	-	>165	>165	>1650	>3.22	<4.02	15 min	Dirty
0.25%	-	<14	<14	<140	<2.15	>5.09	15 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.09	5 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.09	10 min	Dirty
0.50%	-	<14	<14	<140	<2.15	>5.09	15 min	Dirty
2.50%	-	<14	<14	<140	<2.15	>5.09	5 min	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 6

Interpretation:

The product STERISEPT INSTRU (batch no. 211310518) 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 times of 15 min for 0.25% and 0.50% ; 10 min for 0.50%; 5 min for 0.50%. 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, *Enterococcus faecium* VRE ATCC 700221 and *Staphylococcus aureus* MRSA ATCC 33592. Under dirty conditions the 0.25% solution of the tested product was effective against all the reference strains within 15 min and the 0.50% solution was active within 5 min

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **under dirty conditions the 0.25% solution of product STERISEPT INSTRU has a bactericidal effect within 15 min the 0.50% solution of the product has a bactericidal effect within 5 min.**

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Allar Laaneleht

Chief Specialist

15.01.2019