Nordic Tersus Laboratory

Test report No. sd0619

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

Name of the product:	STERISEPT WIPES
Batch number:	14300818W
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 0.45%; Didecyl-Dimethyl-Ammonium Chloride (DDAC) 0.45%
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	60 s
Interfering substance:	15 g/l bovine albumin + 15 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 *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:	08.10.2018 – 16.10.2018
Results:	look appendix 1-6

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ACCREDITED LABORATORY No L263. ISO/IEC 17025 NORDIC TERSUS LABORATORY OÜ REPUBLIC OF ESTONIA

Allar Laaneleht
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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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 10.10.2018
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	$\bar{x}$ = 70	V_{C1}	54	$\bar{x}$ = 54.5	V_{C1}	59	$\bar{x}$ = 53	V_{C1}	61	$\bar{x}$ = 62
V_{C2}	68		V_{C2}	55		V_{C2}	47		V_{C2}	63	
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}	$\bar{x}_{wm}$ = 2.21 x 10^9; log$N$ = 9.35
N and N_0	10^{-7}	233	207	N_0 = N/100; logN_0 =7.35
	10^{-8}	25	22	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	>5.20	60 sec	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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 09.10.2018
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}	69	$\bar{x}$ = 66	V_{C1}	47	$\bar{x}$ = 45.5	V_{C1}	39	$\bar{x}$ = 37	V_{C1}	43	$\bar{x}$ = 41.5
V_{C2}	63		V_{C2}	44		V_{C2}	35		V_{C2}	40	
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}	$\bar{x}_{wm}$ = 2.20 x 10^9; log$N$ = 9.34
N and N_0	10^{-7}	224	218	$N_0 = N/100$; logN_0 =7.34
	10^{-8}	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
Ready to use	-	<14	<14	<140	<2.15	>5.19	60 sec	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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 08.10.2018
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}	96	$\bar{x}$ = 92.5	V_{C1}	74	$\bar{x}$ = 75.5	V_{C1}	68	$\bar{x}$ = 70	V_{C1}	79	$\bar{x}$ = 81
V_{C2}	89		V_{C2}	77		V_{C2}	72		V_{C2}	83	
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}	$\bar{x}_{wm}$ = 2.82 x 10^9; log$N$ = 9.45
	10^{-7}	296	271	N_0 = N/100; logN_0 =7.45
N and N_0	10^{-8}	28	25	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	>5.30	60 sec	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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test:11.10.2018
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}	51	$\bar{x}$ = 48.5	V_{C1}	33	$\bar{x}$ = 35	V_{C1}	32	$\bar{x}$ = 33	V_{C1}	36	$\bar{x}$ = 38.5
V_{C2}	46		V_{C2}	37		V_{C2}	34		V_{C2}	41	
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 10^9; log$N$ = 9.26
	10^{-7}	194	172	N_0 = N/100; logN_0 =7.26
N and N_0	10^{-8}	20	16	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	>5.11	60 sec	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: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test:15.10.2018
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}	75	$\bar{x}$ = 77	V_{C1}	68	$\bar{x}$ = 69	V_{C1}	62	$\bar{x}$ = 59.5	V_{C1}	57	$\bar{x}$ = 55
V_{C2}	79		V_{C2}	70		V_{C2}	57		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}	$\bar{x}_{wm}$ = 2.60 x 10^9; log$N$ = 9.41
N and N_0	10^{-7}	251	268	N_0 = N/100; logN_0 =7.41
	10^{-8}	29	23	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	>5.26	60 sec	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 WIPES (batch no. 14300818W) 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 60 s. 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, *Enterococcus faecium* VRE ATCC 700221 and *Staphylococcus aureus* MRSA ATCC 33592. Under dirty conditions the tested product was effective against all the reference strains within 60 s.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that under dirty conditions the ready to use product STERISEPT WIPES has a bactericidal effect within 60 s.

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Allar Laaneleht

Chief Specialist

15.01.2019