Nordic Tersus
Laboratory

Test report No. 11319sd

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

Name of the product:	**STERISEPT WIPES**
Batch number:	14060919
Order number:	19029
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Tänassilma tee 11, Tänassilma küla, Saku vald, 76406, ESTONIA, Maris Millner, +372 5177090
Date of delivery:	09.07.2019
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:	80%; 50%; 10%
Contact time:	30 s; 60 s
Interfering substance:	3g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Acinetobacter baumannii* ATCC 19606 *Klebsiella pneumoniae* ATCC 700603 *Escherichia coli K12* NCTC 10538
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:	04.09.2019 – 06.09.2019
Results:	look appendix 1-4

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Allar Laaneleht
Chief specialist
Date of test report: 09.09.2019

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: *Acinetobacter baumannii* ATCC 19606;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.;
Date of test:04.09.2019
Responsible person: Allar Laaneleht

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}	$\bar{x}$
88	75	81.5	69	60	64.5	58	58	58	66	79	72.5
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}	$\bar{x}_{wm} = 2.39 \times 10^8$; log$N$ = 8.38
N and N_0	10^{-6}	**247**	**226**	$N_0 = N/10$; logN_0 =7.38
	10^{-7}	**28**	**24**	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
80%	-	<14	<14	<140	<2.15	>5.23	30s	Dirty
80%	-	<14	<14	<140	<2.15	>5.23	60s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.16	30s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.16	60s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.16	30s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.16	60s	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 *Klebsiella pneumoniae* ATCC 700603;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes;
Nordic Tersus Laboratory LLC.;
Date of test: 04.09.2019
Responsible person: Allar Laaneleht

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}	$\bar{x}$
62	69	65.5	54	56	55	52	47	49.5	66	48	57
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}	$\bar{x}_{wm} = 2.15 \times 10^8$; log$N$ = 8.33
N and N_0	10^{-6}	**232**	**194**	$N_0 = N/10$; logN_0 =7.33
	10^{-7}	**21**	**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
80%	-	<14	<14	<140	<2.15	>5.18	30s	Dirty
80%	-	<14	<14	<140	<2.15	>5.18	60s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.11	30s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.11	60s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.11	30s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.11	60s	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 *Escherichia coli K12* NCTC 10538;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes;
Nordic Tersus Laboratory LLC.;
Date of test: 04.09.2019
Responsible person: Allar Laaneleht

Validation and controls
Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	x̄	V_{C1}	V_{C2}	x̄	V_{C1}	V_{C2}	x̄	V_{C1}	V_{C2}	x̄
84	80	82	46	52	49	62	55	58.5	69	63	66
30 ≤ x̄ N_{vo} ≤160?yes X; no □			x̄ A is ≥ 0.5 x̄ N_{vo}?yes X;no □			x̄ **B** is ≥ 0.5 x̄ N_{vo}? yesX; no □			x̄ **C** is ≥ 0.5 x̄ N_{vo}? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.98 \times 10^8$; log$N$ = 8.47
N and N_0	10^{-6}	**307**	**279**	$N_0 = N/10$; logN_0 =7.47
	10^{-7}	**36**	**33**	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
80%	-	<14	<14	<140	<2.15	>5.32	30s	Dirty
80%	-	<14	<14	<140	<2.15	>5.32	60s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.25	30s	Dirty
50%	-	>165	>165	>1650	>3.22	<4.25	60s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.25	30s	Dirty
10%	-	>165	>165	>1650	>3.22	<4.25	60s	Dirty

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

Interpretation:

The product **STERISEPT WIPES** (batch no. 14060919) 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 30s and 60s. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Acinetobacter baumannii* ATCC 19606, *Klebsiella pneumoniae* ATCC 700603 and *Escherichia coli K12* NCTC 10538. Under dirty conditions the tested product was effective against the reference strains within 30 seconds.

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 is effective against: *Acinetobacter baumannii* ATCC 19606, *Klebsiella pneumoniae* ATCC 700603 and *Escherichia coli K12* NCTC 10538 within 30 seconds.**

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Chief Specialist
09.09.2019