Nordic Tersus
Laboratory

Test report No. sd3618

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

Name of the product:	CHLORINEX-60
Batch number:	230318
Order number:	18011
Manufacturer:	Chemi-Pharm Ltd
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	11.06.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	1 tab = 1.5 g active chlorine if dissolved in water, thus 1 tab/1.5 l 1000 ppm active chlorine
Appearance of the product:	White tablet
Test concentration:	1 tab / 1.5 l
Contact time:	15 min;
Interfering substance:	3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Neutralizer:	-
Rinsing liquid:	Sodium thiosulphate 3g/l
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
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 dates:	14.06 – 19.06.2018
Results:	look appendix 1-4

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NORDIC TERSUS LABORATORY OÜ

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Date of test report: 21.06.2018

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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: Sodium thiosulphate 3g/l;
Test organism: *Pseudomonas aeruginosa* ATCC 15442;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 14.06 – 19.06.2018 Responsible person: Raul Raudsepp

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	108	$\bar{x}$ = 94.5	V_{C1}	88	$\bar{x}$ = 95	V_{C1}	61	$\bar{x}$ = 64	V_{C1}	78	$\bar{x}$ = 71.5
V_{C2}	81		V_{C2}	102		V_{C2}	67		V_{C2}	65	
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}	$\bar{x}_{wm}$ = 5.0 x 10^8; log$N$ = 8.70
N and N_0	10^{-6}	>330	>330	N_0 = N/100; logN_0 = 7.70
	10^{-7}	47	53	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
1 tab / 30l	-	>165	>165	>1650	>3,22	<4.48	15 min	dirty
1 tab / 1.5l	-	<14	20	170	2.23	5.47	15 min	dirty
5 tab / 1.5l	-	<14	<14	<140	<2.15	5.55	15 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: Sodium thiosulphate 3g/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 = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 14.06 – 19.06.2018. Responsible person: Raul Raudsepp

Validation and controls
Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	37	$\bar{x}$ = 37.5	V_{C1}	33	$\bar{x}$ = 31.5	V_{C1}	38	$\bar{x}$ = 30.5	V_{C1}	29	$\bar{x}$ = 32
V_{C2}	38		V_{C2}	30		V_{C2}	23		V_{C2}	35	
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}	$\bar{x}_{wm}$ = 1.65 x 10^8; log$N$ = 8,22
N and N_0	10^{-6}	168	147	N_0 = N/10; logN_0 = 7,22
	10^{-7}	37	38	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
1 tab / 30l	-	>165	>165	>1650	>3.22	<4.00	15 min	dirty
1 tab / 1.5l	-	15	<14	185	2.16	5.06	15 min	dirty
5 tab / 1.5l	-	<14	<14	<140	<2.15	>5.07	15 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: Sodium thiosulphate 3g/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 = dirty conditions;
Nordic Tersus Laboratory LLC.;
Date of test: 14.06 – 19.06.2018. Responsible person: Raul Raudsepp

Validation and controls
Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	78	$\bar{x}$ = 79.5	V_{C1}	96	$\bar{x}$ = 90.5	V_{C1}	88	$\bar{x}$ = 88.5	V_{C1}	84	$\bar{x}$ = 84
V_{C2}	81		V_{C2}	85		V_{C2}	89		V_{C2}	84	
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}	$\bar{x}_{wm}$ = 2.46 x 10^8; log$N$ = 8.39
N and N_0	10^{-6}	263	220	N_0 = N/10; logN_0 = 7.39
	10^{-7}	30	29	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
1 tab / 30l	-	>165	>165	>1650	>3.22	<4.17	15 min	dirty
1 tab / 1.5l	-	<14	<14	<140	<2.15	>5.24	15 min	dirty
5 tab / 1.5l	-	<14	<14	<140	<2.15	>5.24	15 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

Interpretation:

The product for surface disinfection **CHLORINEX-60** (batch no.230318) 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 min. The membrane filtration method was used for testing the product's effectiveness against reference strains: *Pseudomonas aeruginosa* ATCC 15442; *Staphylococcus aureus* ATCC 6538 and *Enterococcus hirae* ATCC 10541. Under dirty conditions the tested product was effective against all the reference strains within 15 min of contact time.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **under dirty conditions the 1 tab/1.5 l solution of product CHLORINEX-60 has a bactericidal effect in case of surface disinfection within 15 min.**

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