Nordic Tersus
Laboratory

Test report No. 14319id

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

Name of the product: ALKADENT

Batch number: 13221019
Date of test report: 08/11/2019

Client, representative:
Chemi-Pharm Ltd.
Tänassilma tee 11
Tänassilma küla
Saku vald, 76406
ESTONIA

Nordic Tersus
Laboratory

Test report No. 14319id

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

Name of the product:	**ALKADENT**
Batch number:	13221019
Order number:	19037
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:	23.10.2019
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Quaternary ammonium compounds - 7%
Appearance of the product:	Transparent liquid
Test concentration:	0.5%; 2.0%; 4.0%
Contact time:	10 min
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:	*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 date:	29.10.2019 – 06.11.2019
Results:	Look appendix 1-4

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Nele Aas-Valleriani
Microbiologist
Date of test report: 08.11.2019

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EN ISO/IEC 17025
L263

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: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.;
Date of test: 04.11.2019
Responsible person: Nele Aas-Valleriani

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}	$\bar{x}$
63	69	66	46	49	47.5	42	46	44	33	33	33
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}	$\bar{x}_{wm}$ = 3.66 x 10^8; log$N$ = 8.56
N and N_0	10^{-6}	**370**	**372**	$N_0 = N/10$; logN_0 =7.56
	10^{-7}	**31**	**33**	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
0.5%	-	<14	<14	<140	<2.15	>5.41	10 min	Dirty
2.0%	-	<14	<14	<140	<2.15	>5.41	10 min	Dirty
4.0%	-	<14	<14	<140	<2.15	>5.41	10 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)

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: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes;
Nordic Tersus Laboratory LLC.;
Date of test: 29.10.2019
Responsible person: Nele Aas-Valleriani

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}	$\bar{x}$
102	110	106	114	107	110.5	104	110	107	106	120	113
$30 \leq \bar{x}$ 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}	$\bar{x}_{wm} = 4.84 \times 10^8$; $\log N = 8.68$
N and N_0	10^{-6}	**478**	**493**	$N_0 = N/10$; $\log N_0 = 7.68$
	10^{-7}	**43**	**51**	$7.17 \leq \log N_0 \leq 7.70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
0.5%	-	<14	<14	<140	<2.15	>5.53	10 min	Dirty
2.0%	-	<14	<14	<140	<2.15	>5.53	10 min	Dirty
4.0%	-	<14	<14	<140	<2.15	>5.53	10 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)

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: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes;
Nordic Tersus Laboratory LLC.;
Date of test: 05.11.2019
Responsible person: Nele Aas-Valleriani

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}	$\bar{x}$
22	38	30	25	36	30.5	25	10	17.5	32	28	30
$30 \leq \bar{x}$ **N_{vo}** ≤ 160?yes X; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}$ **N_{vo}**?yes X;no □			$\bar{x}$ **B** is $\geq 0.5\ \bar{x}$ **N_{vo}**? yesX; no □			$\bar{x}$ **C** is $\geq 0.5\ \bar{x}$ **N_{vo}**? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.50 \times 10^8$; log$N$ = 8.18
N and N_0	10^{-6}	**142**	**153**	$N_0 = N/10$; logN_0 =7.18
	10^{-7}	**21**	**15**	$7.17 \leq \log N_0 \leq 7.70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
0.5%	-	>165	>165	>1650	<2.15	<3.96	10 min	Dirty
2.0%	-	<14	<14	<140	<2.15	>5.03	10 min	Dirty
4.0%	-	<14	<14	<140	<2.15	>5.03	10 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)

Interpretation:

The product for **ALKADENT** (batch no. 13221019) 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 10 min. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541 and *Staphylococcus aureus* ATCC 6538. Under dirty conditions the 2% dilution of tested product was effective against all the reference strains within 10 minutes.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **under dirty conditions the 2% dilution of product ALKADENT has a bactericidal effect within 10 minutes.**

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Nele Aas-Valleriani
Microbiologist
08.11.2019

Nordic Tersus
Laboratory

Test report No. id2218

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA (EN 13624)

Name of the product:	Alkadent
Batch number:	13010318
Order number:	17031
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	15.03.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides 3,5%
Appearance of the product:	Transparent liquid
Test concentration:	2%
Contact time:	10 min
Interfering substance:	3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Rinsing liquid:	Tryptone 1 g/l + NaCl 9 g/l
Neutralizer:	-
Test organisms:	*Candida albicans* ATCC 10231
Testing method:	EVS-EN 13624:2013 Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.
Testing date:	19.03.2018 – 21.03.2018
Results:	look appendix 1-2

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Diana Kaare, MSc

Head of laboratory, microbiologist

Date of test report: 22.03.2018

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TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2013; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 19.03.2018 – 21.03.2018
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	54	$\bar{x}$ = 57	V_{C1}	47	$\bar{x}$ = 45	V_{C1}	46	$\bar{x}$ = 42.5	V_{C1}	52	$\bar{x}$ = 53
V_{C2}	60		V_{C2}	43		V_{C2}	39		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}? yesX; no□		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.87 \times 10^7$; log$N$ = 7.27
N and N_0	10^{-5}	194	181	$N_0 = N/10$; logN_0 = 6.27
	10^{-6}	20	16	6.17≤ logN_0≤6.70; yesX; no □

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
0.1 %	-	>165	>165	>1650	>3.22	<3.05	10 min	dirty
2.0 %	-	<14	<14	<140	<2.15	>4.12	10 min	dirty
5.0 %	-	<14	<14	<140	<2.15	>4.12	10 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)

Interpretation:

The 2% solution of product for instrument disinfection **Alkadent** (batch no. 13010318) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C ± 1 °C, under dirty conditions with the contact time of 10 min. The membrane filtration method was used for testing the products effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty conditions the tested product was effective against the reference strain within 10 min of contact time.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **under dirty conditions the 2 % solution of product Alkadent has a yeasticidal effect in case of instrument disinfection within 10 min.**

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Diana Kaare, MSc

Head of laboratory, microbiologist