Nordic Tersus
Laboratory

Test report No. id1619

EVALUATION OF BACTERICIDAL ACTIVITY FOR INSTRUMENTS USED IN MEDICAL AREA (EN 14561)

Name of the product:	STERISEPT WIPES
Batch number:	14300818W
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, 60 min
Interfering substance:	0.3 g/l bovine albumin = clean conditions
Rinsing liquid:	-
Neutralizer:	Polysorbate 80 30g/l; saponin 30 g/l, lecithin 3 g/l
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 *Staphylococcus aureus* ATCC 6538
Testing method:	EVS-EN 14561:2006 Quantitative carrier test for the evaluation of bactericidal activity for instruments used in medical area.
Testing date:	08.10.2018 – 11.10.2018
Results:	look appendix 1-4

Digitally signed by Moraru Grigore
Date: 2025.12.17 16:00:37 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Allar Laaneleht
Chief specialist
Date of test report: 15.01.2019

Nordic Tersus Laboratory OÜ
Harjumaa, Tallinn, Serva tn 44a, 11618
Registrikood: 12561442
Tel: +372 503 0197
E-mail: info@ntl.ee

TEST RESULTS (bactericidal carrier test)

EVS-EN 14561; Phase 2, step 2;
Dilution – neutralization method;
Rinsing liquid: -;
Test organism: *Pseudomonas aeruginosa* ATCC 15442;
Test temperature: +20° C; Incubation temperature: +37° C
Interfering substance: 0.3 g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 08.10.2018
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{vo})			Experimental Conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}=77	V_{C2}=72	$\bar{x}$ = 74.5	V_{C1}=63	V_{C2}=55	$\bar{x}$ = 59	V_{C1}=60	V_{C2}=51	$\bar{x}$ = 55.5	V_{C1}=49	V_{C2}=64	$\bar{x}$ = 56.5
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? yes ☒; no ☐			$\bar{x}$ A is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ B is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ C is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐		

Test suspension

Test suspension (N):	N	V_{C1}	V_{C2}	$\bar{x}$ wm = 2.82 x 10^9; lg N = 9.45
	10^{-7}	296	271	9,17 ≤ lg N ≤ 9,7 yes ☒ ; no ☐
	10^{-8}	28	25	

Water control

Water control (N_W):	N_w	V_{C1}	V_{C2}	$\bar{x}$ x 10 = 2.60 x 10^7
	10^{-5}	24	28	7,15 ≤ lg N_W = 7.24 ≤ (lg N -1,3)? yes ☒; no ☐

Test

Conc. of the pro-duct %	Dilution step	V_{C1}	V_{C2}	Lg *Na* = Lg ($\bar{x}$ *or* $\bar{x}_{wm}$) + 1	Lg *R* (lg N_W = 7.24)	Contact time
Ready to use	10^0	<14	<14	<2,15	>5.26	60 s
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
Ready to use	10^0	<14	<14	<2,15	>5.26	60 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			

Explanations

V_c = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2}
R = reduction (lg R = lg N_W – lg N_a)
If N_a <140, lg R = > [lg N_W – 2,15]

TEST RESULTS (bactericidal carrier test)

EVS-EN 14561; Phase 2, step 2;
Dilution – neutralization method;
Rinsing liquid: -;
Test organism: *Enterococcus hirae* ATCC 10541;
Test temperature: +20° C; Incubation temperature: +37° C
Interfering substance: 0.3 g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 09.10.2018
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{vo})			Experimental Conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}=66	V_{C2}=54	$\bar{x}$ = 60	V_{C1}=49	V_{C2}=43	$\bar{x}$ = 46	V_{C1}=44	V_{C2}=39	$\bar{x}$ = 41.5	V_{C1}=52	V_{C2}=47	$\bar{x}$ = 49.5
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? yes ☒; no ☐			$\bar{x}$ A is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ B is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ C is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐		

Test suspension

Test suspension (N):	N	V_{C1}	V_{C2}	$\bar{x}$ wm = 2.20 x 10^9; lg N = 9.34 9,17 ≤ lg N ≤ 9,7 yes ☒ ; no ☐
	10^{-7}	224	218	
	10^{-8}	22	19	

Water control

Water control (N_W):	N_w	V_{C1}	V_{C2}	$\bar{x}$ x 10 = 1.85 x 10^7 7,15 ≤ lg N_W = 7.29 ≤ (lg N -1,3)? yes ☒; no ☐
	10^{-5}	21	18	

Test

Conc. of the product %	Dilution step	V_{C1}	V_{C2}	Lg *Na* = Lg ($\bar{x}$ *or* $\bar{x}_{wm}$) + *1*	Lg *R* (lg N_W = 7.29)	Contact time
Ready to use	10^0	<14	<14	<2,15	>5.14	60 s
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
Ready to use	10^0	<14	<14	<2,15	>5.14	60 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			

Explanations

V_c = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2}
R = reduction (lg R = lg N_W – lg N_a)
If N_a <140, lg R = > [lg N_W – 2,15]

TEST RESULTS (bactericidal carrier test)

EVS-EN 14561; Phase 2, step 2;
Dilution – neutralization method;
Rinsing liquid: -;
Test organism: *Staphylococcus aureus* ATCC 6538;
Test temperature: +20° C; Incubation temperature: +37° C
Interfering substance: 0.3 g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test:10.10.2018.
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{vo})			Experimental Conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}=81	V_{C2}=60	$\bar{x}$ = 70.5	V_{C1}=58	V_{C2}=53	$\bar{x}$ = 55.5	V_{C1}=44	V_{C2}=47	$\bar{x}$ = 45.5	V_{C1}=62	V_{C2}=62	$\bar{x}$ =62
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? yes ☒; no ☐			$\bar{x}$ A is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ B is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐			$\bar{x}$ C is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒; no ☐		

Test suspension

Test suspension (N):	N	V_{C1}	V_{C2}	
	10^{-7}	233	207	$\bar{x}$ wm = 2.21 x 10^9; lg N = 9.35 9,17 ≤ lg N ≤ 9,7 yes ☒ ; no ☐
	10^{-8}	25	22	

Water control

Water control (N_W):	N_w	V_{C1}	V_{C2}	$\bar{x}$ x 10 = 1.75 x 10^7 7,15 ≤ lg N_W = 7.24 ≤ (lg N -1,3)? yes ☒; no ☐
	10^{-5}	16	19	

Test

Conc. of the pro-duct %	Dilution step	V_{C1}	V_{C2}	Lg *Na* = Lg ($\bar{x}$ *or* $\bar{x}_{wm}$) + 1	Lg *R* (lg N_W = 7.24)	Contact time
Ready to use	10^0	<14	<14	<2,15	>5.09	60 s
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
Ready to use	10^0	<14	<14	<2,15	>5.09	60 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			

Explanations

V_c = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2}
R = reduction (lg R = lg N_w – lg N_a)
If N_a <140, lg R = > [lg N_W – 2,15]

Interpretation

The ready-to-use product **STERISEPT WIPES** (batch no. 14300818W) was tested according to the test method EVS-EN 14561:2006. The test was performed at 20 ± 1 °C, under clean conditions with the contact times of 60 s and 60 min. The dilution – neutralization method was used for testing the products' effectiveness against the reference strains: *Pseudomonas aeruginosa* ATCC 15442; *Enterococcus hirae* ATCC 10541 and *Staphylococcus aureus* ATCC 6538. Under clean conditions the product was effective against all the reference strains within 60 s and 60 min.

Conclusion

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

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

.....

Allar Laaneleht

Chief specialist

15.01.2019