Nordic Tersus
Laboratory

Test report No. sd1418

EVALUATION OF MYCOBACTERICIDAL ACTIVITY (EN 14348)

Name of the product:	Bacticid AF
Batch number:	197101017
Order number:	17028
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, Estonia, Maris Millner, +372-51-77-090
Date of delivery:	15.12.2017
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark;
Active substance – conc.:	Ethyl alcohol 57.0% wt, isopropyl alcohol 6.0% wt
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Test conditions:	Dirty and clean conditions
Contact time:	30 sec, 60 min(obligatory)
Interfering substance:	3,0 g/l bovine albumin + 3,0 ml SBE = dirty conditions; 0,3 g/l bovine albumin = clean conditions
Test neutralizer:	-
Rinsing liquid:	Distilled water
Test organisms:	*Mycobacterium terrae* ATCC 15755; *Mycobacterium avium* ATCC 15769
Testing method base:	EVS-EN 14348:2005 – Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)
Testing date:	29.01.2018 – 19.02.2018
Results:	look appendix 1-3

Diana Kaare, MSc
Head of laboratory, microbiologist
Date of test report: 26.02.2018

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

EN ISO/IEC 17025
L263

Appendix 1

TEST RESULTS (mycobactericidal suspension test)

EVS-EN 14348:2005; Phase 2, step 1;
Membrane filtration method; Spread plate;
Rinsing liquid: distilled water;
Test organism: *Mycobacterium terrae* ATCC 15755;
Test temperature: +20° C; Incubation temperature: +37° C
Solvents: diluent, water;
Interfering substance: 3,0 g/l bovine albumin + 3,0 ml SBE = dirty conditions; 0,3 g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 29.01.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	80	$\bar{x}$ = 76	V_{C1}	49	$\bar{x}$ = 49,5	V_{C1}	62	$\bar{x}$ = 53,5	V_{C1}	74	$\bar{x}$ = 72,5
V_{C2}	72		V_{C2}	50		V_{C2}	45		V_{C2}	71	
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}	$\bar{x}_{wm}$ = 2,56 x 10^9; log$N$ = 9,41
	10^{-7}	262	249	$N_0 = N/10$; logN_0 = 8,41
N and N_0	10^{-8}	30	23	8,17≤ logN_0≤8,7; yes X; no □

Experimental results

Concentration of the product.%	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
RTU	10^0	<14	<14	<140	<2,15	>6,26	30 sec	dirty
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,26	60 min	dirty
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,26	30 sec	clean
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,26	60 min	clean
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					

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 2

TEST RESULTS (mycobactericidal suspension test)

EVS-EN 14348:2005; Phase 2, step 1;
Membrane filtration method; Spread plate;
Rinsing liquid: distilled water;
Test organism: *Mycobacterium avium* ATCC 15769;
Test temperature: +20° C; Incubation temperature: +37° C
Solvents: diluent, water;
Interfering substance: 3,0 g/l bovine albumin + 3,0 ml SBE = dirty conditions; 0,3 g/l bovine albumin = clean conditions
Nordic Tersus Laboratory LLC.;
Date of test: 29.01.2018 – 19.02.2018
Responsible person: Diana Kaare

Validation and controls

Dirty and clean conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	94	$\bar{x}$ = 93	V_{C1}	80	$\bar{x}$ = 74,5	V_{C1}	65	$\bar{x}$ = 62	V_{C1}	93	$\bar{x}$ = 94,5
V_{C2}	92		V_{C2}	69		V_{C2}	59		V_{C2}	96	
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

Test suspension: *N and* N_0	*N*	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2,86 \times 10^9$; log*N* = 9,46 $N_0 = N/10$; logN_0 = 8,46 8,17≤ logN_0≤8,7; yes X; no □
	10^{-7}	283	291	
	10^{-8}	31	25	

Experimental results

Concent-ration of the product.%	Dilu-tion step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Condi-tions
RTU	10^0	<14	<14	<140	<2,15	>6,31	30 sec	dirty
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,31	60 min	dirty
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,31	30 sec	clean
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					
RTU	10^0	<14	<14	<140	<2,15	>6,31	60 min	clean
	10^{-1}	<14	<14					
	10^{-2}	<14	<14					
	10^{-3}	<14	<14					

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 3

Interpretation

Using the EN 14348 standard, there was tested ready to use product – **Bacticid AF**- (No. 197101017), at 20 °C ± 1 °C, with the contact time 30 sec and 60 min under dirty and clean conditions. The membrane filtration method was used for testing products' effectiveness against the reference strains: *Mycobacterium terrae* ATCC 15755, *Mycobacterium avium* ATCC 15769. Under dirty and clean conditions the tested product was active against all the testorganisms at contact times tested.

Conclusion

By the test results can be concluded that as treated by the product the surviving microorganisms count was decreasing at least four grades that under clean and dirty conditions the ready to use product **Bacticid AF** is mycobactericidal in case of surface disinfection, during conctact time of 30 sec.

.....

Diana Kaare

Head of laboratory, microbiologist