

Test report No. shd1318

EVALUATION OF MYCOBACTERICIDAL ACTIVITY (EN 14348)

Name of the product:	Chemisept GEL
Batch number:	198251017
Order number:	17030
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, Estonia, Maris Millner, +372-51-77-090
Date of delivery:	15.01.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark;
Active substance – conc.:	Ethyl alcohol 72.5% wt, isopropyl alcohol 7.5% wt
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Test conditions:	Clean conditions
Contact time:	30 sec, 60 min(obligatory)
Interfering substance:	0,3 g/l bovine albumin = clean conditions
Test neutralizer:	-
Rinsing liquid:	Distilled water
Test organisms:	<i>Mycobacterium terrae</i> ATCC 15755; <i>Mycobacterium avium</i> 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



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Date of test report: 26.02.2018

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: 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

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 $\bar{x} N_{vo}$? yes X; 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}	$\bar{x}_{wm} = 2,56 \times 10^9$; $\log N = 9,41$ $N_0 = N/10$; $\log N_0 = 8,41$ $8,17 \leq \log N_0 \leq 8,7$; yes X; no ☐
	10^{-7}	262	249	
	10^{-8}	30	23	

Experimental results

Concentration of the product. %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	log N_a	log R	Contact time	Conditions
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)

$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in test suspension

N_0 = cfu/ml at the start of the contact time ($t=0$)

N_{v0} = cfu/ml in the validation suspension ($t=0$)

N_a = surviving microbes after the test

R = reduction factor ($R = N_0 / N_a$; $\text{Log} R = \text{Log} N_0 - \text{Log} N_a$)

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: 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

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}	$\bar{x}_{wm} = 2,86 \times 10^9$; $\log N = 9,46$ $N_0 = N/10$; $\log N_0 = 8,46$ $8,17 \leq \log N_0 \leq 8,7$; 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 (= $\bar{x}$ *10)	log Na	logR	Contact time	Condi- tions
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)
- $\bar{x}$ = 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 ($R = N_0 / Na$; $\text{Log}R = \text{Log}N_0 - \text{Log}Na$)

Appendix 3

Interpretation

Using the EN 14348 standard, there was tested ready to use product – Chemisept GEL (Batch No. 198251017) at $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, with the contact time 30 sec under 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 clean conditions the tested product was active against all the testorganisms at contact time 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 conditions the ready to use product Chemisept GEL is mycobactericidal in case of surgical hand disinfection, during contact time of 30 sec.



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