

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: *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



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Diana Kaare, MSc  
Head of laboratory, microbiologist  
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	
$30 \leq \bar{x} N_{vo} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>		

Test suspension and test

Testsuspension:  $N$ 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 <input type="checkbox"/>
	$10^{-7}$	262	249	
	$10^{-8}$	30	23	

Experimental results

Concentration of the product. %	Dilution step	$V_{C1}$	$V_{C2}$	Na (= $\bar{x}$ *10)	log Na	logR	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 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 ( $R = N_0 / Na$ ;  $\text{LogR} = \text{Log}N_0 - \text{Log}Na$ )

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: 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	
$30 \leq \bar{x} N_{vo} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0,5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>		

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 <input type="checkbox"/>
	$10^{-7}$	283	291	
	$10^{-8}$	31	25	

Experimental results

Concentration of the product. %	Dilution step	$V_{C1}$	$V_{C2}$	Na (= $\bar{x}$ *10)	log Na	logR	Contact time	Conditions
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 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)
- $Na$  = surviving microbes after the test
- R = reduction factor ( $R = N_0 / Na$ ;  $\text{LogR} = \text{Log}N_0 - \text{Log}Na$ )

Appendix 3

Interpretation

Using the EN 14348 standard, there was tested ready to use product – Chemisept GEL (Batch No. 198251017) at 20 °C ± 1 °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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Diana Kaare

Head of laboratory, microbiologist