

Test report no. L 06/001 for Chemisept G according to EN 14348:2005

Page 1 of 3

Test report no. L 06/001

Efficacy testing of the surgical skin disinfectant *CHEMISEPT G* according to EN 14348: 2005

In accordance with your request, we tested the preparation *CHEMISEPT G*, referred to in the following as the test preparation, for its efficacy against *Mycobacterium terrae* under low organic load according to EN 14348: 2005.

1. General information and material

a) Client

- Client: Chemi-Pharm AS, Mr Andres Paling, Pollu 132
EST - 10917 Tallinn
- Date of request: 25.11.2005

b) Identification of the testing laboratory

- Dr. Brill + Partner GmbH - Labor für Hygiene und Mikrobiologie, Papenreye 61, 22453 Hamburg; Dr. Holger Brill, Florian Brill, Carmela Jänicke

c) Identification of the sample

- Name of product: *CHEMISEPT G*
- Batch number: 25.11.2005
- Manufacturer: Chemi-Pharm AS, Tallinn, Estonia
- Date of supply: 28.11.2005
- Lagerbedingungen: Raumtemperatur und Dunkelheit

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- Appearance of concentrate: crystal clear solution
 - Odour: aromatic, alcoholic
 - Recommended diluent: potable drinking water
 - Diluent used: water of standardised hardness (WSH)
 - pH-value, 100 %: 9.15
 - Active agents in 100 g test preparation: 75.0 g ethanol
0.1 g blend of N-alkylbenzyltrimethyl ammonium chloride
and N-alkyltrimethyl ammonium chloride

d) Test conditions

- Period of testing: 23.02. to 16.03.2006
- Product test concentrations: 100 volume-%
- Test temperature: $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Exposure times: 0.5; 3 and 5 minutes
- Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$
- Organic load: low (0.03 % bovine albumin)
- Neutraliser mycobacteria: 30 g/L polysorbate 80, 30 g/L saponine, 1 g/L histidine, 5 g/L sodium thiosulphate (TSH-NT) in phosphate buffer
- Test germs: Mycobacterium terrae ATCC 15755

Test report no. L 06/001 for Chemisept G according to EN 14348:2005

Page 3 of 3

2. Results: Determination of the mycobactericidal effect within the quantitative suspension test according to EN 14348: 2005

The results are summarised in table no. 1.1 and 1.2. The sufficiently effective concentration-time relationship (\geq RF 4) for the test organism *Mycobacterium terrae* was at low organic load:

100 % in 30 seconds

Hamburg, 12 April 2006



Dr. Holger Brill

DR. BRILL + PARTNER GMBH

LABOR FÜR HYGIENE UND MIKROBIOLOGIE

Test report no. L 06/001 Table 1.1: Validation (EN 14348: 2005)

Test preparation: Chemisept G
Organic load: low (0.03 % albumin)

Test germ: Mycobacterium terrae
Inactivation: TSH-NT in phosphate buffer

Validation and controls

NV0: Suspension validation		A: Control of test conditions at an exposure time of (in minutes)				B: Control of neutralisation		C: Validation of procedure at 100 %	
		0,5		3		5			
VC1	103	VC1	98	VC1	110	VC1	114	VC1	102
	50		50		61		58		60
	53		48		49		56		42
	Median		Median		Median		Median		Median
VC2	115	VC2	107	VC2	105	VC2	97	VC2	102
	55		56		52		45		58
	60		51		53		52		44

Evaluation validation and controls

30 ≤ median of NV0 ≤ 160 ?	Median of A (0.5') is ≥ 0.5 x median of NV0 ?	Median of A (3') is ≥ 0.5 x median of NV0 ?	Median of A (5') is ≥ 0.5 x median of NV0 ?	Median of B is ≥ 0.5 x median of NV0 ?	Median of C is ≥ 0.5 x median of NV0 ?
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Legend: VC = number of viable cells per ml
Median = average of VC1 and VC2 (1st and 2nd repeated determination)
R = germ reduction (lg R = N0 - lg Na)
weighted average

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Test report no. L 06/001 Table 1.2: Test results (EN 14348: 2005)

Test preparation: Chemisept G
Organic load: low (0.03 % albumin)

Test germ: Mycobacterium terrae
Inactivation: TSH-NT in phosphate buffer

Test suspension and test results

N and N0	Median 1	Factor	Ig
1E-07	258		
	131		
	127		
	243		
	128	1,57E+09	9,20
	115		
1E-08	58		
	22		
	36		
	68		
	35		
	33		
	63	N0 = N/10 =	8,20

Exposure time in minutes	0,5	3	5
Use concentration in %	100	100	100
VC1	12	1	0
VC2	15	2	0
Na = Median x 10	270	30	0
Ig Na	2,43	1,48	0,00
Ig R (N0)	5,76	6,72	8,20

Evaluation of the test suspension:

8.17 ≤ N0 ≤ 8.70: ☒ Yes ☐ No

Legend:

VC = number of viable cells per ml

Median = average of VC1 and VC2 (1st and 2nd repeated determination)

R = Median 1

germ reduction (Ig R = N0 - Ig Na)
weighted average