

Laboratorium Prof. Dr. med. R. Schubert

Grillparzerstraße 72
60320 Frankfurt
Tel.: 069/56 91 92
Fax: 0 69/56 19 70
E-mail: SchubertHygiene@aol.com
E-mail: Auxiliarius@t-online.de

TEST REPORT
EN 14348 Mycobactericidal Activity
Phase 2 Step 1

Identification of the disinfectant-sample:

Name of the product:	Oprezan (Medical Instrument Disinfection)
Batch number:	OP 20002
Manufacturer:	BAB Gencel Pharma
Storage conditions:	room temperature and darkness
Product diluent recommended by the manufacturer for use:	Potable water
Period of testing	Date of delivery of the product: 2010/10/4
Dates of test:	
Results:	

Conclusion:

According to EN 14348, the batch OP 20002 of product **Oprezan**, when diluted at 1 % (w/v) in hard water, possesses tuberculocidal activity in ten minutes at 20°C under clean conditions (0,3 g/l bovine albumin) for referenced strain *Mycobacterium terrae*.
The mean reduction of six replicates with the test organism *Mycobacterium terrae* was $1,0 \times 10^6$.


Scientific Director

Date: 2011/5/22

**Test results (mycobactericidal suspension test)
(phase 2 step 1)**

Product-name: *Oprezan* (Medical Instrument Disinfection)

Batch No: OP 20002

Manufacturer: *BAB&Gencel Pharma*

Formulation Remarks: appearance of the product: *white powder*

Storage conditions (temp. and other): room temperature, darkness

Dilution neutralization method

Spread plate Number of plates 2/ml

Neutralizer: 30 g/l polysorbate 80, 10 g/l Cystein, 30 g Sodiumthiosulfate

Test temperature: 20°C

Interfering substances: 0,3 g/l bovine albumin

Test organism: *Mycobacterium terrae* ATCC 15755

Incubation temp.: 36°C

International lab. no.: 2010/20 Date of test: 2011/4/18; 2011/4/25

Responsible person: *R. Schubert*

Signature: 

Diluent used for product test solutions: *hard water* Appearance of the product test solutions:
slight turbid

Validations and controls

Validation suspension (N _{vo})			Experimental Conditions control (A)			Neutralizer or filtration control (B)			Method validation (C) Product conc.: 10 ml/l		
V _{c1}	96 (40+46)	$\bar{x} = 89$	V _{c1}	80 (39+41)	$\bar{x} = 71$	V _{c1}	80 (36+44)	$\bar{x} = 70$	V _{c1}	87 (42-45)	$\bar{x} = 84,5$
V _{c2}	82 (40+42)		V _{c2}	62 (32+30=)		V _{c2}	60 (28+32)		V _{c2}	82 (39+43)	
45 ≤ \bar{x} of N _{vo} ≤ 180 ? yes			\bar{x} of A is ≥ 0,5 × \bar{x} of N _{vo} ? yes			\bar{x} of B is ≥ 0,5 × \bar{x} of N _{vo} ? yes			\bar{x} of C is ≥ 0,5 × \bar{x} of N _{vo} ? yes		

Test suspension and Test

	N	V _{c1}	V _{c2}	
Test-suspension (N und N _o)	10 ⁻⁷	212	224	$\bar{x}_{wm} = 215,46 \times 10^7, \lg = 9,33$ $N_o = N/10 = \lg 8,33$ $8,17 \leq N_o \leq 8,70 ? \times \text{yes}$
	10 ⁻⁶	18	20	

Test

Conc. of the product %	Dilution step	Counts per plate		V _{c1}	V _{c2}	Lg N _o = ... lg (\bar{X} or \bar{X}_{wm}) + 1	lg R (lg N _w = 8,33)	Contact time (min.)
0,5 %	10 ⁰	> 330+> 330	> 330+ > 330	> 660	> 660	> 6,82	< 1,51	10
	10 ¹	> 330+> 330	> 330+ > 330	> 660	> 660			
	10 ²	> 330+> 330	> 330+ > 330	> 660	> 660			
	10 ³	> 330+> 330	> 330+ > 330	> 660	> 660			
1 %	10 ⁰	243+231	193+186	474	379	3,64	4,69	10
	10 ¹	28+30	22+27	58	49			
	10 ²	1+0	0+0	< 14	< 14			
	10 ³	0+0	0+0	< 14	< 14			
5 %	10 ⁰	0+0	0+0	< 14	< 14	< 2,15	> 6,18	10
	10 ¹	0+0	0+0	< 14	< 14			
	10 ²	0+0	0+0	< 14	< 14			
	10 ³	0+0	0+0	< 14	< 14			

Test suspension and Test

Test-suspension (N und N ₀)	N	V _{c1}	V _{c2}	$\bar{x}_{wm} = 287,5 \times 10^7, \lg = 9,46$ $N_0 = N/10 = \lg 8,46$ $8,17 \leq N_0 \leq 8,70 ? \times \text{yes}$
	10 ⁻⁷	273	302	
	10 ⁻⁸	< 14	< 14	

Test

	Conc. of the product %	Dilution step	Counts per plate		V _{c1}	V _{c2}	Lg N ₀ = ... lg (\bar{X} or \bar{X}_{wm}) + 1	lg R (lg N _w = 8,46)	Contact time (min.)
1	1 %	10 ⁰	19+23	30+27	42	57	< 2,69	5,77	10
		10 ¹	0+0	0+0	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			
2	1 %	10 ⁰	0+0	0+0	< 14	< 14	< 2,15	> 6,31	10
		10 ¹	0+0	0+0	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			
3	1 %	10 ⁰	28+24	22+26	52	48	2,70	5,76	10
		10 ¹	0+3	2+2	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			
4	1 %	10 ⁰	40+35	31+37	75	68	2,85	5,61	10
		10 ¹	4+4	2+3	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			
5	1 %	10 ⁰	0+0	0+0	< 14	< 14	< 2,15	> 6,31	10
		10 ¹	0+0	0+0	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			
6	1 %	10 ⁰	0+0	0+0	< 14	< 14	< 2,15	> 6,31	10
		10 ¹	0+0	0+0	< 14	< 14			
		10 ²	0+0	0+0	< 14	< 14			
		10 ³	0+0	0+0	< 14	< 14			