

TEST REPORT
EN 13727:2003 (E) Bactericidal 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 13727, the batch OP 20002 of product Oprezan, when diluted at 1 % (w/v) in hard water, possesses bactericidal activity in ten minutes at 20°C under clean conditions (0,3 g/l bovine albumin) for referenced strains *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterococcus hirae*. The mean reduction of six replicates with the limiting test organism *Enterococcus hirae* was $1,9 \times 10^6$. All other test organisms were tested once and showed a higher reduction than *Enterococcus hirae*.


Scientific Director

Date: 2011/2/7

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Test results (bactericidal suspension test)

Product-name: *Oprezan*

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: *S. aureus ATCC 6530*

Incubation temp.: 36°C

International lab. no.: 2010/20 Date of test: 2010-11-19

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}	110 (55+55)	$\bar{x} = 112$	V_{c1}	84 (40+44)	$\bar{x} = 88$	V_{c1}	87 (43+44)	$\bar{x} = 92,5$	V_{c1}	84 (41+43)	$\bar{x} = 82,5$
V_{c2}	114 (58+56)		V_{c2}	92 (47+45)		V_{c2}	98 (50+48)		V_{c2}	81 (39+42)	
$45 \leq \bar{x} \text{ of } N_{vo} \leq 180 ?$ yes			$\bar{x} \text{ of A is } \geq 0,5 \times \bar{x} \text{ of } N_{vo} ?$ yes			$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{vo} ?$ yes			$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{vo} ?$ yes		

Test suspension and Test

Test-suspension (N und N_o)	N	V_{c1}	V_{c2}	$\bar{x}_{wm} = 223,18 \times 10^6, \lg = 8,35$ $N_o = N/10 = \lg 7,35$ $7,17 \leq N_o \leq 7,70 ? \times \text{yes}$
	10^{-6}	226	219	
	10^{-7}	24	22	

Conc. of the product %	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	$\lg N_a$	$\lg R$ $N_o = 7,35$	Contact time (in min.)
0,5 %	> 330	> 330	> 3300	> 3,52	< 3,83	10
1 %	9	12	< 140	< 2,15	> 5,20	
2 %	0	0	< 140	< 2,15	> 5,20	

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Test results (bactericidal suspension test)

Product-name: *Oprezan*

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: *P. aeruginosa ATCC 15442*

Incubation temp.: 36°C

International lab. no.: 2010/20 Date of test: 2010-11-22

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}	138 (70+68)	$\bar{x} = 136$	V_{c1}	121 (59+62)	$\bar{x} = 123$	V_{c1}	117 (60+57)	$\bar{x} = 115,5$	V_{c1}	116 (57+59)	$\bar{x} = 117$
V_{c2}	134 (69-65)		V_{c2}	125 (64+61)		V_{c2}	114 (58+56)		V_{c2}	118 (60+58)	
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

Test-suspension (N und N_o)	N	V_{c1}	V_{c2}	$\bar{x}_{wm} = 270,91 \times 10^6$, lg = 8,43 $N_o = N/10 = \lg 7,43$ $7,17 \leq N_o \leq 7,70$? x yes
	10^{-6}	262	279	
	10^{-7}	28	27	

Conc. of the product %	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	lg N_a	lg R $N_o = 7,43$	Contact time (in min.)
0,5 %	273	296	2845	3,45	3,98	10
1 %	0	0	< 140	< 2,15	> 5,28	
2 %	0	0	< 140	< 2,15	> 5,28	

Test results (bactericidal suspension test)Product-name: *Oprezan*

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

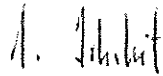
Test organism: *E. hirae ATCC 10541*

Incubation temp.: 36°C

International lab. no.: 2010/20 Date of test: 2010-11-23/2011-11-24

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}	94 (44+50)	x = 101,5	V _{c1}	78 (36+42)	x = 76	V _{c1}	71 (39+32)	x̄ = 70,5	V _{c1}	64 (30+34)	x̄ = 67
V _{c2}	109 (58+51)		V _{c2}	74 (40+34)		V _{c2}	70 (35+35)		V _{c2}	70 (36+34)	
45 ≤ x̄ of N _{vo} ≤ 180 ? yes			x̄ of A is ≥ 0,5 x x̄ of N _{vo} ? yes			x̄ of B is ≥ 0,5 x x̄ of N _{vo} ? yes			x̄ of C is ≥ 0,5 x x̄ of N _{vo} ? yes		

Test suspension and Test

	N	V _{c1}	V _{c2}	
Test-suspension (N und N ₀)	10 ⁻⁶	290	296	x̄ _{wm} = 295,0 x 10 ⁶ , lg = 8,47 N ₀ = N/10 = lg 7,47 7,25 ≤ N ₀ ≤ 7,70 ? x yes
	10 ⁻⁷	33	30	

Conc. of the product %	V _{c1}	V _{c2}	N _a = x̄ x 10	lg N _a	lg R No = 7,47	Contact time (in min.)
0,5 %	> 330	> 330	> 3300	> 3,52	< 3,95	10
1,0 %	24	22	230	2,36	5,11	
2,0 %	0	0	< 140	< 2,15	> 5,32	

Repetition

	Conc. of the product %	V _{c1}	V _{c2}	N _a = x̄ x 10	lg N _a	lg R	Contact time (in min.)
1	1,0 %	8	12	< 140	< 2,15	> 5,32	10
2	1,0 %	0	0	< 140	< 2,15	> 5,32	
3	1,0 %	16	20	180	2,25	5,22	
4	1,0 %	18	21	195	2,29	5,18	
5	1,0 %	0	0	< 140	< 2,15	> 5,32	
6	1,0 %	0	0	< 140	< 2,15	> 5,32	