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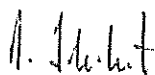
TEST REPORT
EN 13624:2003 (E) Fungicidal Activity
Phase 2 Step 1

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:	2010/11/3 - 2010/11/12
Results:	On the following page

Conclusion:

According to EN 13624, the batch OP 20002 of product Oprezan, when diluted at 1 % (w/v) in hard water, possesses fungicidal activity in ten minutes at 20°C under clean conditions (0,3 g/l bovine albumin) for referenced strain *Candida albicans*. The mean reduction of six replicates with the test organism *Candida albicans* was 1.2×10^4 .



Scientific Director

Date: 2011/2/7

Test results (fungicidal suspension test)

Product-name: *Opresan*

Batch No: OP 20002

Manufacturer: *BAB&Gencei 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

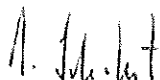
Test organism: *C. albicans ATCC 10231*

Incubation temp.: 30°C

International lab. no.: 2010/20 Date of test: 2010-11-12

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_{v0})			Experimental Conditions control (A)			Neutralizer or filtration control (B)			Method validation (C) Product conc.: 10 ml/l		
V_{c1}	104	$\bar{x} = 108,5$	V_{c1}	98	$\bar{x} = 96,5$	V_{c1}	90	$\bar{x} = 89$	V_{c1}	92	$\bar{x} = 91$
V_{c2}	113		V_{c2}	95		V_{c2}	88		V_{c2}	90	
$45 \leq \bar{x} \text{ of } N_{v0} \leq 180 ?$			$\bar{x} \text{ von A is } \geq 0,5 \times \bar{x} \text{ of } N_{v0} ?$			$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0} ?$			$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0} ?$		
yes			yes			yes			yes		

Test suspension and Test

Test-suspension (N und N_0)	N	V_{c1}	V_{c2}	$\bar{x}_{wm} = 160,5 \times 10^5, \lg = 7,21$ $N_0 = N/10 = \lg 6,21$ $6,21 \leq N_0 \leq 6,70 ? \times \text{yes} \square \text{no}$
	10^{-5}	164	157	
	10^{-6}	11	12	

Conc. of the product %	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	$\lg N_a$	$\lg R$	Contact time (in min.)
0,5 %	> 165	> 165	> 165	> 3,22	2,99	10
1,0	0	0	< 1,40	< 2,15	> 4,06	
2,0	8	0	< 1,40	< 2,15	> 4,06	

Repetition

	Conc. of the product %	V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	$\lg N_a$	$\lg R$	Contact time (in min.)
1	1,0 %	0	0	< 1,40	< 2,15	> 4,06	10
2	1,0 %	6	1	< 1,40	< 2,15	> 4,06	
3	1,0 %	0	0	< 1,40	< 2,15	> 4,06	
4	1,0 %	0	0	< 1,40	< 2,15	> 4,06	
5	1,0 %	0	0	< 1,40	< 2,15	> 4,06	
6	1 %	0	0	< 1,40	< 2,15	> 4,06	