

Test report No. id0518

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY FOR INSTRUMENTS  
USED IN MEDICAL AREA (EN 14562)

Name of the product: Bactacid AF  
Batch number: 197101017  
Order number: 17029  
Manufacturer: Chemi-Pharm Ltd.  
Client, representative: Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA  
Maris Millner, +372-51-77-090  
Date of delivery: 15.12.2017  
Test material conditions: No specific features, sample in the manufacturers tare  
Storage conditions: In room temperature, dark  
Active substance – conc.: Ethyl alcohol 57.0% wt, isopropyl alcohol 6.0% wt  
Appearance of the product: Transparent liquid  
Test concentration: Ready to use  
Contact time: 30 sec, 60 min (obligatory contact time)  
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes= dirty conditions  
Rinsing liquid: -  
Neutralizer: Polysorbate 80 30g/l; saponin 30 g/l, lecithin 3 g/l  
Test organisms: *Candida albicans* ATCC 10231  
Testing method: EVS-EN 14562:2006  
Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in medical area (phase 2, step 2)  
Testing date: 31.01.2018 – 01.02.2018  
Results: look appendix 1-2



Diana Kaare, MSc

Head of laboratory, microbiologist

Date of test report: 05.02.2018

Appendix 1

TEST RESULTS (yeastocidal carrier test)

EVS-EN 14562; Phase 2, step 2;  
Dilution – neutralization method;  
Rinsing liquid: -;  
Test organism: *Candida albicans* ATCC 1023;  
Test temperature: +20° C; Incubation temperature: +30° C  
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes= dirty conditions;  
Nordic Tersus Laboratory LLC.;  
Date of test: 31.01.2018 – 01.02.2018;  
Responsible person: Diana Kaare

Validation and controls

Validation suspension ( $N_{vo}$ )				Experimental Conditions control (A)				Neutralizer control (B)				Method validation (C)			
Counts per plate		$V_{c1}$	$V_{c2}$	Counts per plate		$V_{c1}$	$V_{c2}$	Counts per plate		$V_{c1}$	$V_{c2}$	Counts per plate		$V_{c1}$	$V_{c2}$
29+22	26+23	51	49	18+20	20+15	38	35	19+24	28+31	43	59	18+15	21+17	33	38
$\bar{x} = 50$				$\bar{x} = 36.5$				$\bar{x} = 51$				$\bar{x} = 35.5$			
$30 \leq \bar{x} \text{ of } N_{vo} \leq 160?$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>				$\bar{x} \text{ A is } \geq 0,5 \bar{x} \text{ of } N_{vo}?$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>				$\bar{x} \text{ B is } \geq 0,5 \bar{x} \text{ of } N_{vo}?$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>				$\bar{x} \text{ C is } \geq 0,5 \bar{x} \text{ of } N_{vo}?$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>			

Test suspension

Test suspension ( $N$ ):	$N$	$V_{c1}$	$V_{c2}$	$\bar{x} \text{ wm} = 1.59 \times 10^8; \lg N = 8.20$ $8.17 \leq \lg N \leq 8.7$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
	$10^{-6}$	155	162	
	$10^{-7}$	16	16	

Water control

Water control ( $N_w$ ):	$N_w$	Counts per plate		$V_{c1}$	$V_{c2}$	$\bar{x} \times 10 = 1.55 \times 10^6$ $6.15 \leq \lg N_w = 6.19 \leq (\lg N - 1.3)?$ yes <input checked="" type="checkbox"/> ; no <input type="checkbox"/>
	$10^{-4}$	7+9	9+6	16	15	
	$10^{-5}$	0+1	0+0	<14	<14	

Test

Conc. of the product %	Dilution step	Counts per plate		$V_{C1}$	$V_{C2}$	$Lg N_a = Lg (\bar{x} \text{ or } \bar{x}_{wm}) + 1$	$Lg R (lg N_w = 6.19)$	Contact time
Ready to use	$10^0$	6+9	8+5	15	14	2.16	4.03	30 sec
	$10^{-1}$	0+1	0+1	<14	<14			
	$10^{-2}$	0+0	0+0	<14	<14			
	$10^{-3}$	0+0	0+0	<14	<14			
Ready to use	$10^0$	0+0	0+0	<14	<14	<2.15	>4.04	60 min
	$10^{-1}$	0+0	0+0	<14	<14			
	$10^{-2}$	0+0	0+0	<14	<14			
	$10^{-3}$	0+0	0+0	<14	<14			

Explanations

$V_c$  = count per ml (one plate or more)  
 $\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$

$R$  = reduction ( $lg R = lg N_w - lg N_a$ )  
If  $N_a < 140$ ,  $lg R = > [lg N_w - 2,15]$

Appendix 2

Interpretation

The product for instrument disinfection Bactacid AF (batch no. 197101017) was tested according to the test method EVS-EN 14562:2006. The test was performed at  $20 \pm 1$  °C, under dirty conditions with the contact time of 30 sec. The dilution – neutralization method was used for testing the products' effectiveness against the reference strain *Candida albicans* ATCC 10231. Under dirty conditions the product was effective against the reference strain within 30 sec of contact time.

Conclusion

The surviving count of the reference strain showed at least 4 lg reduction meaning that under dirty conditions the ready to use product Bactacid AF has a yeasticidal effect in case of instrument disinfection within 30 sec.



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Diana Kaare, MSc  
Head of laboratory, microbiologist