

# Test report No. shd0218

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA (EN 13624)

Name of the product:

Chemisept MED

Batch number:

196101017

Order number:

17028

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 72.5% wt, isopropyl alcohol 7.5% wt

Appearance of the product:

Transparent liquid

Test concentration:

Ready to use

Contact time:

15 sec

Interfering substance:

15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes =

Dirty conditions; 3.0 g/l sheep blood erythrocytes = clean conditions

Rinsing liquid:

Tryptone 1 g/l + NaCl 9 g/l

Neutralizer:

Test organisms:

Candida albicans ATCC 10231

Testing method:

EVS-EN 13624:2013

Quantitative suspension test for the evaluation of fungicidal or

yeasticidal activity in the medical area.

Testing date:

23.01.2018 - 25.01.2018

Results:

look appendix 1-2

Diana Kaare, MSc Head of laboratory, microbiologist

Date of test report: 26.01.2018





Appendix 1

# TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2013; Phase 2, step 1;

Membrane filtration method;

Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l; Test organism: Candida albicans ATCC 10231;

Test temperature: +20° C; Incubation temperature: +30° C

Interfering substance: 15 g/l bovine albumin + 15 ml/l sheep blood erythrocytes = Dirty conditions;

3.0g/l sheep blood erythrocytes = clean conditions;

Nordic Tersus Laboratory LLC.; Date of test: 23.01.2018 – 25.01.2018.

Responsible person: Diana Kaare

#### Validation and controls

#### Dirty and clean conditions

Validation suspension $N_{vo}$			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V <sub>C1</sub>	45	x = 43.5	V <sub>C1</sub>	38	x = 35	V <sub>C1</sub>	41	x̄ = 37	V <sub>C1</sub>	39	x = 41.5
$V_{C2}$	42		V <sub>C2</sub>	32		V <sub>C2</sub>	33		V <sub>C2</sub>	44	
30 ≤ x̄ <i>N<sub>vo</sub></i> ≤160?yes X; no □			$\bar{x} \text{ A is } \ge 0.5 \bar{x} N_{vo}?\text{yes X; no } \square$			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ $N_{vo}$ ?yesX; no□			$\bar{x}$ C is $\geq 0.5 \bar{x}$ $N_{vo}$ ? yesX; no		

### Test suspension and test

Testsuspension:	N	V <sub>C1</sub>	V <sub>C2</sub>	$\bar{x}_{wm} = 1.71 \times 10^8$ ; $\log N = 8.23$
	10 <sup>-6</sup>	172	164	$N_0 = N/100$ ; $\log N_0 = 6.23$
N and N₀	10 <sup>-7</sup>	19	22	6.17≤ log <b>N</b> ₀≤6.70; yesX; no □

### Experimental results

Concentration of the product	Dilution step	V <sub>C1</sub>	V <sub>C2</sub>	Na (=x̄*10)	log Na	logR	Contact time	Conditions
Ready to use	-	<14	<14	<140	<2.15	>4.08	15 s	dirty
Ready to use	-	<14	<14	<140	<2.15	>4.08	15 s	clean

#### **Explanations:**

 $V_C$  = count per ml (one plate or more)

 $\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$  (1. + 2. duplicate)

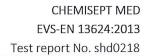
N = cfu/ml microbes in testsuspension

 $N_0$  = cfu/ml at the start of the contact time (t=0)

 $N_{vo}$  = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R=  $N_0/Na$ ; LogR=Log $N_0$  - Log Na)





Appendix 2

## Interpretation:

The ready to use product for surgical hand disinfection CHEMISEPT MED (batch no. 196101017) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C  $\pm$  1 °C, under dirty and clean conditions with the contact time of 15 s. The membrane filtration method was used for testing the products effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty and clean conditions the tested product was effective against the reference strain within 15 s of contact time.

#### Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that under dirty and clean conditions the ready to use product CHEMISEPT MED has a yeasticidal effect in case of surgical hand disinfection within 15 s.

Diana Kaare, MSc

Head of laboratory, microbiologist