

Test report No. shd0318

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

Name of the product:

Chemisept GEL

Batch number:

198251017

Order number:

17030

Manufacturer:

Chemi-Pharm Ltd.

Client, representative:

Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA

Maris Millner, +372-51-77-090

Date of delivery:

15.01.2018

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; 1.5 g/l bovine albumin = 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

Head of laboratory, microbiologist

Date of test report: 26.01.2018

TON Diana Kaare, MSc





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;

1.5g/l bovine albumin = 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 _{C1} | 45 | x = 43.5 | V _{C1} | 38 | x = 35 | V _{C1} | 41 | x = 37 | V _{C1} | 39 | x = 41.5 |
| V _{C2} | 42 | | V _{C2} | 32 | | V_{C2} | 33 | | V _{C2} | 44 | |
| 30 ≤ x̄ N _{vo} ≤160?yes X; no □ | | | $\bar{x} \land is \ge 0.5 \bar{x} N_{vo}?yes X; no \square$ | | | \bar{x} B is $\geq 0.5 \bar{x}$ N_{vo} ?yesX; no | | | \bar{x} C is $\geq 0.5 \bar{x}$ N_{vo} ? yesX; no | | |

Test suspension and test

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

Experimental results

| Concentration | Dilution | V _{C1} | V _{C2} | Na | log Na | logR | Contact | Conditions |
|----------------|----------|-----------------|-----------------|----------|--------|-------|---------|------------|
| of the product | step | | | (=x̄*10) | | | time | |
| 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)

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

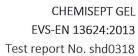
= cfu/ml microbes in testsuspension

 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

= 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 GEL (batch no. 198251017) 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 produts 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 strains showed at least 4 lg reduction meaning that under dirty and clean conditions the ready to use product CHEMISEPT GEL has a yeasticidal effect in case of surgical hand disinfection within 15 sec.

PRATOR SUS ISS

Diana Kaare, MSc

Head of laboratory, microbiologist