Nordic Tersus
Laboratory

# Test report No. sd1419

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

| | |
|---|---|
| Name of the product: | STERISEPT INSTRU |
| Batch number: | 211310518 |
| Order number: | 18014 |
| Manufacturer: | Chemi-Pharm Ltd. |
| Client, representative: | Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA<br>Maris Millner, +372-51-77-090 |
| Date of delivery: | 04.10.2018 |
| Test material conditions: | No specific features, sample in the manufacturers tare |
| Storage conditions: | In room temperature, dark |
| Active substance – conc.: | N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 15%; Didecyl-Dimethyl-Ammonium Chloride (DDAC) 15% |
| Appearance of the product: | Transparent liquid |
| Test concentration: | 0.25% for 15 min and 0.50 % for 5 min and 15 min |
| Contact time: | 5 min, 15 min |
| Interfering substance: | 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes – dirty conditions |
| Rinsing liquid: | Tryptone 1 g/l + NaCl 9 g/l |
| Neutralizer: | - |
| Test organisms: | *Candida albicans* ATCC 10231 |
| Testing method: | EVS-EN 13624:2013<br>Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. |
| Testing date: | 28.10.2018 – 30.10.2018 |
| Results: | look appendix 1-2 |

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Allar Laaneleht
Chief specialist
Date of test report: 15.01.2019

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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: 3.0 g/l bovine albumin + 3.0 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 28.10.2018
Responsible person: Allar Laaneleht

## Validation and controls

### Dirty conditions

| Validation suspension $N_{vo}$ | | | Experimental conditions control (A) | | | Filtration control (B) | | | Method validation (C) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| $V_{C1}$ | 48 | $\bar{x}$ = 46 | $V_{C1}$ | 41 | $\bar{x}$ = 39 | $V_{C1}$ | 33 | $\bar{x}$ = 35 | $V_{C1}$ | 42 | $\bar{x}$ = 42 |
| $V_{C2}$ | 44 | | $V_{C2}$ | 37 | | $V_{C2}$ | 37 | | $V_{C2}$ | 42 | |
| 30 ≤ $\bar{x}$ $N_{vo}$ ≤160?yes X; no □ | | | $\bar{x}$ A is ≥ 0.5 $\bar{x}$ $N_{vo}$?yes X; no □ | | | $\bar{x}$ B is ≥ 0.5 $\bar{x}$ $N_{vo}$?yesX; no□ | | | $\bar{x}$ C is ≥ 0.5 $\bar{x}$ $N_{vo}$? yesX; no□ | | |

### Test suspension and test

| Testsuspension: | $N$ | $V_{C1}$ | $V_{C2}$ | $\bar{x}_{wm} = 2.06 \times 10^7$; log$N$ = 7.22 |
|---|---|---|---|---|
| $N$ and $N_0$ | $10^{-6}$ | 166 | 171 | $N_0 = N/100$; log$N_0$ = 6.22 |
| | $10^{-7}$ | 15 | 16 | 6.17≤ log$N_0$≤6.70; yesX; no □ |

### Experimental results

| Concentration of the product | Dilution step | $V_{C1}$ | $V_{C2}$ | Na (=$\bar{x}$*10) | log Na | logR | Contact time | Conditions |
|---|---|---|---|---|---|---|---|---|
| 0.05% | - | >165 | >165 | >1650 | >3.22 | <3.00 | 5 min | dirty |
| 0.05% | - | >165 | >165 | >1650 | >3.22 | <3.00 | 15 min | dirty |
| 0.25% | - | <14 | <14 | <140 | <2.15 | >4.07 | 15 min | dirty |
| 0.50% | - | <14 | <14 | <140 | <2.15 | >4.07 | 5 min | dirty |
| 0.50% | - | <14 | <14 | <140 | <2.15 | >4.07 | 15 min | dirty |
| 2.50% | - | <14 | <14 | <140 | <2.15 | >4.07 | 15 min | dirty |

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 product for STERISEPT INSTRU (batch no. 211310518) was tested according to the test method EVS-EN 13624:2013. The test was performed at 20 °C ± 1 °C, under dirty conditions during contact times of 5 min and 15 min, with the concentrations of 0.25% and 0.50%. The membrane filtration method was used for testing the produts effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty conditions the tested product was effective against the reference strain within 15 min for 0.25% and 0.50% concentrations and 5 min for 0.50% concentration.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **the 0.50% solution of the product STERISEPT INSTRU has a yeasticidal effect under dirty conditions within 5 min and 0.25% within 15 min.**

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15.01.2019