Nordic Tersus
Laboratory

Test report No. 055023id

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

Name of the product: STERISEPT WIPES

Batch number: 14151022
Date of test report: 04.03.2023

Digitally signed by Moraru Grigore
Date: 2025.12.17 16:00:41 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Client, representative:
Chemi-Pharm Ltd.
Tänassilma tee 11
Tänassilma küla
Saku vald 76406
ESTONIA

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Test report No. 055023id

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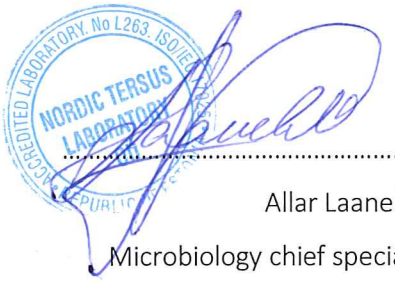
Name of the product:	**STERISEPT WIPES**
Batch number:	14151022
Order number:	20135
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Tänassilma tee 11, Tänassilma küla, Saku vald, 76406, ESTONIA, Siimu Rom
Date of delivery:	16.03.2023
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	At room temperature, dark
Active substance – conc.:	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0.45%; Didecyl-Dimethyl-Ammonium Chloride (DDAC)0.45%
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	3 min
Interfering substance:	3g/l bovine albumin + 3ml/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 period:	27.03.2023-30.03.2023
Results:	look appendix 1-2



Allar Laaneleht

Microbiology chief specialist

Date of test report: 04.03.2023

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Appendix 1

TEST RESULTS (yeasticidal carrier test)

EVS-EN 14562; Phase 2, step 2
Dilution – neutralization method
Rinsing liquid: -
Test organism: *Candida albicans* ATCC 102;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3g/l bovine albumin + 3ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 27.03.2023
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{vo})		Experimental Conditions control (A)		Neutralizer control (B)		Method validation (C)	
V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
82	79	96	75	82	87	80	99
$\bar{x}$ = *60.5*		$\bar{x}$ = *85.5*		$\bar{x}$ = 84.5		$\bar{x}$ = *89.5*	
30 ≤ $\bar{x}$ of N_{vo} ≤ 160? yes ☒ ; no ☐		$\bar{x}$ A is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒ ; no ☐		$\bar{x}$ B is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒ ; no ☐		$\bar{x}$ C is ≥ 0,5 $\bar{x}$ of N_{vo}? yes ☒ ; no ☐	

Test suspension

Test suspension (N):	N	V_{C1}	V_{C2}	$\bar{x}$ wm = 3.31 x 10^8; lg N = 8.68 8.17 ≤ lg N ≤ 8.7 yes ☒ ; no ☐
	10^{-6}	>330	>330	
	10^{-7}	23	34	

Water control

Water control (N_W):	N_w	V_{C1}	V_{C2}	$\bar{x}$ x 10 = 1.6 x 10^6 6.15 ≤ lg N_W = 6.38 ≤ (lg N -1.3)? yes ☒ ; no ☐
	10^{-4}	21	17	
	10^{-5}	2	2	

Test

Conc. of the product %	Dilution step	V_{C1}	V_{C2}	**Lg *Na*** = Lg ($\bar{x}$ *or* $\bar{x}_{wm}$) + 1	**Lg *R*** (lg N_W = 6.18)	Contact time
100%	10^0	14	16	2.20	4.28	3 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50%	10^0	>330	>330	4.96	1.42	3 min
	10^{-1}	>330	>330			
	10^{-2}	85	99			
	10^{-3}	>14	>14			
25%	10^0	>330	>330	5.76	0.62	3 min
	10^{-1}	>330	>330			
	10^{-2}	>330	>330			
	10^{-3}	66	50			

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 **STERISEPT WIPES** (batch no. 14151022) was tested according to the test method EVS-EN 14562:2006. The test was performed at 20 ± 1 °C, under dirty conditions with the contact time of 3 min. 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 3 min.

Conclusion

The surviving count of the reference strain showed at least 4 lg reduction meaning that according to the standard EVS-EN 14562:2006, **under dirty conditions the ready to use product STERISEPT WIPES has a yeasticidal effect within 3 min.**

ACCREDITED LABORATORY No L263. ISO/IEC 17025
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REPUBLIC OF ESTONIA

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Microbiology chief specialist

04.03.2023