Nordic Tersus
Laboratory

Test report No. sd5919

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

Name of the product:	CHLORINEX-60
Batch number:	587641
Order number:	19006
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	20.02.2019
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	1 tab = 1.5 g active chlorine if dissolved in water, thus 1 tab/1.5 l 1000 ppm active chlorine
Appearance of the product:	White tablets
Test concentration:	1 tab / 1.5 l
Contact time:	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:	*Aspergillus brasiliensis* ATCC 16404
Testing method:	**EVS-EN 13624:2013** **Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.**
Testing date:	25.02.2019 – 28.02.2019
Results:	look appendix 1-2

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Allar Laaneleht
Chief specialist
Date of test report:28.02.2019

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Appendix 1

TEST RESULTS (fungicidal 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: *Aspergillus brasiliensis* ATCC 16404;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3.0 g/l bovine albumin + 3.0 g/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 25.02.2019
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}	47	x̄ = 51.5	V_{C1}	32	x̄ = 35	V_{C1}	43	x̄ = 41.5	V_{C1}	59	x̄ = 52
V_{C2}	56		V_{C2}	38		V_{C2}	40		V_{C2}	45	
30 ≤ x̄ N_{vo} ≤160?yes X; no □			x̄ A is ≥ 0.5 x̄ N_{vo}?yes X; no □			x̄ B is ≥ 0.5 x̄ N_{vo}?yesX; no□			x̄ C is ≥ 0.5 x̄ N_{vo}? yesX; no□		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ =1.76 x 10^7 log$N$ = 7.25
	10^{-5}	178	166	$N_0 = N/10$; logN_0 = 6.25
N and N_0	10^{-6}	24	19	6.17≤ logN_0≤6.70; yesX; no □

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
1 tab / 10 l	-	>165	>165	>1650	>3.22	<3.03	15 min	Dirty
1 tab / 1.5 l	-	17	15	160	2.20	4.05	15 min	Dirty
3 tab / 1.5 l	-	<14	<14	<140	<2.15	>4.10	15 min	Dirty

Explanations:
V_C = count per ml (one plate or more)
x̄ = 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=LogN_0 - Log Na)

Appendix 2

Interpretation:

The product **CHLORINEX-60** (batch no. 587641) 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 time of 15 min. The membrane filtration method was used for testing the produt's effectiveness against the reference strain: *Aspergillus brasiliensis* ATCC 16404. Under dirty conditions the tested product was effective against the reference strain within contact time tested.

Conclusion:

The surviving count of the reference strain showed at least 4 lg reduction meaning that **1 tab / 1.5 l solution of the product CHLORINEX-60 has a fungicidal effect under dirty conditions within 15 min.**

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28.02.2019