

Test report No. hd6019

EVALUATION OF BASIC FUNGICIDAL OR BASIC YEASTICIDAL ACTIVITY (EN 1275)

Name of the product: CHEMISEPT MED
Batch number: 196291118
Order number: 19008
Manufacturer: Chemi-Pharm Ltd..
Client, representative: Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA
Maris Millner, +372-51-77-090
Date of delivery: 10.02.2019
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
Product diluent: -
Contact time: 30 s, 60 s, 15 min (obligatory contact time)
Neutralizer: -
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l
Test organisms: *Candida albicans* ATCC 10231
Aspergillus brasiliensis ATCC 16404
Testing method: EVS-EN 1275:2006
Chemical disinfectants and antiseptics – Quantitative suspension test
for the evaluation of basic fungicidal or basic yeasticidal activity of
chemical disinfectants and antiseptics – Test method and
requirements (phase 1)
Testing date: 25.02.2019 – 28.02.2019
Results: look appendix 1-3



Allar Laaneleht
Chief specialist
Date of test report: 28.02.2019

Appendix 1

TEST RESULTS (yeasticidal suspension test)

EVS-EN 1275:2006; Phase 1, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30 °C
Nordic Tersus Laboratory LLC.;
Date of test: 25.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	63	$\bar{x} = 56.5$	V_{C1}	49	$\bar{x} = 50.5$	V_{C1}	37	$\bar{x} = 41$	V_{C1}	61	$\bar{x} = 57$
V_{C2}	50		V_{C2}	52		V_{C2}	45		V_{C2}	53	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no ☐			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yesX; no ☐			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.74 \times 10^9$; $\log N = 7.24$ $N_0 = N/10$; $\log N_0 = 6.24$ $6.17 \leq \log N_0 \leq 7.70$; yes X; no ☐
	10^{-5}	180	163	
	10^{-6}	19	21	

Experimental results

Concentration of the product %	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	lgNa	lgR	Contact time
Ready to use	<14	<14	<140	<2.15	>4.09	30 s
Ready to use	<14	<14	<140	<2.15	>4.09	60 s
Ready to use	<14	<14	<140	<2.15	>4.09	15 min

Explanations:

V_C = count per ml (one plate or more)
 $\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
 $\bar{x}_{wm}$ = weighter mean of $\bar{x}$
R = reduction factor ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

Appendix 2

TEST RESULTS (fungicidal suspension test)

EVS-EN 1275:2006; Phase 1, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l;
Test organism: *Aspergillus brasiliensis* ATCC 16404;
Test temperature: +20° C; Incubation temperature: +30 °C
Nordic Tersus Laboratory LLC.;
Date of test: 25.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	47	$\bar{x} = 51.5$	V_{C1}	32	$\bar{x} = 33.5$	V_{C1}	43	$\bar{x} = 41.5$	V_{C1}	45	$\bar{x} = 47.5$
V_{C2}	56		V_{C2}	35		V_{C2}	40		V_{C2}	50	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no ☐			$\bar{x} A \geq 0.5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} B \geq 0.5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} C \geq 0.5 \bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.76 \times 10^7$; $\log N = 7.25$ $N_0 = N/10$; $\log N_0 = 6.25$ $6.17 \leq \log N_0 \leq 7.70$; yes X; no ☐
	10^{-5}	178	166	
	10^{-6}	24	19	

Experimental results

Concentration of the product %	V_{C1}	V_{C2}	Na ($=\bar{x} \times 10$)	lgNa	lgR	Contact time
Ready to use	<14	<14	<140	<2.15	>4.10	30 s
Ready to use	<14	<14	<140	<2.15	>4.10	60 s
Ready to use	<14	<14	<140	<2.15	>4.10	15 min

Explanations:

V_C = count per ml (one plate or more)
 $\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
 $\bar{x}_{wm}$ = weighter mean of $\bar{x}$
R = reduction factor ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

Appendix 3

Interpretation:

The product CHEMISEPT MED (batch no. 196291118) was tested according to the test method EVS-EN 1275:2006. The test was performed at $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, within the contact times of 30s, 60s and obligatory 15min. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404. The tested product was effective against both reference strains within the contact times tested.

Conclusion:

The surviving count of reference strains showed at least 4lg reduction meaning that the ready to use product CHEMISEPT MED has a basic yeasticidal and fungicidal effect within 30 s.



Allar Laaneleht
Chief Specialist
28.02.2019