

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
yeastocidal activity in the medical area.
Testing date: 23.01.2018 – 25.01.2018
Results: look appendix 1-2



Diana Kaare, MSc
Head of laboratory, microbiologist

Date of test report: 26.01.2018

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	$\bar{x} = 43.5$	V_{C1}	38	$\bar{x} = 35$	V_{C1}	41	$\bar{x} = 37$	V_{C1}	39	$\bar{x} = 41.5$
V_{C2}	42		V_{C2}	32		V_{C2}	33		V_{C2}	44	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/>		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.71 \times 10^8$; $\log N = 8.23$ $N_0 = N/100$; $\log N_0 = 6.23$ $6.17 \leq \log N_0 \leq 6.70$; yes X; no <input type="checkbox"/>
N and N_0	10^{-6}	172	164	
	10^{-7}	19	22	

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	Contact time	Conditions
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)
- \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)
- N_a = surviving microbes after the test
- R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

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 $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, under dirty and clean conditions with the contact time of 15 s. The membrane filtration method was used for testing the products 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.



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