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Mikrobioloogia Kesklabor • Central Laboratory of Microbiology

Akrediteeritud L013

MIKROBIOLOOGILINE UURING NR. 4590

Uuritav materjal: CHEMIPHARM DES NEW

Täiendavad andmed: valmistatud 06.01.2006

Suunav asutus, isik: AS Chemi-Pharm, laborijuhataja M. Millner, 6 778 806

Proovi võtmise koht: AS Chemi-Pharm Põllu 132 Tallinn 10917

Proovi võtmise kuupäev, kellaaeg: 06.01.2006

Uuringu eesmärk: Desinfitseerivate omaduste määramine EN 1040:1997 järgi

Laborisse saabumise aeg: 06.01.2006 kell 09.30

Proovi seisund laborisse saabumisel: Ilma iseärasusteta tootja pakend

Säilitamise tingimused: toatemperatuuril pimedas

Toimaine: kvaternaarsed ammooniumiühendid

Neutraliseerija: polüsorbaat 80 30 g/l, saponiin 30 g/l, L-histidiin 1 g/l, L-tsüsteiin 1 g/l lahustatuna trüptoon-soola lahuses

Katsetamise aeg: 06.02.- 10.02.2006

Uurimise tulemused: Vt lisa 1 ja 2

Kokkuvõte: Toode CHEMIPHARM DES NEW toimis bakteritsiidselt 0,5% lahusena 10 min ja 15 min jooksul ja 1 % lahusena 10 min, 15 min ja 30 min jooksul *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 8043 ja *Pseudomonas aeruginosa* ATCC 15442 suhtes (reduktsioonifaktor oli suurem kui 10^5).

10.02.2006

Mikrobioloog [redacted]

* – EAK poolt akrediteerimata

Terviseamet
Kesklabor

Health Board
Central Laboratory

Registreerimisnumber L013

Labor on volitatud Põllumajandusministri käskkirjaga nr.203 29.06.2000 toidutoorme ja toidu järelvalveks võetud proovide analüüsimiseks

TEST REPORT NR. 815

Product name: CHEMIPHARM DES NEW

Manufacturer: AS Chemi - Pharm

Date of delivery: 02.01.2012

Storage conditions: room temperature, in the dark

Appearance of the product: colourless, clear liquid

Active substances: quaternary ammonium compounds

Delution neutralization method: EN 1275:1997*

Dates of testing: 04.01.2012 – 06.01.2012

Product concentration: 1%

Test temperature: 20 ± 1 ^{0}C

Contact time: 5 min, 10 min, 15 min

Neutralizer: 60 g/l TWEEN 80, 30 g/l Saponin, 1 g/l Cysteine, 1 g/l Histidine, 3g/l Lecithin

Test results: See annex 1 (attached). All controls and validation were within the basic limits.

Conclusion: According to EN 1275:1997* product CHEMIPHARM DES NEW (1%), possesses yeasticidal activity in 5 min, 10 min, 15 min at 20 ± 1 ^{0}C for referenced strain *Candida albicans* ATCC 10231.

Tallinn, 09.01.2012 Microbiologist J.Viktorov

Test results are valid for sample examined. Official report is to be copied in its entirety only.
*** - The method is not accredited.**

Kotka 2, Tallinn 11315
www.terviseamet.ee

Tel. 6 943 600 fax 6 943 601
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EN 1275:1997
Annex 1

The results (yeasticidal suspension test)
Product name: CHEMIPHARM DES NEW (nr. 815)

Test organism	Validation and controls			Test suspension and Test				
	Validation suspension N_V; $N_{VO}=N_V/10$	Neutralizer control B	Method validation C	Test suspension N; $N_O=N/10$		Concentration of the product: **1% / 0,1%** contact time: 5 min test result	10 min test result	15 min test result
Candida albicans **ATCC 10231**	V_C: 115; 103 N_V: $1,1*10^3$ N_{VO}: $1,1*10^2$ $0,5N_{VO}$: 55	V_C: 154; 110 **B**: 132	$V_{C\,1\%}$: 0; 0 $V_{C\,0,1\%}$: 67; 71 **C**: 69	10^{-5}: 323; 280 10^{-6}: 40; 38 **N**: $3,1*10^7$ N_O: $3,1*10^6$	V_C N_a **R**	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$

Explanations:
V_C – viable count per ml;
N – number of cells per ml in the test suspension ($1,5*10^7$-$5,0*10^7$ cfu/ml);
N_V – number of cells per ml in the validation suspension ($6,0*10^2$ – $1,5*10^3$ cfu/ml);
N_O – number of viable cells per ml in the test mixture in the beginning of the test
N_a – number of survivors per ml in the test mixture in the end of the test;
R – reduction in viability.

Remarks:
$60 \leq N_{VO} \leq 150$
B, $C \geq 0,5\ N_{VO}$
$R = N_O/N_a$, should be > 10^4

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TEST REPORT No 3379 r **Koopia**

Name of the product: Chemipharm DES new

Manufactured: Chemi-Pharm Ltd.,

Sampled by: Chemi-Pharm Ltd., R. Oltjer, 21.08.2000

Place of sampling: Chemi-Pharm Ltd., Põllu132, Tallinn11618

Active substance(s) and its/their concentration(s): not indicated

Aim of the examination: detection of disinfecting properties

Date and hour of receipt: 21.08.2000.at 12.00

Storage condition: room temperature and darkness

Nature and characteristics of the sample: no deviation the packaging and the labelling

Period of analysis: 21.08.-26.08.2000

Test method: in-house method dilution-neutralization of Central Laboratory of Microbiology* Dilutions of tested products were prepared with steriled drinking water from waterworks. Used neutralizer consists polysorbate 80 – 30 g/l, lecithin 3 g/l and L-histidine – 1 g/l.

Conditions of the examination: 20±1°C for application and 37°C for incubation

Test results:

Concent-ration	Contact time	*Escheri-chia coli* ATCC 10538	*Staphylo-coccus aureus* ATCC 6538	*Streptococcus faecalis* ATCC 29212	*Pseudomo-nas aeruginosa* ATCC 15442	*Bacillus cereus* ATCC 11778	*Candida Albicans* ATCC 10231
1%	5 min	0	0	0	0	0	0
0.3%	10 min	0	0	0	0	0	0
Growth of tested strains		+	+	+	+	+	+

\+ the growth of the organisms exists

0 the growth of the organisms is absent

The test results applies for the tested sample only

* – EAK poolt akrediteerimata

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Conclusion: According to the in-house dilution-neutralization method of Central Laboratory of Microbiology, the tested product „Chemipharm DES new " had the bactericidal effects in 1% dilutions during contact time 5 min and 0,3% dilutions during contact time 10 min to all referenced strains *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Streptococcus faecalis* ATCC 29212, *Pseudomonas aeruginosa* ATCC27853 and *Candida albicans* ATCC 10231

Microbiologist Birk*

* – EAK poolt akrediteerimata

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Akrediteeritud L013

TEST REPORT No 3380 **Koopia**

Name of the product: Chemipharm Des New

Manufactured: Chemi-Pharm Ltd.,

Sampled by: Chemi-Pharm Ltd., M. Millner

Place of sampling: Chemi-Pharm Ltd., Põllu 132, Tallinn10917

Active substance(s) and its/their concentration(s): not indicated

Aim of the examination: detection of disinfecting properties

Date and hour of receipt: 21.08.2000

Storage condition: room temperature and darkness

Nature and characteristics of the sample: no deviation the packaging and the labelling

Period of analysis: 25.11.2002.-30.11.2002

Aim of the examination: detection of disinfecting properties

Test method: in-house method dilution-neutralization of Central Laboratory of Microbiology* Dilutions of tested products were prepared with steriled drinking water from waterworks. Used neutralizer consists polysorbate 80 – 30 g/l, lecithin 3 g/l and L-histidine – 1 g/l.

Conditions of the examination: 20±1°C for application and 37±1°C for incubation

Test results:

Concent-ration	Contact time	*Escheri-chia coli* ATCC 10538	*Staphylo-coccus aureus* ATCC 6538	*Streptcoc-cus faecalis* ATCC 29212	*Pseudomo-nas aeruginosa* ATCC 15442	*Bacillus cereus* ATCC 11778	*Candida albicans* ATCC 10231
0.3%	10 min	0	0	0	0	0	0
Growth of tested strains		+	+	+	+	+	+

\+ the growth of the organisms exists

0 the growth of the organisms is absent

The test results applies for the tested sample only

* – EAK poolt akrediteerimata

EESTI VABARIIK NAKKUSHAIG LABOR TERVISEAI

Kotka 2 11315 Tallinn Tel. 372 6 943 670; Fax 372 6943 651

Akrediteeritud L013

Conclusion: According to the in-house dilution-neutralization method of Central Laboratory of Microbiology, the tested product „Chemipharm Des New“ had the bactericidal effects in 0,3% dilutions during contact time 10 min to all referenced strains *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Streptococcus faecalis* ATCC 29212, *Pseudomonas aeruginosa* ATCC27853 and *Candida albicans* ATCC 10231

Microbiologist K. Birk

EESTI VABARIIK AKUSHAIGUSTE TERVISEAMET

* – EAK poolt akrediteerimata

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Akrediteeritud L013

TEST REPORT No 3377 **Koopia**

Name of the product: Chemi-Pharm DES NEW

Manufactured: Chemi-Pharm Ltd., Tallinn

Sampled by: Chemi-Pharm Ltd., R. Oltjer

Place of sampling: Chemi-Pharm Ltd., Serva 44a, Tallinn11618

Active substance(s) and its/their concentration(s): not indicated

Aim of the examination: detection of disinfecting properties

Date and hour of receipt: 28.08.2000

Storage condition: room temperature and darkness

Nature and characteristics of the sample: no deviation the packaging and the labelling

Period of analysis: 28.08.-01.09.2000

Condition of the examination: 20±1°C for application and 37° for incubation

Test method: in-house method dilution-neutralization of Central Laboratory of Microbiology* Dilutions of tested products were prepared with steriled drinking water from waterworks. Used neutralizer consists polysorbate 80 – 30 g/l, lecithin 3 g/l and L-histidine – 1 g/l.

Test results:

Concent-ration	Contact time	*Escheri-chia coli* ATCC 10538	*Staphylo-coccus aureus* ATCC 6538	*Streptococcus faecalis* ATCC 29212	*Pseudomonas aeruginosa* ATCC 15442	*Bacillus cereus* ATCC 11778	*Candida albicans* ATCC 10231
0.5%	5 min	0	0	0	0	0	0
Growth of tested strains		+	+	+	+	+	+

\+ the growth of the organisms exists

0 the growth of the organisms is absent

The test results applies for the tested sample only

* – EAK poolt akrediteerimata

EESTI VABARIIK NAKKUSHAIGLABOR TERVISEAMET

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Mikrobioloogia Kesklabor • Central Laboratory of Microbiology

Akrediteeritud L013

Conclusion: According to the in-house dilution-neutralization method of Central Laboratory of Microbiology, the tested product „ Chemi-Pharm DES NEW " had the bactericidal effects in 0,5% dilutions during contact time 5 min to all referenced strains *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Streptococcus faecalis* ATCC 29212, *Pseudomonas aeruginosa* ATCC27853 and *Candida albicans* ATCC 10231

Microbiologist K. Birk

EESTI VABARIIK JEAMET

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DANAK

Reg. No. 444

Akrediteeritud L013

TEST REPORT No 3377 **Copy**

Name of the product: Chemipharm Des New

Manufacturer: Chemi-Pharm Ltd Põllu str 132 Tallinn 10917 Estonia

Date of delivery: 28.08.2000

Storage conditions: room temperature and darkness

Active substance(s) and its /their concentration(s) (optional) not indicated

Test method: dilution-neutralization *

Neutralizer: Tween

Experimental conditions:

Period of analysis	28.08.2000 to 01.09.2000
Product Test concentration	0,5%
Test temperature	$20^0C \pm 1^0C$
Contact times	5 min
Temperature of incubation	$37^0C \pm 1^0C$

Test results:

Test organism	Viable count for test mixture: Contact time: 5 min
Escherichia coli ATCC 2592	0 cfu/ml
Staphylococcus aureus ATCC 25923	0 cfu/ml
Streptococcus faecalis ATCC 29212	0 cfu/ml
Pseudomonas aeruginosa ATCC 27853	0 cfu/ml
Bacillus cereus ATCC 11778	0 cfu/ml
Candida albicans ATCC 10231	0 cfu/ml

Tallinn, 04.12.2003

Microbiologist K. Birk

* – not acreditated by DANAK and EAK

Lai 15, 10133 Tallinn Tel. 372 6 943 670; Fax. 372 6943 651

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DANAK

Reg. No. 444

Akrediteeritud L013

TEST REPORT No 3380 **Copy**

Name of the product: Chemipharm Des New

Manufacturer: Chemi-Pharm Ltd Põllu str 132 Tallinn 10917 Estonia

Date of delivery: 21.08.2000

Storage conditions: room temperature and darkness

Active substance(s) and its /their concentration(s) (optional) not indicated

Test method: dilution-neutralization *

Neutralizer: Tween

Experimental conditions:

Period of analysis	21.08.2000 to 26.08.2000
Product Test concentration	0,3%
Test temperature	$20^0C \pm 1^0C$
Contact times	10 min
Temperature of incubation	$37^0C \pm 1^0C$

Test results:

Test organism	Viable count for test mixture: Contact time: 10 min
Escherichia coli ATCC 2592	0 cfu/ml
Staphylococcus aureus ATCC 25923	0 cfu/ml
Streptococcus faecalis ATCC 29212	0 cfu/ml
Pseudomonas aeruginosa ATCC 27853	0 cfu/ml
Bacillus cereus ATCC 11778	0 cfu/ml
Candida albicans ATCC 10231	0 cfu/ml

Tallinn, 09.12.2003

Microbiologist K. Birk

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MIKROBIOLOOGILINE UURING NR. 3379-3380

Uuritav materjal: toode CHEMIPHARM DES NEW

Täiendavad andmed:

Suunav asutus, isik: AS Chemi-Pharm

Proovi võtmise koht: AS Chemi-Pharm, Serva 44a Tallinn 11618

Proovi võtmise kuupäev, kellaaeg: 20.08.2000

Uuringu eesmärk: desinfitseerivate omaduste määramine

Laborisse saabumise aeg: 21.08.2000 kell 12.00

Proovi seisund laborisse saabumisel: ilma iseärasusteta

Mikrobioloogilise uuringu algus:

Uuringu tulemused: Katsetatud 40±1^{0}C juures

		KASUTATUD TESTKULTUURID					
Lahuse kontsentratsioon	Toimeaeg	*Escherichia coli* ATCC 25922	*Staphylococcus aureus* ATCC 25923	*Streptococcus faecalis* ATCC 29212	*Pseudomonas aeruginosa* ATCC 27853	*Bacillus cereus* ATCC 11778	*Candida Albicans* ATCC 10231
1 %	5 min	-	-	-	-	-	-
0,3 %	10 min	-	-	-	-	-	-

Tähistused: + Testkultuur kasvab, lahusel puudub bakteritsiidne toime
- Testkultuuri kasv puudub, lahus toimib bakteritsiidselt.

Uuringu tulemused kehtivad antud proovi kohta.

Katseprotokolli paljundamine on lubatud ainult tervikuna.

26.08.2000

Arst-mikrobioloog .....K. Birk

Lai 15, Tallinn 10133 Tel. 372 6 448 784; fax 372 6 411 639

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MIKROBIOLOOGILINE UURING NR. 3377

Uuritav materjal: Chemi-Pharm DES NEW

Täiendavad andmed:

Suunav asutus, isik: AS Chemi-Pharm

Proovi võtmise koht: AS Chemi-Pharm, Serva 44a Tallinn

Proovi võtmise kuupäev, kellaaeg: 28.08.2000

Uuringu eesmärk: desinfitseerivate omaduste määramine

Laborisse saabumise aeg: 28.08.2000

Proovi seisund laborisse saabumisel: ilma iseärasusteta

Mikrobioloogilise uuringu algus: 28.08.2000

Uuringu tulemused: Katsetatud 20±1^{0}C juures

		KASUTATUD TESTKULTUURID					
Lahuse kontsentratsioon	Toime - aeg	*Escherichia coli* ATCC 25922	*Staphylococcus aureus* ATCC 25923	*Streptococcus faecalis* ATCC 29212	*Pseudomonas aeruginosa* ATCC 27853	*Bacillus cereus* ATCC 11778	*Candida Albicans* ATCC 10231
0,5 %	5 min	-	-	-	-	-	-

Tähistused: + Testkultuur kasvab, lahusel puudub bakteritsiidne toime
- Testkultuuri kasv puudub, lahus toimib bakteritsiidselt.

Uuringu tulemused kehtivad antud proovi kohta.

Katseprotokolli paljundamine on lubatud ainult tervikuna.

01.09.2000

Arst-mikrobioloog .....K. Birk

Lai 15, Tallinn 10133 Tel. 372 6 448 784; fax 372 6 411 639

Nordic Tersus
Laboratory

Test report No. 102/2016

EVALUATION OF YEASTICIDAL AND FUNGICIDAL ACTIVITIES OF A DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product:	**CHEMIPHARM DES NEW**
Batch number:	25031116
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	13.12.2016
Test material conditions:	no specific features, sample in the manufacturers tare
Storage conditions:	in room temperature, dark
Active substance – conc.:	7% Blend of quaternary ammonium compounds: benzyl-C12-18-alkyldimethyl chlorides and C12-14-alkyl[(ethylphenyl)methyl] dimethyl chlorides
Appearance of the product:	Transparent liquid
Test concentration:	0,3%, 0,5%; 1%
Contact time:	10 min for 0,3% and 0,5%; 5 min for 1%
Interfering substance:	0,3 g/l bovine albumin = Clean conditions; 3 g/l bovine albumin + 3 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** **Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.**
Testing date:	15.12.2016 – 17.12.2016
Results:	look appendix 1-2

ACCREDITED LABORATORY No L263 ISO/IEC 17025 NORDIC ESTONIA

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Diana Kaare, MSc
Head of laboratory, microbiologist
date of test report: 19.12.2016

Nordic Tersus Laboratory OÜ
Põllu 132
0917 Tallinn, Estonia
registrikood: 12561442
tel: +372 503 0197
e-mail: info@ntl.ee

EESTI AKREDITEERIMISKESKUS ESTONIAN ACCREDITATION CENTRE
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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: 0,3 g/l bovine albumin = Clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 15.12.2016 – 17.12.2016.
Responsible person: Diana Kaare

Validation and controls

Clean and dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	29	$\bar{x}$ = 30,5	V_{C1}	17	$\bar{x}$ = 18	V_{C1}	23	$\bar{x}$ = 24,5	V_{C1}	22	$\bar{x}$ = 25,5
V_{C2}	32		V_{C2}	19		V_{C2}	26		V_{C2}	29	
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}? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1,51 x 10^7; log$N$ = 7,18
N and N_0	10^{-5}	**147**	**153**	N_0 = N/10; logN_0 = 6,18
	10^{-6}	**14**	**18**	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
0,1%	-	136	142	1390	3,14	3,04	5 min	clean
0,1%	-	24	20	220	2,34	3,84	10 min	clean
0,1%	-	>165	>165	>1650	>3,22	<2,98	5 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<2,98	10 min	dirty
0,3%	-	<14	<14	<140	<2,15	>4,03	10 min	clean
0,3%	-	<14	<14	<140	<2,15	>4,03	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>4,03	10 min	clean
0,5%	-	<14	<14	<140	<2,15	>4,03	10 min	dirty
1%	-	<14	<14	<140	<2,15	>4,03	5 min	clean
1%	-	<14	<14	<140	<2,15	>4,03	5 min	dirty
3%	-	<14	<14	<140	<2,15	>4,03	5 min	clean
3%	-	<14	<14	<140	<2,15	>4,03	5 min	dirty
3%	-	<14	<14	<140	<2,15	>4,03	10 min	clean
3%	-	<14	<14	<140	<2,15	>4,03	10 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:

Using the EN 13624 standard, there was tested product for surface disinfection– **CHEMIPHARM DES NEW** (Batch nr. 25031116) under temperature conditions at 20 °C ± 1 °C, with the contact times: 10 min for 0,3%; 10 min for 0,5%; 5 min for 1% under clean and dirty conditions. The membrane filtration method was used for the testing of product effect against the microorganism: *Candida albicans* ATCC 10231. Under clean and dirty conditions (the test regimes) tested product was active against the testorganism at 0,3% - 10min; 0,5% - 10 min and 1% - 5min.

Conclusion:

By the test results can be made conclusions that tested product **CHEMIPHARM DES NEW has yeasticidal effect in case of surfce disinfection under clean and dirty conditions at 0,3% - 10 min; 0,5% 10 min and 1% 5min**, as treated by the product the surviving microorganisms count was decreasing at least four grades.

ACCREDITED LABORATORY No L263, ISO/IEC 17025
NORDIC TERSUS LABORATORY

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Diana Kaare, MSc

Head of laboratory, microbiologist

date of test report: 19.12.2016

Nordic Tersus
Laboratory

Test report No. 103/2016

EVALUATION OF BACTERICIDICAL ACTIVITIES OF A DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product:	**CHEMIPHARM DES NEW**
Batch number:	25031116
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	13.12.2016
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	7% Blend of quaternary ammonium compounds: benzyl-C12-18-alkyldimethyl chlorides and C12-14-alkyl[(ethylphenyl)methyl] dimethyl chlorides
Appearance of the product:	Transparent liquid
Test concentration:	0,3%; 0,5%; 1,0%
Contact time:	5 min for 1%; 10 min for 0,3% and 0,5%; 15 min for 1%, 30 min for 1%
Interfering substance:	0,3 g/l bovine albumin = Clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Staphylococcus aureus* MRSA ATCC 33592 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
Testing method:	**EVS-EN 13727:2012+A2:2015** **Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)**
Testing date:	05.01.2017 – 11.01.2017
Results:	look appendix 1-5

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Diana Kaare, MSc
Head of laboratory, microbiologist

date of test report: 13.11.2017

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TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Staphylococcus aureus* MRSA ATCC 33592;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 05.01.2017 – 11.01.2017
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	64	$\bar{x} = 63$	V_{C1}	58	$\bar{x} = 60$	V_{C1}	67	$\bar{x} = 68,5$	V_{C1}	56	$\bar{x} = 57,5$
V_{C2}	62		V_{C2}	62		V_{C2}	70		V_{C2}	59	
$30 \leq \bar{x}\ N_{vo} \leq 160$? 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	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1,74 \times 10^8$; $\log N = 8,24$
N and N_0	10^{-6}	**177**	**172**	$N_0 = N/10$; $\log N_0 = 7,24$
	10^{-7}	**18**	**16**	$7,17 \leq \log N_0 \leq 7,70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,1%	-	>165	>165	>1650	>3,22	<4,02	5 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,02	10 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,02	15 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,02	30 min	dirty
0,1%	-	38	31	345	2,54	4,70	5 min	clean
0,1%	-	25	23	240	2,38	4,86	10 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,09	15 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,09	30 min	clean
0,3%	-	<14	<14	<140	<2,15	>5,09	10 min	dirty
0,3%	-	<14	<14	<140	<2,15	>5,09	10 min	clean
0,5%	-	<14	<14	<140	<2,15	>5,09	5 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,09	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,09	5 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	5 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,09	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,09	30 min	clean

Concentration of the product %	**Dilution step**	V_{C1}	V_{C2}	**Na** (=x̄*10)	**log Na**	**logR**	**Contact time**	**Conditions**
3,0%	-	<14	<14	<140	<2,15	>5,09	5 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	5 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,09	10 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,09	15 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,09	30 min	clean

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)

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Staphylococcus aureus* ATCC 6538;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 05.01.2017 – 11.01.2017
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	49	$\bar{x} = 46,5$	V_{C1}	51	$\bar{x} = 52$	V_{C1}	48	$\bar{x} = 48$	V_{C1}	56	$\bar{x} = 54$
V_{C2}	44		V_{C2}	53		V_{C2}	48		V_{C2}	52	
$30 \leq \bar{x}\ N_{vo} \leq 160$? 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	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1,67 \times 10^8$; $\log N = 8,22$
N and N_0	10^{-6}	**163**	**170**	$N_0 = N/10$; $\log N_0 = 7,22$
	10^{-7}	**18**	**17**	$7,17 \leq \log N_0 \leq 7,70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
0,1%	-	>165	>165	>1650	>3,22	<4,00	5 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,00	10 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,00	15 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<4,00	30 min	dirty
0,1%	-	29	24	265	2,42	4,80	5 min	clean
0,1%	-	19	20	195	2,29	4,93	10 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,07	15 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,07	30 min	clean
0,3%	-	<14	<14	<140	<2,15	>5,07	10 min	dirty
0,3%	-	<14	<14	<140	<2,15	>5,07	10 min	clean
0,5%	-	<14	<14	<140	<2,15	>5,07	5 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,07	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,07	5 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,07	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,07	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,07	5 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,07	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,07	30 min	clean

Concentration of the product %	**Dilution step**	V_{C1}	V_{C2}	**Na** (=$\bar{x}$*10)	**log Na**	**logR**	**Contact time**	**Conditions**
3,0%	-	<14	<14	<140	<2,15	>5,07	5 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,07	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,07	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,07	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,07	5 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,07	10 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,07	15 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,07	30 min	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)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Enterococcus hirae* ATCC 10541;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 05.01.2017 – 11.01.2017
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{v0}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	44	$\bar{x} = 42,5$	V_{C1}	50	$\bar{x} = 48,5$	V_{C1}	53	$\bar{x} = 51,5$	V_{C1}	51	$\bar{x} = 48,5$
V_{C2}	41		V_{C2}	47		V_{C2}	50		V_{C2}	46	
$30 \leq \bar{x}\ N_{v0} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0,5\ \bar{x}\ N_{v0}$? yes X; no □			$\bar{x}$ **B** is $\geq 0,5\ \bar{x}\ N_{v0}$? yesX; no □			$\bar{x}$ **C** is $\geq 0,5\ \bar{x}\ N_{v0}$? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1,57 \times 10^8$; $\log N = 8,20$
N and N_0	10^{-6}	**158**	**153**	$N_0 = N/10$; $\log N_0 = 7,20$
	10^{-7}	**16**	**18**	$7,17 \leq \log N_0 \leq 7,70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,1%	-	>165	>165	>1650	>3,22	<3,98	5 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,98	10 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,98	15 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,98	30 min	dirty
0,1%	-	44	35	395	2,60	4,60	5 min	clean
0,1%	-	27	32	295	2,47	4,73	10 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,05	15 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,05	30 min	clean
0,3%	-	<14	<14	<140	<2,15	>5,05	10 min	dirty
0,3%	-	<14	<14	<140	<2,15	>5,05	10 min	clean
0,5%	-	<14	<14	<140	<2,15	>5,05	5 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,05	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,05	5 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,05	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,05	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,05	5 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,05	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,05	30 min	clean

Concentration of the product %	**Dilution step**	V_{C1}	V_{C2}	**Na** (=x̄*10)	**log Na**	**logR**	**Contact time**	**Conditions**
3,0%	-	<14	<14	<140	<2,15	>5,05	5 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,05	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,05	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,05	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,05	5 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,05	10 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,05	15 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,05	30 min	clean

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 4

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Pseudomonas aeruginosa* ATCC 15442
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 05.01.2017 – 11.01.2017
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	62	$\bar{x}$ = 60,5	V_{C1}	64	$\bar{x}$ = 65,5	V_{C1}	58	$\bar{x}$ = 60,5	V_{C1}	68	$\bar{x}$ = 67
V_{C2}	59		V_{C2}	67		V_{C2}	63		V_{C2}	66	
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}? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1,61 x 10^8; log$N$ = 8,21
N and N_0	10^{-6}	**157**	**165**	N_0 = N/10; logN_0 = 7,21
	10^{-7}	**18**	**14**	7,17≤ logN_0≤7,70; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,1%	-	>165	>165	>1650	>3,22	<3,99	5 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,99	10 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,99	15 min	dirty
0,1%	-	>165	>165	>1650	>3,22	<3,99	30 min	dirty
0,1%	-	51	44	475	2,68	4,53	5 min	clean
0,1%	-	37	28	325	2,51	4,70	10 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,06	15 min	clean
0,1%	-	<14	<14	<140	<2,15	>5,06	30 min	clean
0,3%	-	<14	<14	<140	<2,15	>5,06	10 min	dirty
0,3%	-	<14	<14	<140	<2,15	>5,06	10 min	clean
0,5%	-	<14	<14	<140	<2,15	>5,06	5 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,06	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,06	5 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,06	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,06	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,06	5 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,06	15 min	clean
1,0%	-	<14	<14	<140	<2,15	>5,06	30 min	clean

Concentration of the product %	**Dilution step**	V_{C1}	V_{C2}	**Na** (=$\bar{x}$*10)	**log Na**	**logR**	**Contact time**	**Conditions**
3,0%	-	<14	<14	<140	<2,15	>5,06	5 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,06	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,06	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,06	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,06	5 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,06	10 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,06	15 min	clean
3,0%	-	<14	<14	<140	<2,15	>5,06	30 min	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)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Interpretation:

Using the EN 13727 standard, there was tested product for surface disinfection – **CHEMIPHARM DES NEW** (25031116), concentrations 0,3% - 10 min; 0,5% - 10 min and 1% - 5 min, 15 min and 30 min in temperature conditions at 20 °C ± 1 °C. The membrane filtration method was used for the testing of product effect against the microorganisms: *Staphylococcus aureus* MRSA ATCC 33592, *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541, *Staphylococcus aureus* ATCC 6538. In clean and dirty conditions tested product was active against all the testorganims at all tested contact times.

Conclusion:

By the test results can be made conclusions that tested product **CHEMIPHARM DES NEW has a bactericidal effect in case of a surface disinfection under clean and dirty conditions at 0,3% - 10 min; 0,5% - 10 min and at 1% - 5 min, 15 min, 30 min**, as treated by the product, the surviving microorganisms count was decreasing at least five grades.

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Diana Kaare, MSc
Head of laboratory, microbiologist

date of test report: 13.11.2017