



Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2018.

Copy No.: 1
Issue No.: 1

Test report No. S381-1/2019

DETERMINATION OF TUBERCULOCIDAL (EN 14348:2005) ACTIVITY OF THE PRODUCT **Sterisept Plus**

Sample ID: S381/2019

Sample name: **Sterisept Plus**

Client: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Producer: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Sampling point: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Page: 1

From pages: 4

Incoming date:
9.12.2019

Delivery date:
5.6.2020

Hodonín, 5.6.2020



Ing. Jana Slitrová, Head of Laboratory

The report may be reproduced only as a whole, in parts only upon written permission of the laboratory. The test results relate only to the samples stated in the Test Report. The Lab does not take any guarantee for the identity of samples not taken by the lab personnel.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S381/2019

Rep No: 30

Sample name: **Sterisept Plus**

Sampled: by client

Sampling point: AS CHEMI-PHARM, Põllu 132, Tallinn, Estonia

Client: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Sampling date: 6.12.2019

Sample delivered: 9.12.2019

Testing date: 11.2. – 3.3.2020

Delivered amount: 100 ml

Batch No: not available

Page: 2

Subject of testing:

Determination of tuberculocidal activity of the product.

Identification of the sample:

Name of the product:

Sterisept Plus

Batch number:

not available

Date of manufacture:

05.11.2019

Expiry date:

05.11.2021

Manufacturer:

AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Incoming date:

9.12.2019

Storage conditions:

room temperature, dark area

Active ingredients:

Didecyl-Dimethyl-Ammonium Chloride (DDAC) 12,5 g

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 12,5 g

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 14348:2005)

Period of analysis:

11.2. – 3.3.2020

Test temperature:

20 °C ± 1 °C

Test method:

membrane filtration method

Filtration diluent:

rinsing liquid

Product diluent:

hard water

Appearance of the product:

colourless gel

Test concentration:

0.5%, 1.0%

Contact time:

15 min, 30 min

Interfering substances:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

Test organisms:

Mycobacterium terrae ATCC 15755

Incubation conditions:

37 °C ± 1 °C, 21 days

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least a 4 lg reduction (10^4).

Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least a 4 lg reduction (10^4).

$R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

The standard:

EN 14348:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test method and requirements (phase 2, step 1) January 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S381/2019

Rep No: 30

Sample name: **Sterisept Plus**

Sampled: by client

Sampling point: AS CHEMI-PHARM, Põllu 132, Tallinn, Estonia

Client: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

Sampling date: 6.12.2019

Sample delivered: 9.12.2019

Testing date: 11.2. – 3.3.2020

Delivered amount: 100 ml

Batch No: not available

Page: 3

The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **Sterisept Plus** on *Mycobacterium terrae* ATCC 15755

Tab No. 1.1 Verification of methodology, dirty conditions

Validation of suspension (N _{vo})				Validation of selected experimental conditions (A)				Membrane filtration control (B)				Method validation (C) Product conc.: 1.0%			
V _{c1}	35	Φ _{N_{vo}} = 42		V _{c1}	39	Φ _A = 36		V _{c1}	28	Φ _B = 33.5		V _{c1}	40	Φ _C = 36	
V _{c2}	49			V _{c2}	33			V _{c2}	39			V _{c2}	32		
30 < Φ _{N_{vo}} ≤ 160				Φ _A > 0.5 Φ _{N_{vo}}				Φ _B > 0.5 Φ _{N_{vo}}				Φ _C > 0.5 Φ _{N_{vo}}			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 1.2 Test suspensions

Test suspension N $\Phi = 43 \times 10^8 = \lg 9.63$ $9.17 \leq \lg N \leq 9.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 8.63$ $8.17 \leq \lg N_0 \leq 8.70$
	10^{-7}	>165	>165	
	10^{-8}	41	45	
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **Sterisept Plus** on *Mycobacterium terrae* ATCC 15755

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 8.63$)
0.5 / 30 / dirty	10^{-2}	41	27	4.53	4.10
1.0 / 15 / dirty	10^{-2}	22	33	4.44	4.19

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0“), N_a = the number of surviving bacteria per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0} = the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

2. Evaluation of tuberculocidal activity of the product **Sterisept Plus**

Tab No. 2.1 The efficacy of chemical disinfectant **Sterisept Plus** on test strain – tuberculocidal activity

Mycobactericidal and tuberculocidal activity of the product (EN 14348:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	$\lg R$ EN 14348:2005	$\lg R$
<i>Mycobacterium terrae</i> ATCC 15755	20	30	0.5	dirty	≥ 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	15	1.0	dirty	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0“), N_a = the number of surviving bacteria per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0} = the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S381/2019

Rep No: 30

Sample name: **Sterisept Plus**

Sampled: by client

Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia

Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Sampling date: 6.12.2019

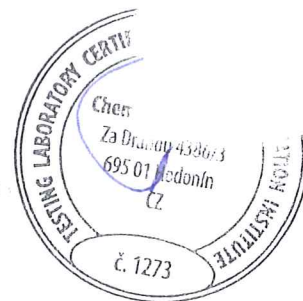
Sample delivered: 9.12.2019

Testing date: 11.2. – 3.3.2020

Delivered amount: 100 ml

Batch No: not available

Page: 4



Interpretation:

Results of tests are in Tabs.

The tested product **Sterisept Plus**, batch No. not available, in the concentration 0.5%, diluted in hard water, and in the contact time 30 min and in the concentration 1.0%, diluted in hard water, and in the contact time 15 min under dirty conditions at temperature $20\text{ °C} \pm 1\text{ °C}$ by the membrane filtration method **decreased** the number of viable cells of *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction (EN 14348:2005).

Conclusion:

The product **Sterisept Plus** is capable of reducing the number of viable mycobacterial cells of the relevant test organism under defined conditions (EN 14348:2005, M.t. – 0.5%, 30 min, 1.0%, 15 min, dirty, 20 °C) to the declared values, and consequently, may be called tuberculocidal.

5.6.2020, Hodonín

Ing. Barbora Stoklasková, Leader of Study

