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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

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Issue No.: 1

Test report No. S74/2018

DETERMINATION OF VIRUCIDAL (EN 14476:2013+A1:2015) ACTIVITY OF THE PRODUCT **Chemisept med**

Sample ID: S74/2018
Sample name: **Chemisept med**
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Producer: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Sampling point: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Page: 1
From pages: 4

Incoming date:
25.4.2018

Delivery date:
3.7.2018

Hodonín, 3.7.2018



Ing. Jana Šlitrová, Head of Laboratory

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Sample ID: S74/2018

Rep No: 65

Sample name: **Chemisept med**

Sampled: by client

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

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

Sampling date: 24.4.2018

Sample delivered: 25.4.2018

Testing date: 18.5. – 25.5.2018

Delivered amount: 50 ml

Batch No: 196101017

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Subject of testing:

Determination of virucidal activity of the product.

Identification of the sample:

Name of the product:

Chemisept med

Batch number:

196101017

Date of manufacture:

24.04.2018

Expiry date:

10.10.2020

Manufacturer:

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

Incoming date:

25.4.2018

Storage conditions:

room temperature, dark area

Active ingredients in 100 g:

Ethyl alcohol 72,5 g

Isopropyl alcohol 7,5 g

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A1:2015)

Period of analysis:

18.5. – 25.5.2018

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the products:

colourless liquid

Test concentration:

100% (concentrated) *

Contact time:

1 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K50163503815, expiry date: 30.4.2020

Test virus:

Poliovirus type 1, LSc-2ab (1st passage)

Cell lines:

HeLa cells

Incubation:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the cell culture
3. Preparation of the test virus suspension
4. Test of the viral infectivity
5. Virus titration with the interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for the virucidal activity of the product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least a 4 lg reduction.

* Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Description: Testing the efficacy of chemical disinfectants and antiseptics

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

1. Testing the efficacy of chemical disinfectant **Chemisept med** on *Poliovirus* type 1, LSc-2ab

Tab No. 1.1 Table of results of product **Chemisept med** on *Poliovirus* type 1, LSc-2ab

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 1 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
Chemisept med	100%*	clean	≤4.50	4.50	-	-
Formaldehyde	0.7 % (w/v)	PBS	≤4.50	-	7.33	6.17
			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.50	9.33
Virus control	-	clean	9.50	9.50	-	-

Tab No. 1.2 Testing the efficacy of chemical disinfectant **Chemisept med** on *Poliovirus* type 1, LSc-2ab

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
100%*	9.50	clean	1 min	4.50	5.00

2. Evaluation of virucidal activity of the product **Chemisept med**

Tab No. 2.1 The efficacy of chemical disinfectant **Chemisept med** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A1:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A1:2015	Δlog ₁₀ TCID ₅₀
<i>Poliovirus</i> type 1, LSc-2ab	20	1	100*	clean	≥ 4	> 4

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

* Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Bc. Iva Čížová, Lab Technician

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Interpretation:

Results of tests are in Tabs.

According to EN 14476:2013+A1:2015 the tested concentrated* product **Chemisept med**, batch No: 196101017, in the contact time 1 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Poliovirus* type 1, LSc-2ab particles under defined conditions by at least a 4 lg reduction.

* Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

Conclusion:

The product **Chemisept med** is capable of reducing the number of infectious *Poliovirus* particles under defined conditions to the declared values and, consequently, may be called virucidal on *Poliovirus*.

3.7.2018, Hodonín

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Ing. Barbora Stoklášková, Leader of Study

