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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.

Copy No.: 2
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

Incoming date:
25.4.2018

Delivery date:
3.7.2018

Hodonín, 3.7.2018

Chemila, spol. s.r.o. Za Dráhou 4386/3 695 01 Hodonín č. 1273

Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: S74/2018
Rep No: 65
Sample name: **Chemisept med**
Sampled: by client
Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Pöllu 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

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, Pöllu 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 % CO_2, 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*

Sample ID: S74/2018
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Sampling point: AS CHEMI-PHARM, Põllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Põllu 132, 109 17 Tallinn, Estonia

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Delivered amount: 50 ml
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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 cytoxicity	- $\log_{10}$ $TCID_{50}$ 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	$\Delta\log_{10}$ $TCID_{50}$
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	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013 +A1:2015	$\Delta\log_{10}$ $TCID_{50}$
Poliovirus type 1, LSc-2ab	20	1	100*	clean	≥ 4	**> 4**

Note:
$TCID_{50}$- 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

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

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Delivered amount: 50 ml
Batch No: 196101017

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 °C ± 1 °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 Stoklásková, Leader of Study