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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.: 1
Issue No.: 1

Test report No. S241/2018

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

Sample ID: S241/2018
Sample name: **Chemisept GEL**
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:
17.9.2018

Delivery date:
20.11.2018

Hodonín, 20.11.2018

Ing. Jana Šlitrová, Head of Laboratory

Digitally signed by Moraru Grigore
Date: 2024.10.14 11:34:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Sample ID: S241/2018
Rep No: 144
Sample name: **Chemisept GEL**
Sampled: by client
Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Sampling date: 14.9.2018
Sample delivered: 17.9.2018
Testing date: 26.10. – 2.11.2018
Delivered amount: 100 ml
Batch No: 198060918

Subject of testing:
Determination of virucidal activity of the product.

Identification of the sample:

Name of the product:	**Chemisept GEL**
Batch number:	198060918
Date of manufacture:	06.09.2018
Expiry date:	06.09.2021
Manufacturer:	AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Incoming date:	17.9.2018
Storage conditions:	room temperature, dark area
Active ingredients in 100 g:	Ethyl alcohol 72,5 g CAS 64-17-5 Isopropyl alcohol 7,5 g CAS 67-63-0

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:	26.10. – 2.11.2018
Test temperature:	20 °C ± 1 °C
Method of titration:	virus titration on monolayers of cells on microtitre plates
Appearance of the product:	colourless liquid
Test concentration:	100% (concentrated)*/**
Contact time:	30 s (0.5 min), 1 min, 2 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:	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 (3rd 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 cell culture
3. Preparation of the test virus suspension
4. Test of viral infectivity
5. Virus titration with interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for virucidal activity of 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 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.
** The mixture from the product solution and the suspension of virus and the interfering substance makes a clot despite mixing with glass beads.

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

Sample ID: S241/2018
Rep No: 144
Sample name: **Chemisept GEL**
Sampled: by client
Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Sampling date: 14.9.2018
Sample delivered: 17.9.2018
Testing date: 26.10. – 2.11.2018
Delivered amount: 100 ml
Batch No: 198060918

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

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

1. Testing the efficacy of chemical disinfectant **Chemisept GEL** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Tab No. 1.1 Table of results of product **Chemisept GEL** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Product	Concentration **	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 0.5 min	- $\log_{10}$ $TCID_{50}$ after 1 min	- $\log_{10}$ $TCID_{50}$ after 2 min	- $\log_{10}$ $TCID_{50}$ after 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
Chemisept GEL	100%*	clean	3.50	4.83	4.50	4.50	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-	-	6.33	5.67
			Virus titration, time = 0					
Virus control	-	PBS	9.50	-	-	-	9.50	9.50
Virus control	-	clean	9.50	9.50	9.50	9.50	-	-

Tab No. 1.2 Testing the efficacy of chemical disinfectant **Chemisept GEL** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

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	0.5 min	4.83	**4.67**
100%*	9.50	clean	1 min	4.50	**5.00**
100%*	9.50	clean	2 min	4.50	**5.00**

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

Tab No. 2.1 The efficacy of chemical disinfectant **Chemisept GEL** 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	$\Delta\log_{10}$ $TCID_{50}$
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	0.5	100*	clean	≥ 4	> **4**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	1	100*	clean	≥ 4	> **4**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	2	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 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.
** The mixture from the product solution and the suspension of virus and the interfering substance makes a clot despite mixing with glass beads.

Prepared by: Bc. Iva Čížová, Lab Technician

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

Sample ID: S241/2018
Rep No: 144
Sample name: **Chemisept GEL**
Sampled: by client
Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Sampling date: 14.9.2018
Sample delivered: 17.9.2018
Testing date: 26.10. – 2.11.2018
Delivered amount: 100 ml
Batch No: 198060918

Interpretation:
Results of tests are in Tabs.
According to EN 14476:2013+A1:2015 the tested concentrated*/** product **Chemisept GEL,** batch No. 198060918, in the contact times 30 s (0.5 min), 1 min and 2 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 *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 particles under defined conditions by at least a 4 lg reduction.

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance (9.7 ml of product + 0.2 ml of the 5 fold concentrated interfering substance + 0.1 ml of test suspension, titre of the test suspension shall be at least 10^8 $TCID_{50}$/ml, therefore the real concentration is 97%).
** The mixture from the product solution and the suspension of virus and the interfering substance makes a clot despite mixing with glass beads.

Conclusion:
The product **Chemisept GEL** is capable of reducing the number of infectious *Adenovirus* under defined conditions to the declared values, and consequently, can be called virucidal on *Adenovirus*.

20.11.2018, Hodonín

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

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Ing. Barbora Stoklásková, Leader of Study

Raw data – product **Chemisept GEL** tested against *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Sample S241/2018, the test report S241/2018,

period of analysis: 26.10. – 2.11.2018

EN14476+A1: *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 – 3rd passage (LGC Standards Sp. z o.o., PL, 26.6. 2013),
HeLa cells – 55th passage (LGC Standards Sp. z o.o., PL, 1.10. 2014)

the test conditions: 100%(97%)*/**, 0.5 min (30 s), 1 min and 2 min, clean conditions, 20 °C

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

Product	Concentration	Interfering substance	Contact time min	Dilution								
				2	3	4	5	6	7	8	9	10
Chemisept GEL	100%(97%)	clean	0.5	n.a.	444 444	222 222	002 200	000 000	000 000	000 000	000 000	000 000
Chemisept GEL	100%(97%)	clean	1	n.a.	444 444	222 222	000 000	000 000	000 000	000 000	000 000	000 000
Chemisept GEL	100%(97%)	clean	2	n.a.	444 444	222 222	000 000	000 000	000 000	000 000	000 000	000 000
Chemisept GEL cytotoxicity	100%(97%)	clean	n.a.	n.a.	444 444	000 000	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Formaldehyde	0.7 (w/v)	PBS	30	444 444	444 444	233 332	222 222	200 220	000 220	000 000	000 000	000 000
			60	444 444	444 444	333 333	022 322	202 000	000 000	000 000	000 000	000 000
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	444 444	444 444	000 000	000 000	000 000	000 000	000 000	000 000	000 000
Interference control	non-cytotoxic concentration	n.a.	n.a.	444 444	444 444	444 444	444 444	323 333	333 233	222 222	022 200	022 200
Neutralization	100%(97%)	clean	n.a.	n.d.	n.d.	444 444	444 444	333 333	333 323	222 222	n.d.	n.d.
Virus control	n.a.	PBS	0	444 444	444 444	444 444	444 444	333 333	333 333	222 222	220 022	002 200
			30	444 444	444 444	444 444	444 444	333 333	333 333	222 222	020 200	222 200
			60	444 444	444 444	444 444	444 444	333 333	333 333	222 222	000 222	000 222
Virus control	n.a.	clean	0	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 222	000 000
			0.5	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 000	002 220
			1	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 000	000 222
			2	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 000	000 222

n.a. – not available
n.d. – not done
* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.
** The mixture from the product solution and the suspension of virus and the interfering substance makes a clot despite mixing with glass beads.

Prepared by: Bc. Iva Čížová, Lab Technician
Controlled by: Ing. Barbora Stoklásková, Leader of Study