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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

Page: 1
From pages: 4

Incoming date:
17.9.2018

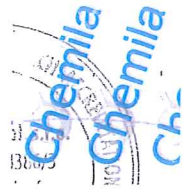
Delivery date:
20.11.2018

Hodonín, 20.11.2018



Ing. Jana Šlitrová, Head of Laboratory

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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, Põllu 132, Tallinn, Estonia

Client: AS CHEMI-PHARM, Põllu 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

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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, Põllu 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 % 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 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.

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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 cytotoxicity	- 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	Δlog 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

Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Virucidal activity of the product (EN 14476:2013+A1:2015)	
					Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	Δlog ₁₀ TCID ₅₀
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	0.5	100*	clean	≥ 4	> 4
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	1	100*	clean	≥ 4	> 4
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	2	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 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

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Rep No: 144

Sample name: **Chemisept GEL**

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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 $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *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 TCID₅₀/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



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	222	002	000	000	000	000	000	000
				444	222	200	000	000	000	000	000		
Chemisept GEL	100%(97%)	clean	1	n.a.	444	222	000	000	000	000	000	000	000
				444	222	000	000	000	000	000	000		
Chemisept GEL	100%(97%)	clean	2	n.a.	444	222	000	000	000	000	000	000	000
				444	222	000	000	000	000	000	000		
Chemisept GEL cytotoxicity	100%(97%)	clean	n.a.	n.a.	444	000	000	000	n.d.	n.d.	n.d.	n.d.	
				444	000	000	n.d.	n.d.	n.d.	n.d.			
Formaldehyde	0.7 (w/v)	PBS	30	444	444	233	222	200	000	000	000	000	
			444	444	332	222	220	220	000	000	000	000	
Formaldehyde	0.7 (w/v)	PBS	60	444	444	333	022	202	000	000	000	000	
			444	444	333	322	000	000	000	000	000	000	
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	444	444	000	000	000	000	000	000	000	
				444	444	000	000	000	000	000	000	000	
Interference control	non-cytotoxic concentration	n.a.	n.a.	444	444	444	444	323	333	222	022	022	
				444	444	444	444	333	233	222	200	200	
Neutralization	100%(97%)	clean	n.a.	n.d.	n.d.	444	444	333	333	222	n.d.	n.d.	
				444	444	333	323	222	n.d.	n.d.			
Virus control	n.a.	PBS	0	444	444	444	444	333	333	222	220	002	
			444	444	444	444	333	333	222	022	200		
			30	444	444	444	444	333	333	222	020	222	
			444	444	444	444	333	333	222	200	200		
			60	444	444	444	444	333	333	222	000	000	
			444	444	444	444	333	333	222	222	222		
Virus control	n.a.	clean	0	444	444	444	444	333	333	222	222	000	
			444	444	444	444	333	333	222	222	000		
			0.5	444	444	444	444	333	333	222	222	002	
			444	444	444	444	333	333	222	000	220		
			1	444	444	444	444	333	333	222	222	000	
			444	444	444	444	333	333	222	000	222		
			2	444	444	444	444	333	333	222	222	000	
			444	444	444	444	333	333	222	000	222		

n.a. – not available

n.d. – not done

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Controlled by: Ing. Barbora Stoklásková, Leader of Study