BTL SAV
Jarkova 269/17
Šarišské Michaľany
Slovak Republic

Translation from Slovak into English

Test Report

DETERMINATION OF VIRUCIDAL EFFICACY OF THE PRODUCT according to EN 14476 + A2

Registration number: 2122RUVI-BA02

Product name: RUVIREX GEL, Ruvirex, a.s.

This test was performed under validation of the Standard Working Protocol for the method.

In Bratislava on 22.1.2021

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RNDr. Vladimir Zelnik CSc.
Head of Biotechnology Laboratories BMC SAS

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Jarkova 269/17
Šarišské Michaľany
Slovak Republic

Test report no. 2122RUVI-BA02

Sample data

Registration number:	2122RUVI-BA02	Batch number:	Date of Manufacture: 7.9.2020
Test subject / sample type:	Microbiology-Virology	Size of Packaging:	250 ml
Sample name:	RUVIREX GEL	Sample Taken By:	Client
Test requirement:	Virucidal efficacy of the preparation according to EN 14476 + A2		
Customer report number:			

Customer Data

Client / customer:	RUVIREX, a.s.	Date of receipt of samples:	1.12.2020
Organizational unit		Date of tests performed from:	10.1.2021
Contract /order	ZoD 91/200/2020	| To:	18.1.2021
		Date of report:	

Statement of compliance / non-compliance

The product meets the requirements for virucidal activity according to the standard.

This test was performed as part of the validation of the Standard Working Protocol for the method.

Statements and notices

- Biotechnological laboratories of BMC SAS are, as a testing laboratory, the holder of the Certificate on compliance with the principles of Good Manufacturing Practice for manufacturers no. SK / 002V / 2020.
- This report may only be reproduced in its entirety, part of the report only with the consent of the test laboratory.
- The test equipment and gauges used for the tests have been calibrated and verified in accordance with the applicable metrological regulations.

Complaints and storage of samples

- The results of laboratory tests can be claimed within 30 days from the date of issue of the report.
- Only written complaints are accepted and handled.
- Only samples for which the original properties do not change are retained, until the expiration of the complaint period.
- Return of the remaining samples - samples are returned to the customer only at their request and at their own costs.

Responsible for the test report and its accuracy: Dr. V. Zelník.

The report will be sent to: Ing. M. Obrk, RUVIREX, ***LLC.

Date: 1/22/2021 Approved by: RNDr. V. Zelník CSc.
Contact details: viruzelo@savba.sk

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Experimental test conditions

Testing of disinfection efficiency of chemical disinfectants by suspension method SOP … (in preparation)

According to EN 14476: 2013 + A2: 2019: Quantitative test to evaluate Virucidal activity for chemical disinfectants and antiseptics used in medicine
Test method and requirements (phase 2, step 1)
Testing for hygienic means for washing and disinfecting hands

Test temperature: 20 ° C ± 1 ° C
Titration method: Titration of the virus on a monolayer of susceptible cells in microtiter plates
Dilution medium: Undiluted preparation
Appearance of the product: Gel suspension, slightly cloudy
Product concentration: 100%
Contact time: 60 sec (30-120 sec according to standard)
Load conditions: no load
Reference preparation: Not tested
Stopping the effect of the product: Transfer to ice
Virus used: Modified vaccinia virus (MVA) strain Ankara, recommended by the standard as a reference enveloped virus
Cell line: BHK-21, + 22th passage
Virus incubation conditions: 37 ° C ± 1 ° C
Virus titer calculation: $TCID_{50}$ according to the Spearman-Kärber method

Description of abbreviations:

Abbreviation	Description
$TCID_{50}$	50% infectious dose producing cytopathic effect on cells
CPE	Cytopathic effect
CFU	Colony forming unit
pfu	Plaque forming unit

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Test results

Tested according to: EN 14476 + A2

Test/measured quantity /parameter	Test method	Unit of measurement	Limit value	Test Result	Declaration of compliance	Tested On
Virucidal effect of the tested preparation	Virus titration	$TCID_{50}$	min. 4 log titer reduction	≥ -4 log reduction	Satisfies	13.1.2021
Virus infectivity test	Virus titration	$TCID_{50}$	min. 10^5	1,78 x10^6	Satisfies	13.1.2021
Virucidal effect of the reference product	Virus titration	$TCID_{50}$	0,75 – 3,5	Not Tested	-	
Cytotoxic effect of the tested preparation	Observation of cytopathic effect	CPE		10^{-2} partially	-	13.1.2021
Microbiological load of the tested preparation	Determination of the population of microorganisms on products	CFU	0	Not Tested	-	

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1. Testing the virucidal effect of the preparation on the virus

Preparation: RUVIREX GEL
Virus: MVA reference enveloped virus according to standard
Susceptible cells: BHK-21.
Virus incubation time on cells: 96 hours.
CPE of the virus observed by fluorescence microscopy.

Virus Dilution	Number of holes showing CPE		
	Virus Control	Virucidal activity of the preparation	Cytopathic effect of the product
10^{-2}	8/8	0/8	8/8 partial
10^{-2}	8/8	0/8	0/8
10^{-2}	8/8	0/8	0/8
10^{-2}	5/8	0/8	0/8
10^{-2}	1/8	0/8	0/8
10^{-2}	0/8	0/8	0/8
10^{-2}	0/8	0/8	0/8
10^{-2}	0/8	0/8	0/8
10^{-2}			
10^{-2}			
$TCID_{50}$	$5{,}62 \times 10^5$	0	-

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For correct translation:
I, the undersigned certified translator of the English and German language, duly commissioned by decree no. 20 179/2004 of 15th November 2004 of the Slovak Ministry of Justice, enrolled in the register of expert valuators, translators and interpreters of the Slovak Ministry of Justice under registration number 970034, do hereby certify that this is a true translation of the attached document from Slovak into English. Translation registration number: 25/2021.

PhDr. Josef Borišinec
certified translator