



Chemila, spol. s r.o., Za Dráhou 4386/3, 695 01 Hodonín, CZ, Phone/Fax +420518340919, [chemila@chemila.cz](mailto:chemila@chemila.cz)  
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute.

Copy No.: 1  
Issue No.: 1

Test report No. D166/2013

DETERMINATION OF MYCOBACTERICIDAL AND TUBERCULOCIDAL  
(EN 14348) ACTIVITY OF THE PRODUCT **QUATRODES FORTE**  
DETERMINATION OF VIRUCIDAL ACTIVITY (EN 14476+A1) OF THE  
PRODUCT **QUATRODES FORTE** AGAINST BVDV AND VACCINIA  
VIRUS

Sample ID: D166/2013

Sample name: **Quatrodes Forte**

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Producer: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Page: 1

From pages: 10

Incoming date:  
8.11.2013

Delivery date:  
20.2.2014

Hodonín, 20.2.2014



Zuzana Matušková, Head of Laboratory

The report may be reproduced only as a whole, in parts only upon written permission of the laboratory. The test results relate only to the samples stated in the Test Report. The Lab does not take any guarantee for the identity of samples not taken by the lab personnel.

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodes Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 2

Subject of testing:

Determination of mycobactericidal and tuberculocidal activity of the product. Determination of virucidal activity of the product on BVDV and Vaccinia virus.

Identification of the sample:

Name of the product:

**Quatrodes Forte**

Batch number:

A-25-PAZ-33

Date of manufacture:

25.10.2013

Expiry date:

04.2016

Manufacturer:

Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Incoming date:

8.11.2013

Storage conditions:

stated by the manufacturer

Active ingredients, 100 g contains:

CAS 2372-82-9 N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine 3,76 g

CAS 94667-33-1 N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium propionate 3,39 g

Experimental conditions:

**Quantitative suspension test for evaluation of mycobactericidal and tuberculocidal activity SOP-M-19-00 (EN 14348)**

Period of analysis:

11.12.2013 - 2.1.2014

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Product diluent:

hard water

Appearance of the products:

yellow liquid

Test concentration:

1% and 4%

Contact time:

15 min, 30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

Test organisms:

*Mycobacterium terrae* ATCC 15755

*Mycobacterium avium* ATCC 15769

Incubation conditions:

37 °C ± 1 °C, 21 days

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least 4 orders ( $10^4$ ).

Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least 4 orders ( $10^4$ ).

$R = N_0 / N_a$  nebo  $\lg R = \lg N_0 - \lg N_a$  the reduction in viability

The standard:

EN 14348 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test method and requirements (phase 2, step 1) January 2005

ption: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D166/2013

Sample no: 173

Sample name: **Quatrodex Forte**

Prepared by: client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Address: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 3

Number of CFU in the tested product **Quatrodex Forte**: 0 CFU/ml

Testing the efficacy of chemical disinfectant **Quatrodex Forte** on *Mycobacterium avium* ATCC 15769

**1.1.1 Verification of methodology, clean conditions**

Concentration of suspension ( $N_{v0}$ )		Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 4%			
30	$\Phi_{N_{v0}} = 33$	$V_{c1}$	29	$\Phi_A = 30.5$	$V_{c1}$	31	$\Phi_B = 28$	$V_{c1}$	35	$\Phi_C = 33$	$V_{c1}$	35	
36		$V_{c2}$	32		$V_{c2}$	25		$V_{c2}$	31				
$N_{v0} \leq 160$		$\Phi_A \geq 0.5 \Phi_{N_{v0}}$			$\Phi_B \geq 0.5 \Phi_{N_{v0}}$			$\Phi_C \geq 0.5 \Phi_{N_{v0}}$					
	no	x	yes	no	x	yes	no	x	yes	no			

**1.1.2 Verification of methodology, dirty conditions**

Concentration of suspension ( $N_{v0}$ )		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc.: 4%				
30	$\Phi_{N_{v0}} = 33$	$V_{c1}$	30	$\Phi_A = 32$	$V_{c1}$	31	$\Phi_B = 28$	$V_{c1}$	28	$\Phi_C = 30.5$
36		$V_{c2}$	34		$V_{c2}$	25		$V_{c2}$	33	
$N_{v0} \leq 160$		$\Phi_A \geq 0.5 \Phi_{N_{v0}}$			$\Phi_B \geq 0.5 \Phi_{N_{v0}}$			$\Phi_C \geq 0.5 \Phi_{N_{v0}}$		
yes	no	x	yes	no	x	yes	no	x	yes	no

**1.2 Test suspensions**

Test suspension $N$	$N$	$V_{c1}$	$V_{c1}$	Test suspension $N_0$ (time = 0) $\lg N_0 = \lg N/10 = \lg 8.24$ $8.17 \leq \lg N_0 \leq 8.70$	
$74 \times 10^7 = \lg 9.24$	$10^{-7}$	167	182	x	yes
$17 \leq \lg N \leq 9.70$	$10^{-8}$	18	15		no

**1.3 Testing the efficacy of chemical disinfectant **Quatrodex Forte** on *Mycobacterium avium* ATCC**

Concentration (%) / Contact time (min) / Conditions	Dilution after test procedure	$V_{c1}$	$V_{c2}$	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ( $\lg N_0 - \lg 8.24$ )
1/30/clean	$10^{-1}$	<14	<14	< 3.15	$\geq 5.09$
1/30/dirty	$10^{-1}$	<14	<14	< 3.15	$\geq 5.09$
4/15/clean	$10^{-1}$	<14	<14	< 3.15	$\geq 5.09$
4/15/dirty	$10^{-1}$	<14	<14	< 3.15	$\geq 5.09$

$V_c$  = value is the number of cfu per ml,  $\Phi$  = average  $V_{c1}$  a  $V_{c2}$  (1. + 2. duplicate  $V_c$  values),  $N$  = the number of cfu/ml of the bacterial test suspension,  $N_0$  = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time (time „0“),  $N_a$  = the number of survivors per ml in the test mixture at the end of the contact time and before the dilution neutralization method,  $N_v$  = the number of cfu/ml of the bacterial test suspension for validation,  $N_{v0}$  = the number of cfu/ml of the bacterial test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralization validation, C – method validation)  
 $\lg N_0 / N_a$  nebo  $\lg R = \lg N_0 - \lg N_a$  the reduction in viability

Prepared by: Mgr. Mirka Horáková, Ph.D., Lab Technician



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

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodos Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 4

**2. Testing the efficacy of chemical disinfectant Quatrodos Forte on *Mycobacterium terrae* ATCC 15755**

**Tab No. 2.1.1 Verification of methodology, clean conditions**

Validation of suspension ( $N_{v0}$ )				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 4%			
$V_{c1}$	30	$\Phi_{N_{v0}} = 31.5$		$V_{c1}$	29	$\Phi_A = 31$		$V_{c1}$	37	$\Phi_B = 34.5$		$V_{c1}$	32	$\Phi_C = 35$	
$V_{c2}$	33			$V_{c2}$	33			$V_{c2}$	32			$V_{c2}$	38		
$30 \leq \Phi_{N_{v0}} \leq 160$				$\Phi_A \geq 0.5 \Phi_{N_{v0}}$				$\Phi_B \geq 0.5 \Phi_{N_{v0}}$				$\Phi_C \geq 0.5 \Phi_{N_{v0}}$			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

**Tab No. 2.1.2 Verification of methodology, dirty conditions**

Validation of suspension ( $N_{v0}$ )				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 4%			
$V_{c1}$	30	$\Phi_{N_{v0}} = 31.5$		$V_{c1}$	32	$\Phi_A = 31$		$V_{c1}$	37	$\Phi_B = 34.5$		$V_{c1}$	28	$\Phi_C = 30.5$	
$V_{c2}$	33			$V_{c2}$	30			$V_{c2}$	32			$V_{c2}$	33		
$30 \leq \Phi_{N_{v0}} \leq 160$				$\Phi_A \geq 0.5 \Phi_{N_{v0}}$				$\Phi_B \geq 0.5 \Phi_{N_{v0}}$				$\Phi_C \geq 0.5 \Phi_{N_{v0}}$			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

**Tab No. 2.2 Test suspensions**

Test suspension N $\Phi = 190 \times 10^7 = \lg 9.28$ $9.17 \leq \lg N \leq 9.70$	N	$V_{c1}$	$V_{c2}$	Test suspension $N_0$ (time = 0) $\lg N_0 = \lg N/10 = \lg 8.28$ $8.17 \leq \lg N_0 \leq 8.70$
	$10^{-7}$	183	193	
	$10^{-8}$	20	22	
				x yes no

**Tab No. 2.3 Testing the efficacy of chemical disinfectant Quatrodos Forte on *Mycobacterium terrae* ATCC 15755**

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	$V_{c1}$	$V_{c2}$	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ( $\lg N_0 = \lg 8.28$ )
1/30/clean	$10^{-1}$	<14	<14	< 3.15	$\geq 5.13$
1/30/dirty	$10^{-1}$	<14	<14	< 3.15	$\geq 5.13$
4/15/clean	$10^{-1}$	<14	<14	< 3.15	$\geq 5.13$
4/15/dirty	$10^{-1}$	<14	<14	< 3.15	$\geq 5.13$

Note:  $V_c$  = value is the number of cfu per ml,  $\Phi$  = average  $V_{c1}$  a  $V_{c2}$  (1. + 2. duplicate  $V_c$  values), N = the number of cfu/ml of the bacterial test suspension,  $N_0$  = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time (time „0“),  $N_a$  = the number of survivors per ml in the test mixture at the end of the contact time and before the dilution neutralization method,  $N_v$  = the number of cfu/ml of the bacterial test suspension for validation,  $N_{v0}$  = the number of cfu/ml of the bacterial test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralization validation, C – method validation)

$R = N_0 / N_a$  nebo  $\lg R = \lg N_0 - \lg N_a$  the reduction in viability

Prepared by: Mgr. Mirka Horáková, Ph.D., Lab Technician



Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodos Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 5

3. Evaluation of tuberculocidal activity of the product **Quatrodos Forte**

Tab No. 3.1 The efficacy of chemical disinfectant **Quatrodos Forte** on test strain – mycobactericidal and tuberculocidal activity

Mycobactericidal and tuberculocidal activity of the product (EN 14348)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	lg R EN 14348	lg R
<i>Mycobacterium avium</i> ATCC 15769	20	30	1	clean	> 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	30	1	clean	> 4	> 4
<i>Mycobacterium avium</i> ATCC 15769	20	30	1	dirty	> 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	30	1	dirty	> 4	> 4
<i>Mycobacterium avium</i> ATCC 15769	20	15	4	clean	> 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	15	4	clean	> 4	> 4
<i>Mycobacterium avium</i> ATCC 15769	20	15	4	dirty	> 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	15	4	dirty	> 4	> 4

Note:  $V_c$  = value is the number of cfu per ml,  $\Phi$  = average  $V_{c1}$  a  $V_{c2}$  (1. + 2. duplicate  $V_c$  values), N = the number of cfu/ml of the bacterial test suspension,  $N_0$  = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time (time „0“),  $N_a$  = the number of survivors per ml in the test mixture at the end of the contact time and before the dilution neutralization method,  $N_v$  = the number of cfu/ml of the bacterial test suspension for validation,  $N_{v0}$  = the number of cfu/ml of the bacterial test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralization validation, C – method validation)

$R = N_0 / N_a$  nebo  $lg R = lg N_0 - lg N_a$  the reduction in viability

Prepared by: Mgr. Mirka Horáková, Ph.D., Lab Technician



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

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodex Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 6

Experiment conditions:

**Quantitative test for evaluation of virucidal activity**

SOP-M-19-00 (EN 14476+A1)

Period of analysis:

15. 11. - 21. 11. 2013

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtiter plates

Appearance of the products:

yellow liquid

Product diluent:

hard water

Test concentration:

0.5%

Contact time:

15 min

Interfering substances:

0.3 g/l BSA (clean conditions)

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

Reference product:

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

K44006603245, expiry date: 30.11.14

Procedure to stop action of product: The virucidal activity is immediately suppressed by transfer of the sample into 9 volumes of ice-cold diluent. The dilutions are transferred into cell culture units-wells of micro titre plates. For the quantal test are inoculated 6 units with each dilution. For validation is used reference item. Incubation: 36 °C ± 1 °C, 5 % CO<sub>2</sub>, 96 h, and additional period of 24 h, 48 hours. After incubation, the titre infectivity is calculated according to Spearman-Kärber method. The reduction of virus inactivation are calculated from differences of lg virus titres before and after treatment with test product – virucidal effect.

Test virus:

*Vaccinia virus* strain Elstree CAMP V-160 (2<sup>th</sup> passage)

Cell lines:

VERO cells

Titre values are calculated according to Spearman and Kärber.

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 4 (lg) orders.

The standard:

EN 14476+A1 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine – Test method and requirements (phase 2, step 1) October 2006

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodos Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 7

4. Testing the efficacy of chemical disinfectant **Quatrodos Forte** on *Vaccinia virus* strain Elstree CAMP V-160

Tab No. 4.1 Table of results of product **Quatrodos Forte** on *Vaccinia virus* strain Elstree CAMP V-160

Product	Concentration	Interfering substances	Level of cytotoxicity	- log <sub>10</sub> TCID <sub>50</sub> after 15 min	- log <sub>10</sub> TCID <sub>50</sub> after 30 min
<b>Quatrodos Forte</b>	0.5%	clean	2.50	4.00	-
<b>Quatrodos Forte</b>	0.5%	dirty	2.50	4.50	-
<b>Formaldehyde</b>	0.7 % (w/v)	PBS	3.50	-	6.67
			Virus titration, time = 0		
Virus control	-	PBS	8.50	-	8.50
Virus control	-	clean	8.50	8.50	-
Virus control	-	dirty	8.50	8.50	-

Tab No. 4.2 Testing the efficacy of chemical disinfectant **Quatrodos Forte** on *Vaccinia virus* strain Elstree CAMP V-160

Test concentration	Titre of the virus suspension - log <sub>10</sub> TCID <sub>50</sub>	Interfering substances	Contact time	- log <sub>10</sub> TCID <sub>50</sub> after test procedure	Δlog <sub>10</sub> TCID <sub>50</sub>
0.5%	8.50	clean	15 min	4.00	<b>4.50</b>
0.5%	8.50	dirty	15 min	4.50	<b>4.00</b>

5. Evaluation of virucidal activity of the product **Quatrodos Forte**

Tab No. 5.1 The efficacy of chemical disinfectant **Quatrodos Forte** on test viruses – virucidal activity

Virucidal activity of the product						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	Δlog <sub>10</sub> TCID <sub>50</sub> EN 14476+A1	Δlog <sub>10</sub> TCID <sub>50</sub>
<i>Vaccinia virus</i> strain Elstree CAMP V-160	20	15	0.5	clean	≥ 4	> 4
<i>Vaccinia virus</i> strain Elstree CAMP V-160	20	15	0.5	dirty	≥ 4	4

Note:

TCID<sub>50</sub>- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, Lab Technician



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

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodes Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 8

Experiment conditions:

Period of analysis:

Test temperature:

Method of titration:

Appearance of the products:

Product diluent:

Test concentration:

Contact time:

Interfering substances:

Reference product:

**Quantitative test for evaluation of virucidal activity**

SOP-M-19-00 (EN 14476+A1)

28. 11. - 5. 12. 2013

20 °C ± 1 °C

virus titration on monolayers of cells on microtiter plates

yellow liquid

hard water

0.5%

15 min

0.3 g/l BSA (clean conditions)

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

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

K44006603245, expiry date: 30.11.14

Procedure to stop action of product: The virucidal activity is immediately suppressed by transfer of the sample into 9 volumes of ice-cold diluent. The dilutions are transferred into cell culture units-wells of micro titre plates. For the quantal test are inoculated 6 units with each dilution. For validation is used reference item. Incubation: 36 °C ± 1 °C, 5 % CO<sub>2</sub>, 96 h, and additional period of 24 h, 48 hours. After incubation, the titre infectivity is calculated according to Spearman-Kärber method. The reduction of virus inactivation are calculated from differences of lg virus titres before and after treatment with test product – virucidal effect.

Test virus: *BVDV* strain NADL ATCC-VR-534 (6<sup>th</sup> passage)

Cell lines: MDBK cells

Titre values are calculated according to Spearman and Kärber.

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 4 (lg) orders.

The standard:

EN 14476+A1 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine – Test method and requirements (phase 2, step 1) October 2006

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatrodex Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 9

6. Testing the efficacy of chemical disinfectant **Quatrodex Forte** on *BVDV* strain NADL ATCC-VR-534

Tab No. 6.1 Table of results of product **Quatrodex Forte** on *BVDV* strain NADL ATCC-VR-534

Product	Concentration	Interfering substances	Level of cytotoxicity	- log <sub>10</sub> TCID <sub>50</sub> after 15 min	- log <sub>10</sub> TCID <sub>50</sub> after 30 min
<b>Quatrodex Forte</b>	0.5%	clean	2.50	3.67	-
<b>Quatrodex Forte</b>	0.5%	dirty	2.50	4.00	-
<b>Formaldehyde</b>	0.7 % (w/v)	PBS	3.50	-	6.00
			Virus titration, time = 0		
Virus control	-	PBS	8.50	-	8.50
Virus control	-	clean	8.50	8.50	-
Virus control	-	dirty	8.50	8.50	-

Tab No. 6.2 Testing the efficacy of chemical disinfectant **Quatrodex Forte** on *BVDV* strain NADL ATCC-VR-534

Test concentration	Titre of the virus suspension - log <sub>10</sub> TCID <sub>50</sub>	Interfering substances	Contact time	- log <sub>10</sub> TCID <sub>50</sub> after test procedure	Δlog <sub>10</sub> TCID <sub>50</sub>
0.5%	8.50	clean	15 min	3.67	<b>4.83</b>
0.5%	8.50	dirty	15 min	4.00	<b>4.50</b>

7. Evaluation of virucidal activity of the product **Quatrodex Forte**

Tab No. 7.1 The efficacy of chemical disinfectant **Quatrodex Forte** on test viruses – virucidal activity

Virucidal activity of the product						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	Δlog <sub>10</sub> TCID <sub>50</sub> EN 14476+A1	Δlog <sub>10</sub> TCID <sub>50</sub>
<i>BVDV</i> strain NADL ATCC-VR-534	20	15	0.5	clean	≥ 4	> 4
<i>BVDV</i> strain NADL ATCC-VR-534	20	15	0.5	dirty	≥ 4	> 4

Note:

TCID<sub>50</sub> - 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*

Sample ID: D166/2013

Rep No: 173

Sample name: **Quatroles Forte**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Sampling date: 6.11.2013

Sample delivered: 8.11.2013

Testing date: 15.11.2013-2.1.2014

Delivered amount: 250 ml

Batch No: A-25-PAZ-33

Page: 10

Interpretation:

Results of tests are in Tabs.

The tested product **Quatroles Forte**, batch No. A-25-PAZ-33, in the concentration 1%, diluted in hard water, and the contact time 30 min and in the concentration 4%, diluted in hard water, and the contact time 15 min under clean and dirty conditions at temperature  $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$  by the dilution-neutralization method **decreased** the number of alive microbes *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 by 4 (lg) orders (EN 14348).

The tested product **Quatroles Forte**, batch No. A-25-PAZ-33, in the concentration 0.5%, diluted in hard water, and the contact time 15 min under clean and dirty 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 microtiter plates to reduce the number of infectious *Vaccinia virus* strain Elstree CAMP V-160 particles under defined conditions by at least 4 (lg) orders (EN 14476+A1).

The tested product **Quatroles Forte**, batch No. A-25-PAZ-33, in the concentration 0.5%, diluted in hard water, and the contact time 15 min under clean and dirty 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 microtiter plates to reduce the number of infectious *BVDV* strain NADL ATCC-VR-534 particles under defined conditions by at least 4 (lg) orders (EN 14476+A1).

Conclusion:

The product **Quatroles Forte** is capable of reducing the number of viable mycobacterial cells of the relevant organism under defined conditions to the declared values, and consequently, may be called mycobactericidal and tuberculocidal.

The product **Quatroles Forte** is capable of reducing the number of infectious *Vaccinia virus* strain Elstree CAMP V-160 particles under defined conditions to the declared values, and consequently, can be called virucidal on *Vaccinia virus*. The product **Quatroles Forte** is capable of reducing the number of infectious *BVDV* strain NADL ATCC-VR-534 particles under defined conditions to the declared values, and consequently, can be called virucidal on *BVDV*.

20.2.2014, Hodonín

