



Chemila, spol. s r.o., Za Dráhou 4386/3, 695 01 Hodonín, CZ, Phone/Fax +420518340919, 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

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From pages: 10

Incoming date:

8.11.2013

Delivery date:

20.2.2014

Hodonín, 20.2.2014



Zuzana Matušková, Head of Laboratory

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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:	<i>Mycobacterium terrae</i> ATCC 15755 <i>Mycobacterium avium</i> 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

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
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Delivered amount: 250 ml
Batch No: A-25-PAZ-33
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The Number of CFU in the tested product **Quatrodos Forte**: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **Quatrodos Forte** on *Mycobacterium avium* ATCC 15769

Tab No. 1.1.1 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	$\Phi_{N_{v0}} = 33$		V_{c1}	29	$\Phi_A = 30.5$		V_{c1}	31	$\Phi_B = 28$		V_{c1}	35	$\Phi_C = 33$	
V_{c2}	36			V_{c2}	32			V_{c2}	25			V_{c2}	31		
$30 < \Phi_{N_{v0}} \leq 160$				$\Phi_A \geq 0.5 \Phi_{N_{v0}}$				$\Phi_B \geq 0.5 \Phi_{N_{v0}}$				$\Phi_C \geq 0.5 \Phi_{N_{v0}}$			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 1.1.2 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	$\Phi_{N_{v0}} = 33$		V_{c1}	30	$\Phi_A = 32$		V_{c1}	31	$\Phi_B = 28$		V_{c1}	28	$\Phi_C = 30.5$	
V_{c2}	36			V_{c2}	34			V_{c2}	25			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. 1.2 Test suspensions

Test suspension N $\Phi = 174 \times 10^7 = \lg 9.24$ $9.17 \leq \lg N \leq 9.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 8.24$ $8.17 \leq \lg N_0 \leq 8.70$	
	10^{-7}	167	182		
	10^{-8}	18	15		
				x	yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **Quatrodos Forte** on *Mycobacterium avium* ATCC 15769

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

Note: V_c = value is the number of cfu per ml, Φ = 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

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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	≥ 5.13
1/30/dirty	10^{-1}	<14	<14	< 3.15	≥ 5.13
4/15/clean	10^{-1}	<14	<14	< 3.15	≥ 5.13
4/15/dirty	10^{-1}	<14	<14	< 3.15	≥ 5.13

Note: V_c = value is the number of cfu per ml, Φ = 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: **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

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

Tab No. 3.1 The efficacy of chemical disinfectant **Quatrodes 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, Φ = 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: **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

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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 % CO₂, 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 (2th 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: **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

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

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

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min
Quatroles Forte	0.5%	clean	2.50	4.00	-
Quatroles Forte	0.5%	dirty	2.50	4.50	-
Formaldehyde	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 **Quatroles Forte** on *Vaccinia virus* strain Elstree CAMP V-160

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
0.5%	8.50	clean	15 min	4.00	4.50
0.5%	8.50	dirty	15 min	4.50	4.00

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

Tab No. 5.1 The efficacy of chemical disinfectant **Quatroles 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 ₁₀ TCID ₅₀ EN 14476+A1	Δlog ₁₀ TCID ₅₀
<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:

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

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: **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: 8

Experiment conditions:

Quantitative test for evaluation of virucidal activity

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

Period of analysis:

28. 11. - 5. 12. 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 % CO₂, 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 (6th 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: **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

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

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

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min
Quatroles Forte	0.5%	clean	2.50	3.67	-
Quatroles Forte	0.5%	dirty	2.50	4.00	-
Formaldehyde	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 **Quatroles Forte** on *BVDV* strain NADL ATCC-VR-534

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
0.5%	8.50	clean	15 min	3.67	4.83
0.5%	8.50	dirty	15 min	4.00	4.50

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

Tab No. 7.1 The efficacy of chemical disinfectant **Quatroles 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 ₁₀ TCID ₅₀ EN 14476+A1	Δlog ₁₀ TCID ₅₀
<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:

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 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: **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

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Interpretation:

Results of tests are in Tabs.

The tested product **Quatrodos 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 **Quatrodos 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 **Quatrodos 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 **Quatrodos 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 **Quatrodos 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 **Quatrodos 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

