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Copy No.: 1 Issue No.: 1

Test report No. S569/2020

DETERMINATION OF FUNGICIDAL (EN 13624:2013), MYCOBACTERICIDAL AND TUBERCULOCIDAL (EN 14348:2005) **ACTIVITY OF THE PRODUCT** VELOX OXY ETA DETERMINATION OF VIRUCIDAL (EN 14476:2013 +A2:2019) ACTIVITY OF THE PRODUCT VELOX OXY ETA

Sample ID: S569/2020

Sample name: Velox Oxy ETA

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Producer: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Page: 1

From pages: 19

Incoming date:

27.11.2020

Delivery date: 14.10.2021

Hodonín, 14.10.2021

Ing. Jana Sitrová, Head of Laboratory

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Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021 Delivered amount: 2 x 1 1

Batch No: 231120-92

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Subject of testing:

Determination of fungicidal, mycobactericidal, tuberculocidal and virucidal activity of the product.

Identification of the sample:

Name of the product:

Batch number:

Date of manufacture: Expiry date:

Manufacturer:

Incoming date:

Storage conditions: Active ingredients in 100 g: Velox Oxy ETA 231120-92

23.11.2020 23.05.2022

MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

27.11.2020

at room temperature in dark area

Ethanol 72,8 g Propan-2-ol 7,2 g

Hydrogen peroxide 3 g

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and

Period of analysis:

Test temperature:

Test method:

Filtration diluent: Appearance of the product:

Test concentration:

Contact time:

Interfering substances: Test organisms:

Incubation conditions:

antiseptic agents by suspension method

SOP-M-19-00 (EN 14348:2005)

15.3. - 5.4.2021

 $20 \, ^{\circ}\text{C} \pm 1 \, ^{\circ}\text{C}$

membrane filtration method

rinsing liquid colourless liquid

100% (concentrated)* 30 s (0.5 min), 3 min

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

Mycobacterium avium

ATCC 15769 ATCC 15755 Mycobacterium terrae

 $37 \,^{\circ}\text{C} \pm 1 \,^{\circ}\text{C}$, 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 a 4 lg reduction (104). 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 a 4 lg reduction (104).

 $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

The standard:

EN 14348:2005 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

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021 Delivered amount: 2 x 11

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Batch No: 231120-92

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

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

1. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Mycobacterium avium ATCC 15769

Tab No. 1.1 Verification of methodology, dirty conditions

Val	lidation of susp	pension (N _{vo})	Validation of selected experimental conditions (A)			Me (B)	mbrane filtra	ation control	Method validation (C) Product conc.: 100%*		
V_{c1}	48	Ø - 10 5	Vcl	55	A 10	Vc1	43		Vcl	58	
V_{c2}	51	$\Phi_{\text{Nvo}} = 49.5$	V_{c2}	41	$\Phi_{A} = 48$	V _{c2}	60	$\Phi_{\rm B} = 51.5$	V _{c2}	38	$\Phi_{\rm C} = 48$
30 <	$\leq \Phi_{\text{Nvo}} \leq 160$		$\Phi_A \ge 0$	0.5 Φ _{Nvo}		Фв	≥ 0.5 Φ _{Nvo}		$\Phi_{\rm C} \ge$	0.5 Φ _{Nvo}	
X	yes	no	X	yes	no	X	yes	no	X	yes	no

Tab No. 1.2 Test suspensions

Test suspension N	N	Vcl	V _{c1}	Test suspension No (time			
$\Phi = 49 \times 10^8 = \lg 9.69$	10-7	> 165	> 165	$\lg N_0 = \lg N/10 = \lg 8.69$			
$9.17 \le \lg N \le 9.70$	10-8	46	52		1/1/2/2017	$\leq \lg N_0 \leq 8.70$	
The state of the s				x	ves	no	

Tab No. 1.3 Testing the efficacy of chemical disinfectant Velox Oxy ETA 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) $	
100* / 0.5 / dirty	10-4	26	42	6.53	2.16
100* / 3 / dirty	10-2	16	19	4.24	4.45

2. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Mycobacterium terrae ATCC 15755

Tab No. 2.1 Verification of methodology, dirty conditions

Val	lidation of susp	ension (N _{vo})		dation or	of selected ditions (A)	Me (B)	mbrane filti	ration control	5 9 9 9 9 9	thod validati	
V_{c1}	37	A 27.5	Vel	36	* 22.5	Vcl	37		Vcl	41	
V _{e2}	38	$\Phi_{\text{Nvo}} = 37.5$	V_{c2} 31 $\Phi_A = 33.5$		_	V_{c2} 35 $\Phi_B = 36$			V_{c2} 37 Φ_C		
30	$\leq \Phi_{\text{Nvo}} \leq 160$		$\Phi_A \ge$	0.5 Φ _{Nvo}		Фв	≥ 0.5 Φ _{Nvo}			≥ 0.5 Φ _{Nvo}	
X	yes	no	X	yes	no	х	yes	no	X	yes	no

Tab No. 2.2 Test suspensions

Test suspension N	N	V_{c1}	Vel	Test suspension N_0 (time = 0				
$\phi = 40.5 \times 10^8 = \lg 9.61$	10-7 > 165		> 165	$\lg N_0 = \lg N/10 = \lg 8.61$				
$9.17 \le \lg N \le 9.70$	10-8	40	41		$N_0 \le 8.70$			

Tab No. 2.3 Testing the efficacy of chemical disinfectant Velox Oxy ETA on Mycobacterium terrae ATCC 15755

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	Vel	V _{c2}	$\begin{array}{c} lg \; N_a = \\ lg \; (\Phi_a x \; 10) \end{array}$	
100* / 0.5 / dirty	10-2	95	106	5.00	3.61
100* / 3 / dirty	10-1	<14	<14	< 3.15	> 5.46

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 test suspension, No = the number of cfu/ml of the test suspension at the beginning of the contact time (time "0"), Na = the number of viable cells per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0} = the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time ,,0"), A,B,C = the number of viable cells per ml in control tests (A - experimental conditions control, B - membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021

Delivered amount: 2 x 11

Batch No: 231120-92

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3. Evaluation of mycobactericidal and tuberculocidal activity of the product Velox Oxy ETA

Tab No. 3.1 The efficacy of chemical disinfectant Velox Oxy ETA on test strain - mycobactericidal and tuberculocidal activity

Strain	Test temperature	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 14348:2005	lg R
	[°C]		100	dirty	≥4	< 4
Mycobacterium avium ATCC 15769	20	0.5	100	dirty	>4	< 4
Mycobacterium terrae ATCC 15755	20	0.5		dirty	>4	>4
Mycobacterium avium ATCC 15769	20	3	100		24	>4
Mycobacterium terrae ATCC 15755	20	3	100	dirty	24	-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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time "0"), Na = the number of viable cells per ml in the test mixture at the end of the contact time and before the membrane filtration, N_{ν} = the number of cfu/ml of the test suspension for validation, $N_{\nu 0}$ = the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time "0"), A,B,C = the number of viable cells per ml in control tests (A - experimental conditions control, B - membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Ing. Eva Kremlová, Lab Technician Prepared by:

Sample ID: S569/2020 Sampling date: 23.11.2020 Rep No: 20 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021 Sample name: Velox Oxy ETA

Sampled: by client Delivered amount: 2 x 11 Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Page: 5

Experimental conditions: Testing of disinfecting efficiency of chemical disinfecting and

antiseptic agents by suspension method

Batch No: 231120-92

SOP-M-19-00 (EN 13624:2013)

Period of analysis: 26.3. - 29.3.2021Test temperature: 20 °C ± 1 °C

Test method: membrane filtration method

Filtration diluent: rinsing liquid Appearance of the product: colourless liquid Test concentration: 100% (concentrated)*

Contact time: 15 s (0.25 min), 30 s (0.5 min), 1 min, 3 min

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

Test organisms: Candida albicans ATCC 10231 Aspergillus brasiliensis (niger) ATCC 16404

30 °C \pm 1 °C, 48 hours and additional period of 24 or 48 hours Incubation conditions:

Test procedure:

1. Preparation of test suspension

2. Preparation of product test solutions

3. Quantitative suspension test4. Incubation and calculation

5. Expression and interpretation of results

Note:

Presence of a high concentration (at least 75%) of Aspergillus brasiliensis spiny spores in the test suspension –

Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi belonging to reference strains under defined conditions by at least a 4 lg reduction (10⁴).

Yeasticidal activity - the capability of a product to produce a reduction in the number of viable yeast cells of relevant test organisms under defined conditions by at least a 4 lg reduction (10⁴).

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

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

The standard:

EN 13624:2013 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1) September 2013

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Delivered amount: 2 x 1 l

Batch No: 231120-92

Sampling date: 23.11.2020

Sample delivered: 27.11.2020

Testing date: 15.3. - 12.5.2021

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

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4. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Candida albicans ATCC 10231

Tab No. 4.1 Verification of methodology, dirty conditions

Tab No. 4.1 Verification of Validation of Suspension (N _{V0})	Valie	dation rimental cor	of	selected	Mem	brane filt	ration c	control (l	B)	Me Pro	thod validation	on (C 100%*)
$\frac{V_{c1}}{V_{c2}}$ $\frac{62}{57}$ $\Phi_{Nvo} = 59.5$	V _{c1}	58 48		= 53	V _{c1}	6		Фв =	= 59	V _c	$ \begin{array}{c c} & 47 \\ \hline 2 & 52 \\ \hline > \ge 0.5 \Phi_{\text{Nyo}} \end{array} $	Фс	= 49.5
$30 \le \Phi_{\text{Nvo}} \le 160$	$\Phi_{A} \ge$	0.5 Φ _{Nvo}			_	0.5 Φ _{Nνο}			no	Y Y	ves		no
x yes no	X	yes		no	X	yes			110	A	100	- XV 3= 1	
. (21)	T X/	63	V _{c2}	55		Φ _{NVB}	5	9	30 <	Φ _{NVB}	$(N_{VB}/1000) \le$	160	
Validation of suspension (N _{VB})	Vcl	0.5	V C2	00					X	yes			no

b No. 4.2 Test suspens	N	Vel	V _{c1}	Test suspe	nsion N_0 (time = 0)		
Test suspension N $p = 21 \times 10^6 = \lg 7.32$	10-5	> 165	> 165				
$\phi = 21 \times 10^{-1} \text{ lg } 7.32$ $7.17 \le \text{ lg } N \le 7.70$	10-6	19	23	6.17	$\leq \lg N_0 \leq 6.70$		

Tab No. 4.3 Testing the efficacy of chemical disinfectant Velox Oxy ETA on Candida albicans ATCC 10231

Tab No. 4.3 Testin Test concentration (%) / contact time	Dilution after test	V _{c1}	V _{c2}	$ \lg N_a = \\ \lg (\Phi_a \times 10) $		
(min)/conditions			<14	< 2.15	≥ 4.17	
100* / 0.25 / dirty	10°	<14	<14	2.15	≥ 4.17	
100* / 0.5 / dirty	10°	<14	<14	< 2.15	es) N = the number	

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, Na = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A - experimental conditions control, B - membrane filtration validation, C - method validation), R = $N_0 \! / \; N_a$ = the reduction in viability, or lg R = lg $N_0 - lg \; N_a$

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sample ID: S569/2020

Rep No: 20 Sample name: Velox Oxy ETA

Sampled: by client

Sampling date: 23.11.2020 Sample delivered: 27.11.2020

Testing date: 15.3. – 12.5.2021 Delivered amount: 2 x 1 1

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Batch No: 231120-92

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5. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Aspergillus brasiliensis (niger) ATCC 16404

Tab No. 5.1 Verification of methodology, dirty conditions

Valida	tion of sus	spension (N _{V0})	1 / / /	lation rimental con		selected A)	Me	embrane	filtration	control (B)		thod valid		
Vcl	50	$\Phi_{\text{Nvo}} = 45.5$	Vel	40	Φ	- 27 5	V	c1	41	4	115	Vci	47		
V _{c2}	41	Ψ _{Nvo} - 43.3	V _{c2}	35	Φ_{A} =	= 37.5	Ve		48	$\Phi_{\mathbf{B}} =$	44.5	Vez	41	- q	$o_{\rm C} = 44$
30 ≤ Φ	_{Nvo} ≤160		$\Phi_A \ge$	0.5 Φ _{Nvo}			Фв	≥ 0.5 Φ	Nvo			Фс	≥ 0.5 Φ _{Nvo}		
x ye	es	no	X	yes		no	х	yes			no	X	yes		no
									_						
Valida	tion of sus	pension (N _{VB})	Vcl	57	V _{c2}	45		Φ_{NVB}		51	30 <	Φ_{NVB} ($N_{VB}/1000$)	≤ 160	
											X	ves			no

Tab No. 5.2 Test suspension

Test suspension N	N	V_{cl}	Vel	Test suspension N ₀ (time =				
$\Phi = 21.5 \times 10^6 = \lg 7.33$	10-5	> 55	> 55			N/10 = lg 6.33		
$7.17 \le \lg N \le 7.70$	10-6	23	20		10 TO	$N_0 \le 6.70$		
				х	ves	no		

Tab No. 5.3 Testing the efficacy of chemical disinfectant Velox Oxy ETA on Aspergillus brasiliensis (niger) ATCC 16404

Test concentration (%) / contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$ \lg N_a = \\ \lg (\Phi_a \times 10) $	
100* / 1 / dirty	10°	<14	<14	< 2.15	≥ 4.18
100* / 3 / dirty	10°	<14	<14	< 2.15	≥ 4.18

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N_0/N_a = the reduction in viability, or $\log R = \log N_0 - \log N_a$

^{*} The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Testing date: 15.3. - 12.5.2021 Delivered amount: 2 x 11

Sample delivered: 27.11.2020

Sampling date: 23.11.2020

Batch No: 231120-92 Page: 8

6. Evaluation of fungicidal activity of the product Velox Oxy ETA

Tab No. 6.1 The efficacy of chemical disinfectant Velox Oxy ETA on test strains - fungicidal activity

	Fungicidal activ	vity of the pro	duct (EN 13624:201)	3)	1 1 5	I- D
Strain	Test temperature	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 13624:2013	lg R
Candida albicans ATCC 10231	20	0.25	100	dirty	≥ 4	> 4
Aspergillus brasiliensis (niger) ATCC 16404	20	1	100	dirty	≥ 4	> 4
Candida albicans ATCC 10231	20	0.5	100	dirty	≥ 4	> 4
Aspergillus brasiliensis (niger)	20	3	100	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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A - experimental conditions control, B - membrane filtration validation, C - method validation), R = N_0/N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Hana Konevalíková, Lab Technician Prepared by:

 Sample ID: S569/2020
 Sampling date: 23.11.2020

 Rep No: 20
 Sample delivered: 27.11.2020

 Sample name: Velox Oxy ETA
 Testing date: 15.3. – 12.5.2021

Sampled: by client Delivered amount: 2 x 11

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
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Experiment conditions: Testing of disinfecting efficiency of chemical disinfecting and

antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A2:2019)

Period of analysis: 5.5. - 12.5.2021Test temperature: $20 \,^{\circ}\text{C} \pm 1 \,^{\circ}\text{C}$

Method of titration: virus titration on monolayers of cells on microtitre plates

Appearance of the product: colourless liquid

Test concentration: 100% (concentrated)*/**

Contact time: 15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)

Interfering substances: 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:

K52955003, expiry date: 30.11.2022

Test virus: Adenovirus type 5, strain Adenoid 75, ATCC VR-5 (2nd passage)

Cell lines: HeLa cells (18th passage)

Incubation: $36 \,^{\circ}\text{C} \pm 1 \,^{\circ}\text{C}$, $5 \,^{\circ}\text{CO}_2$, $96 \,^{\circ}\text{h}$, 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.

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

The standard:

EN 14476:2013 +A2:2019 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 + July 2019

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

VR-5

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021 Delivered amount: 2 x 11

Sampling date: 23.11.2020

Batch No: 231120-92 Page: 10

7. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Adenovirus type 5, strain Adenoid 75, ATCC

Tab No. 7.1 Table of results of product Velox Oxy ETA on Adenovirus type 5, strain Adenoid 75, ATCC VR-5

Product	Concentration **	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 s	- log ₁₀ TCID ₅₀ after 30 s	- log ₁₀ TCID ₅₀ after 1 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
Velox Oxy ETA	100%*	dirty***	4.50	6.00	5.50	5.33	2.7	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	(*)	- 1	5.83	5.00
			Virus titration, time = 0					0.50
Virus control	2	PBS	9.33	-	/e:	(-	9.50	9.50
Virus control	_	dirty	9.50		-	9.50	-	-

Tab No. 7.2 Testing the efficacy of chemical disinfectant Velox Oxy ETA 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	dirtv***	15 s	6.00	3.50
100%*	9.50	dirty***	30 s	5.50	4.00
100%*	9.50	dirty***	60 s	5.33	4.17

Tab No. 7.3 Testing the efficacy of reference item Formaldehyde on Adenovirus type 5, strain Adenoid 75, ATCC VD 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
0.7 % (w/v)	9.33	PBS	30 min	5.83	3.50
0.7 % (w/v)	9.33	PBS	60 min	5.00	4.33

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

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Sample ID: S569/2020

Rep No: 20 Sample name: Velox Oxy ETA

Sampled: by client

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. – 12.5.2021

Delivered amount: 2 x 11

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Batch No: 231120-92

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

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8. Evaluation of virucidal activity of the product Velox Oxy ETA

Tab No. 8.1 The efficacy of chemical disinfectant Velox Oxy ETA on test viruses - virucidal activity

			. Trong City Estin	OII TODE TIL GOOD	THUCIAMI ACTIV	ity
	Virucida	al activity of t	he product (EN 14476	5:2013 +A2:2019)		
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations **	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	15	100%*	dirty***	≥4	< 4
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	30	100%*	dirty***	≥4	4
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	60	100%*	dirty***	≥ 4	> 4

Tab No. 8.2 The efficacy of reference item Formaldehyde on test viruses - virucidal activity

	Virucida	l activity of th	ne product (EN 14476	5:2013+A2:2019)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations **	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A2:2019	Δlog ₁₀ TCID ₅₀
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	30	0.7 % (w/v)	PBS	3.0 – 5.0	3.50
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	60	0.7 % (w/v)	PBS	3.5 – 5.5	4.33

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

- * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
- ** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.
- *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by:

Ing. Eva Kremlová, Lab Technician Bc. Iva Čížová, Lab Technician

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. – 12.5.2021

Delivered amount: 2 x 1 1

Batch No: 231120-92

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

(EN 14476:2013 +A2:2019)

Period of analysis:

Test temperature:

Method of titration:

Appearance of the product:

Test concentration:

Contact time:

Interfering substances:

Reference product:

antiseptic agents by suspension method SOP-M-19-00

4.5. - 11.5.202120 °C ± 1 °C

virus titration on monolayers of cells on microtitre plates

colourless liquid 100% (concentrated)*/**

15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)*** Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K52955003, expiry date: 30.11.2022 Poliovirus type 1, LSc-2ab (2nd passage)

Test virus: HeLa cells (18th passage) Cell lines:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After Incubation:

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

Preparation of the cell culture 2.

3. Preparation of the test virus suspension

4. Test of the viral infectivity

5. Virus titration with the interfering substance

6. Cytotoxicity of the product

7. Reference virus inactivation test

8. Test procedure for the virucidal activity of the product

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 (10⁴).

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

The standard:

EN 14476:2013 +A2:2019 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 + July 2019

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021

Delivered amount: 2 x 1 1 Batch No: 231120-92

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9. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Poliovirus type 1, LSc-2ab

Tab No. 9.1 Table of results of product Velox Oxy ETA on Poliovirus type 1 I Sc-2ab

Product	Concentration **	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 s	- log ₁₀ TCID ₅₀ after 30 s	- log ₁₀ TCID ₅₀ after 1 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
Velox Oxy ETA	100%*	dirty***	4.50	6.17	6.17	6.00	(*)	S#3
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-		8.50	6.50
			Virus titration, time = 0					
Virus control	-	PBS	9.67	-	-	-	9.67	9.50
Virus control	-	dirty	9.50	-	-	9.50	-	-

Tab No. 9.2 Testing the efficacy of chemical disinfectant Velox Oxy ETA on Poliovirus type 1, LSc-2ab

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	dirty***	15 s	6.17	3.33
100%*	9.50	dirty***	30 s	6.17	3,33
100%*	9.50	dirty***	60 s	6.00	3.50

Tab No. 9.3 Testing the efficacy of reference item Formaldehyde on Poliovirus type 1, LSc-2ab

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
0.7 % (w/v)	9.67	PBS	30 min	8.50	1.17
0.7 % (w/v)	9.67	PBS	60 min	6.50	3.17

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

^{*} The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

^{**} Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

^{***} The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sample delivered: 27.11.2020 Testing date: 15.3. – 12.5.2021

Sampling date: 23.11.2020

Delivered amount: 2 x 11 Batch No: 231120-92

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10. Evaluation of virucidal activity of the product Velox Oxy ETA

Tab No. 10.1 The efficacy of chemical disinfectant Velox Oxy ETA on test viruses - virucidal activity

	Virucida	al activity of t	he product (EN 14476	5:2013 +A2:2019)		more
Strain	Test temperature [°C]	Contact time	Product test concentrations **	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
D. Harrison towns 1 I So 2oh	20	15	100%*	dirty***	≥4	< 4
Poliovirus type 1, LSc-2ab	20	30	100%*	dirty***	≥4	< 4
Poliovirus type 1, LSc-2ab			100%*	dirtv***	> 4	< 4
Poliovirus type 1, LSc-2ab	20	60	10076	dirty		

Tak No. 10.2 The efficacy of reference item Formaldehyde on test viruses – virucidal activity

	Virucid	al activity of t	he product (EN 1447	6:2013+A2:2019)		u TCID
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations **	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A2:2019	Δlog ₁₀ TCID ₅₀
D. I 1 I So 2ah	20	30	0.7 % (w/v)	PBS	0.5 - 2.5	1.17
Poliovirus type 1, LSc-2ab				PBS	2.0 - 4.5	3.17
Poliovirus type 1, LSc-2ab	20	60	0.7 % (w/v)	PDS	2.0 - 4.5	541

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

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by:

Ing. Eva Kremlová, Lab Technician

Bc. Iva Čížová, Lab Technician

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sample ID: S569/2020 Sampling date: 23.11.2020 Rep No: 20 Sample delivered: 27.11.2020

Sample name: Velox Oxy ETA Testing date: 15.3. - 12.5.2021 Sampled: by client Delivered amount: 2 x 1 l

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Page: 15

Testing of disinfecting efficiency of chemical disinfecting and **Experiment conditions:**

antiseptic agents by suspension method SOP-M-19-00

Batch No: 231120-92

(EN 14476:2013 +A2:2019)

20.4. - 27.4.2021Period of analysis: 20 °C ± 1 °C

Test temperature: Method of titration:

virus titration on monolayers of cells on microtitre plates Appearance of the product: colourless liquid

Test concentration: 100% (concentrated)*/**

15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min) Contact time:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)*** Interfering substances:

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

K52955003, expiry date: 30.11.2022

Vaccinia virus strain Elstree ATCC-VR-1549 (2nd passage) Test virus:

Cell lines: VERO cells ATCC-CCL-81 (6th passage)

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After Incubation:

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

Preparation of cell culture
 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

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. The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013 +A2:2019).

- * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
- ** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.
- *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

The standard:

EN 14476:2013 +A2:2019 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 + July 2019

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021

Delivered amount: 2 x 1 1

Batch No: 231120-92

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11. Testing the efficacy of chemical disinfectant Velox Oxy ETA on Vaccinia virus strain Elstree ATCC-VR-1549

Tab No. 13.1 Table of results of product Velox Oxy ETA on Vaccinia virus strain Elstree ATCC-VR-1549

Product	Concentration	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 s	- log ₁₀ TCID ₅₀ after 30 s	- log ₁₀ TCID ₅₀ after 1 min	- log ₁₀ TCID ₅₀ after 5 min	- log ₁₀ TCID ₅₀ after 15 min
Velox Oxy ETA	100%*	dirty***	4.50	6.67	6.17	5.83	-	- 0.50
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-	-	9.17	8.50
			Virus titration, time = 0				10.22	10.22
Virus control		PBS	10.50	-	-	-	10.33	10.33
Virus control	-	dirty	10.50	-	-	10.33	-	

Tab No. 13.2 Testing the efficacy of chemical disinfectant Velox Oxy ETA on Vaccinia virus strain Elstree

AT	CC-1	R-1	1549
Te	est con	centra	ation

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	$\Delta log_{10} TCID_{50}$
1000/*	10.50	dirty***	15 s	6.67	3.83
100%*	10.50	dirty***	30 s	6.17	4.33
100%*		dirty***	60 s	5.83	4.67
100%*	10.50	unty	003		

Tab No. 13.3 Testing the efficacy of chemical disinfectant Formaldehyde on Vaccinia virus strain Elstree ATCC-

R-1549 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
0.7.0/ (/)	10.50	PBS	5 min	9.17	1.33
0.7 % (w/v)			15 min	8.50	2.00
0.7 % (w/v)	10.50	PBS	13 11111	0.50	

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

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020

Testing date: 15.3. – 12.5.2021

Delivered amount: 2 x 1 1 Batch No: 231120-92

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14. Evaluation of virucidal activity of the product Velox Oxy ETA

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Tab No. 14.1 The efficacy of chemical disinfectant Velox Oxy ETA on test viruses - virucidal activity

	Virucida	activity of th	e product (EN 14476	:2013 +A2:2019)		
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
Vaccinia virus strain Elstree ATCC-VR-1549	20	15	100%*	dirty***	≥4	< 4
Vaccinia virus strain Elstree ATCC-VR-1549	20	30	100%*	dirty***	≥4	>4
Vaccinia virus strain Elstree ATCC-VR-1549	20	60	100%*	dirty***	≥4	> 4

Tab No. 14.2 The efficacy of chemical disinfectant Formaldehyde on test viruses - virucidal activity

	Virucid	al activity of t	he product (EN 14476	5:2013 +A2:2019)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
Vaccinia virus strain Elstree ATCC-VR-1549	20	5	0.7 % (w/v)	PBS	0.75 – 3.5	1.33
Vaccinia virus strain Elstree ATCC-VR-1549	20	15	0.7 % (w/v)	PBS	2.0 -≥ 4.0	2.00

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

- * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
- ** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.
- *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Bc. Iva Čížová, Lab Technician Prepared by:

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020 Testing date: 15.3. - 12.5.2021

Delivered amount: 2 x 1 1

Batch No: 231120-92 Page: 18

Interpretation:

Results of tests are in Tabs.

The tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact time 3 min under dirty conditions at temperature 20 °C ± 1 °C by the membrane filtration method decreased the number of viable mycobacterial cells of Mycobacterium avium ATCC 15769 and Mycobacterium terrae ATCC 15755 by at least a 4 lg reduction (EN 14348:2005).

According to EN 13624:2013 the tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact times 15 s and 30 s under dirty conditions at temperature 20 °C \pm 1 °C by the membrane filtration method decreased the number of vegetative yeast cells of Candida albicans ATCC 10231 by at least a 4 lg reduction.

According to EN 13624:2013 the tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact times 60 s and 180 s under dirty conditions at temperature 20 °C \pm 1 °C by the membrane filtration method decreased the number of mould spores of Aspergillus brasiliensis (niger) ATCC 16404 by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact times 30 s and 60 s under dirty conditions at temperature 20 °C ± 1 °C proved by the method of virus titration on monolayers of cells on microtiter 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.

According to EN 14476:2013+A2:2019 the tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact times 15 s, 30 s and 60 s under dirty conditions at temperature 20 °C \pm 1 °C did not prove by the method of virus titration on monolayers of cells on microtiter plates to reduce the number of infectious Poliovirus type 1, LSc-2ab particles under defined conditions by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested concentrated* product Velox Oxy ETA, batch No: 231120-92, in the contact times 30 s and 60 s under dirty conditions at temperature 20 °C \pm 1 °C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious Vaccinia virus strain Elstree ATCC-VR-1549 particles under defined conditions by at least a 4 lg reduction.

The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013 +A2:2019)

- * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
- ** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019.
- *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Sample ID: S569/2020

Rep No: 20

Sample name: Velox Oxy ETA

Sampled: by client

Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020 Sample delivered: 27.11.2020

Testing date: 15.3. - 12.5.2021 Delivered amount: 2 x 1 1

Batch No: 231120-92

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Conclusion:

The product Velox Oxy ETA is capable of reducing the number of viable mycobacterial cells of the relevant test organisms under defined conditions (EN 14348:2005 - concentrated, 3 min, dirty conditions, 20 °C) to the declared values, and consequently, can be called mycobactericidal and tuberculocidal.

The product Velox Oxy ETA is capable of reducing the number of vegetative yeast cells of the relevant organism under defined conditions (EN 13624:2013 - concentrated, 15 s and 30 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called yeasticidal.

The product Velox Oxy ETA is capable of reducing the number of mould spores of the relevant organism under defined conditions (EN 13624:2013 - concentrated, 60 s and 3 min, dirty conditions, 20 °C) to the declared values, and consequently, can be called fungicidal.

The product Velox Oxy ETA is capable of reducing the number of infectious Adenovirus particles under defined conditions (EN 14476:2013 +A2:2019 - concentrated, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called virucidal on Adenovirus.

The product Velox Oxy ETA is not capable of reducing the number of infectious Poliovirus particles under defined conditions (EN 14476:2013 +A2:2019 - concentrated, 15 s, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, cannot be called virucidal on Poliovirus.

The product Velox Oxy ETA is capable of reducing the number of infectious Vaccinia virus particles under defined conditions (EN 14476:2013 +A2:2019 - concentrated, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called virucidal on enveloped viruses.

14.10.2021, Hodonín

Ing. Barbora Stoklásková, Leader of Study Approved by:



Raw data - product Velox Oxy ETA tested against Adenovirus type 5, strain Adenoid 75, ATCC VR-5

Sample S569/2020, the test report S569/2020,

EN14476+A2: Adenovirus type 5, strain Adenoid 75, ATCC VR-5 - 2nd passage (LGC Standards Sp. z o.o., PL, 26.6. 2013), HeLa cells - 18th passage (DSMZ, 22.5.2019)

Period of analysis:

5.5. - 12.5.2021

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:

15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)

Interfering substances: Reference product:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)*** Formaldehyde 36 - 38% solution p.a., CAS: 50-00-0, Batch No: K52955003, expiry

			date:	30.11.202	2							
Product	Concentration	Interfering	Contact]	Dilution (lg	g) ^a			
	***	substance	time min	2	3	4	5	6	7	8	9	10
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444 444	444 444	333 333	200 202	000	000	000	000
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444 444	333 333	222 222	000	000	000	000	000
Velox Oxy ETA	100%*	dirty***	1	n.a.	444 444	333 333	222 202	000	000	000	000	000
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000	000	n.d.	n.d.	n.d.	n.d
Velox Oxy ETA cytotoxicity without MicroSpin TM S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	444 444	444 444	n.d.	n.d.	n.d.	n.d.
Formaldehyde	0.7 (w/v)	PBS	30	n.a.	333 333	333 333	200 222	220 220	000	000	000 000	000
	0.7 (W/V)	T B3	60	n.a.	333 333	222 222	200 022	000	000	000	000	000
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	n.a.	444 444	000	000	000	000 000	000	000	000
Interference control	non-cytotoxic concentration	n.a.	n.a.	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	222 200	022
Neutralization	100%*	dirty***	n.a.	n.d.	n.d.	444 444	444 444	333 333	333 333	222 222	n.d.	n.d
			0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	202 222	000
Virus control	n.a.	PBS	30	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	200 222	000
			60	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	020 220	000
Views control		P. A.	0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	002 222	002
Virus control	n.a.	dirty	1	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	202 200	002
Virus control MicroSpin TM S 400 HR	n.a.	dirty	0	444 444	444 444	444 444	444 444	333 333	333 333	322 222	202 220	020 022

a - dilution, 1 to 4 - degree of CPE in 6 cell culture units, 0 - no CPE, n.a. - not applicable, n.d. - not done

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

The calculation of the viral infectivity titre according to EN14476+A2

Negative logarithm of the 50 % end point = negative logarithm of the highest virus concentration used - [({Sum of % affected at each dilution/100} - 0,5) x (lg of dilutions)]

- * The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering
- ** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019. *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by:

Ing. Eva Kremlová, Lab Technician

Bc. Iva Čížová, Lab Technician

Approved by:

Ing. Barbora Stoklásková, Leader of Study

Raw data - product Velox Oxy ETA tested against Poliovirus type 1, LSc-2ab

Sample S569/2020, the test report S569/2020,

EN14476+A2: Poliovirus type 1, LSc-2ab - 2nd passage (NIBSC, 28.3.2018),

HeLa cells - 18th passage (DSMZ, 22.5.2019)

Period of analysis: Test temperature:

4.5. - 11.5.202120 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product: Test concentration:

colourless liquid

Contact time:

100% (concentrated)*/**

15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)

Interfering substances: Reference product:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)*** Formaldehyde 36 - 38% solution p.a., CAS: 50-00-0, Batch No: K52955003, expiry

Product	Concentration Interfering Contact Dilution (lg) ^a													
Troduct	***	substance	time min	2	3	4	5	6	7	8	9	10		
					444	444	222	022	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444	444	222	220	000	000	000	000		
					444	444	222	200	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444	444	222	222	000	000	000	000		
					444	444	222	022	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	1	n.a.	444	444	222	002	000	000	000	000		
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000 000	000	n.d.	n.d.	n.d.	n.d.		
Velox Oxy ETA cytotoxicity without MicroSpin TM S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	000 000	000	n.d.	n.d.	n.d.	n.d.		
			30	n.a.	444	444	333	333	222	222	000	000		
Formueldshude	0.7 (w/v)	PBS	30	n.a.	444	444	333	333	222	222	000	000		
Formaldehyde	0.7 (W/V)	PDS	60	n.a.	444	333	333	222	000	000	000	000		
			00	11.4.	444	333	333	222	000	000	000	000		
Formaldehyde	ormaldehyde 0.7 (w/v) PBS	(w/v) PBS n.a	.7 (w/v) PBS n.a.	PBS n.a.	n.a.	444	000	000	000	000	000	000	000	
cytotoxicity	0.7 (W/Y)			n.u.	11.00	444	000	000	000	000	000	000	000	
Interference	non-cytotoxic	n.a.	n.a.	n.a.	444	444	444	333	333	222	222	000		
control	concentration	11.0.			444	444	444	333	333	222	020	220		
Neutralization	100%*	dirty***	n.a.	n.d.	n.d.	444 444	444 444	333 333	333 333	222	n.d.	n.d.		
an way wan kemenanan an		100000			444	444	444	333	333	222	222	000		
			0	n.a.	444	444	444	333	333	222	200	222		
					444	444	444	333	333	222	022	220		
Virus control	n.a.	PBS	30	n.a.	444	444	444	333	333	222	222	000		
	5-4400				444	444	444	333	333	222	020	022		
			60	n.a.	444	444	444	333	333	222	220	200		
			11900	W-2-2	444	444	444	333	333	222	220	002		
			0	n.a.	444	444	444	333	333	222	220	020		
Virus control	n.a.	dirty		(198990)	444	444	444	333	333	222	200	022		
			1	n.a.	444	444	444	333	333	222	220	200		
Virus control MicroSpin TM S 400 HR	n.a.	dirty	0	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 222	000 020		

a - dilution, 1 to 4 - degree of CPE in 6 cell culture units, 0 - no CPE, n.a. - not applicable, n.d. - not done

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

The calculation of the viral infectivity titre according to EN14476+A2

The formula is:

Negative logarithm of the 50 % end point = negative logarithm of the highest virus concentration used - [({Sum of % affected at each dilution/100} - 0,5) x (lg of dilutions)]

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering

** Due to the high cytotoxicity of the product the test was performed by using MicroSpinTM S 400 HR according to EN 14476:2013 +A2:2019. *** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by:

Ing. Eva Kremlová, Lab Technician

Bc. Iva Čížová, Lab Technician

Approved by:

Ing. Barbora Stoklásková, Leader of Study

Raw data - product Velox Oxy ETA tested against Vaccinia virus strain Elstree ATCC-VR-1549

Sample S569/2020, the test report S569/2020,

EN 14476+A2: *Vaccinia virus* strain Elstree ATCC-VR-1549 – 2nd passage (LGC Standards Sp. z o.o., PL, 8.10.2019), VERO cells – Vero, Kidney, African Green Monkey, ATCC-CCL-81 – 6th passage (LGC Standards Sp. z o.o., PL, 25.1. 2019)

Period of analysis: Test temperature: 20.4. – 27.4.2021 20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product: Test concentration: colourless liquid 100% (concentrated)*/**

Contact time:

15 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)

Interfering substances:

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: K52955003, expiry

date: 30.11.2022

				ate: 30.11	2022				4						
Product	Concentration	Interfering	Contact					Dilutio	-						
	***	substance	time min	2	3	4	5	6	7	8	9	10	11		
	1000/#	1' . ***	0.25	22.2	444	444	333	222	020	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444	444	322	222	000	000	000	000	000		
Ministry Sen Session Newsyses	1000/4 11 444	1'	0.5	512,452	444	444	222	220	000	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444	444	222	022	000	000	000	000	000		
5000 L 2000	1000/4	11		16000	444	444	222	002	000	000	000	000	000		
Velox Oxy ETA	100%*	dirty***	1	n.a.	444	444	222	200	000	000	000	000	000		
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000 000	000	n.d.	n.d.	n.d.	n.d.	n.d.		
Velox Oxy ETA cytotoxicity without MicroSpin TM S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	444 444	000	n.d.	n.d.	n.d.	n.d.	n.d.		
			20	150/5	444	444	333	333	222	222	000	200	000		
		ppg	30	n.a.	444	444	333	333	222	222	222	000	000		
Formaldehyde	0.7 (w/v)	/v) PBS	CO	10202	444	333	333	222	222	222	000	000	000		
			60	n.a.	444	443	333	222	222	000	222	000	000		
Formaldehyde	0.7 (w/v)	PBS	DDC	1100000	702702	444	000	000	000	000	000	000	000	000	
evtotoxicity			n.a.	n.a.	444	000	000	000	000	000	000	000	000		
Interference	non-cytotoxic	ic na na			444	444	444	444	333	222	222	222	000		
control	concentration	n.a.	n.a.	n.a.	444	444	444	444	333	222	222	220	020		
N	100%*	dirty***	n.a.	n.d.	n.d.	444	444	444	333	222	n.d.	n.d.	n.d.		
Neutralization	100%*	diffy	n.a.	n.u.	(780,780.5)	444	444	444	333	222		100,000,000			
			0	n.a.	444	444	444	444	333	222	222	222	000		
			U	n.a.	444	444	444	444	333	232	222	222	000		
Virus control	n.a.	PBS	30	n.a.	444	444	444	444	333	222	222	202	020		
virus control	n.a.	LP2	30	n.a.	444	444	444	444	333	222	222	202	000		
			60	n.a.	444	444	444	444	333	222	222	022	000		
			00	II.a.	444	444	444	444	333	222	222	222	000		
			0	n.a.	444	444	444	444	333	222	222	222	020		
372		dirty	U	II.a.	444	444	444	444	333	222	222	220	000		
Virus control	n.a.	dirty	1	n a	444	444	444	444	333	333	222	202	000		
			1	1 n.a.	444	444	444	444	333	222	222	222	000		
Virus control				444	444	444	444	333	333	332	222	222	200		
MicroSpin TM S 400 HR	n.a.	dirty	0	444	444	444	444	333	333	232	222	222	000		

a - dilution, 1 to 4 - degree of CPE in 6 cell culture units, 0 - no CPE, n.a. - not applicable, n.d. - not done

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Prepared by:

Bc. Iva Čížová, Lab Technician

Approved by:

Ing. Barbora Stoklásková, Leader of Study