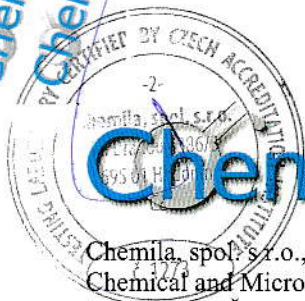


Chemila
Chemila
Chemila



Chemila



Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S164/2018

DETERMINATION OF MYCOBACTERICIDAL AND TUBERCULOCIDAL (EN 14348) ACTIVITY OF THE PRODUCT JACLOR®

Sample ID: S164/2018

Sample name: **JACLOR®**

Client: Romdezimed Production SrL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti, Romania

Producer: Romdezimed Production SrL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti, Romania

Sampling point: Romdezimed Production SrL, Nb.6 Mioritei Str., Sacele, Brasov, Romania

Page: 1

From pages: 5

Incoming date:
12.7.2018

Delivery date:
30.10.2018

Hodonín, 30.10.2018



Ing. Jana Šlitrová, 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: S164/2018
Rep No: 95
Sample name: **JACLOR®**
Sampled: by client
Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania
Client: Romdezimed Production SrL, Sector 5, Bucuresti, Romania

Sampling date: 6.7.2018
Sample delivered: 12.7.2018
Testing date: 3.10. – 24.10.2018
Delivered amount: 250 tabs
Batch No: 25
Page: 2

Subject of testing:

Determination of mycobactericidal and tuberculocidal activity of the product.

Identification of the sample:

Name of the product: **JACLOR®**
Batch number: 25
Date of manufacture: 20-06-2018
Expiry date: 20-06-2021
Manufacturer: Romdezimed Production SrL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti, Romania
Incoming date: 12.7.2018
Storage conditions: stated by the manufacturer
Active compounds and concentrations:
Dichloroisocyanurate sodium salt dihydrate 78 % (CAS 51580-86-0, CE 220-767-7)

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method
SOP-M-19-00 (EN 14348:2005)
Period of analysis: 3.10. – 24.10.2018
Test temperature: 20 °C ± 1 °C
Test method: membrane filtration method
Filtration diluent: rinsing liquid
Product diluent: hard water
Appearance of the product: white tab
Test concentration: 1 tab/2 l, 1 tab/3 l (1 tab = 3.6294 g)
Contact time: 30 min and 60 min
Interfering substances: 0.3 g/l BSA (clean conditions)
Test organisms: *Mycobacterium avium* ATCC 15769
Mycobacterium terrae ATCC 15755
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 a 4 lg reduction (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 a 4 lg reduction (10^4).
 $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

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

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S164/2018

Rep No: 95

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania

Client: Romdezimed Production SrL, Sector 5, Bucuresti, Romania

Sampling date: 6.7.2018

Sample delivered: 12.7.2018

Testing date: 3.10. – 24.10.2018

Delivered amount: 250 tabs

Batch No: 25

Page: 3

The Number of CFU in the tested product: $<10^1$ CFU/g

1. Testing the efficacy of chemical disinfectant **JACLOR®** on *Mycobacterium avium* ATCC 15769

Tab No. 1.1 Verification of methodology, temperature 20 °C, clean conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 1 tab/2 l		
V_{c1}	80	$\Phi_{N_{vo}} = 76$	V_{c1}	69	$\Phi_A = 71$	V_{c1}	56	$\Phi_B = 69$	V_{c1}	72	$\Phi_C = 66.5$
V_{c2}	72		V_{c2}	73		V_{c2}	82		V_{c2}	61	
$30 \leq \Phi_{N_{vo}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{vo}}$			$\Phi_B \geq 0.5 \Phi_{N_{vo}}$			$\Phi_C \geq 0.5 \Phi_{N_{vo}}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 1.2 Test suspensions

Test suspension N $\Phi = 30.5 \times 10^8 = \lg 9.48$ $9.17 \leq \lg N \leq 9.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 8.48$ $8.17 \leq \lg N_0 \leq 8.70$
	10^{-7}	>165	>165	x
	10^{-8}	26	35	
				no

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

Test concentration /contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 8.48$)
1 tab/2 l /30/clean	10^{-1}	<14	<14	<3.15	≥ 5.33
1 tab/3 l /60/clean	10^{-1}	<14	<14	<3.15	≥ 5.33

2. Testing the efficacy of chemical disinfectant **JACLOR®** on *Mycobacterium terrae* ATCC 15755

Tab No. 2.1 Verification of methodology, temperature 20 °C, clean conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 1 tab/2 l		
V_{c1}	48	$\Phi_{N_{vo}} = 47.5$	V_{c1}	51	$\Phi_A = 44.5$	V_{c1}	38	$\Phi_B = 39$	V_{c1}	44	$\Phi_C = 42.5$
V_{c2}	47		V_{c2}	38		V_{c2}	40		V_{c2}	41	
$30 \leq \Phi_{N_{vo}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{vo}}$			$\Phi_B \geq 0.5 \Phi_{N_{vo}}$			$\Phi_C \geq 0.5 \Phi_{N_{vo}}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 2.2 Test suspensions

Test suspension N $\Phi = 19.5 \times 10^8 = \lg 9.29$ $9.17 \leq \lg N \leq 9.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 8.29$ $8.17 \leq \lg N_0 \leq 8.70$
	10^{-7}	>165	>165	x
	10^{-8}	21	18	
				no

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

Test concentration /contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 8.29$)
1 tab/2 l /30/clean	10^{-1}	<14	<14	<3.15	≥ 5.14
1 tab/3 l /60/clean	10^{-1}	<14	<14	<3.15	≥ 5.14

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“), N_a = the number of surviving bacteria 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_{vo} = 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 surviving bacteria 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

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S164/2018

Rep No: 95

Sample name: **JACLOR**[®]

Sampled: by client

Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania

Client: Romdezimed Production SrL, Sector 5, Bucuresti, Romania

Sampling date: 6.7.2018

Sample delivered: 12.7.2018

Testing date: 3.10. – 24.10.2018

Delivered amount: 250 tabs

Batch No: 25

Page: 4

3. Evaluation of mycobactericidal and tuberculocidal activity of the product **JACLOR**[®]

Tab No. 3.1 The efficacy of chemical disinfectant **JACLOR**[®] on test strain – mycobactericidal and tuberculocidal activity

Mycobactericidal and tuberculocidal activity of the product (EN 14348:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 14348:2005	lg R
<i>Mycobacterium avium</i> ATCC 15769	20	30	1 tab/2 l	clean	≥ 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	30	1 tab/2 l	clean	≥ 4	> 4
<i>Mycobacterium avium</i> ATCC 15769	20	60	1 tab/3 l	clean	≥ 4	> 4
<i>Mycobacterium terrae</i> ATCC 15755	20	60	1 tab/3 l	clean	≥ 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 (time „0“), N_a = the number of surviving bacteria 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 surviving bacteria 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

Prepared by: Ing. Eva Kremlová, Lab Technician

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

Sample ID: S164/2018

Rep No: 95

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania

Client: Romdezimed Production SrL, Sector 5, Bucuresti, Romania

Sampling date: 6.7.2018

Sample delivered: 12.7.2018

Testing date: 3.10. – 24.10.2018

Delivered amount: 250 tabs

Batch No: 25

Page: 5

Interpretation:

Results of tests are in Tabs.

According to EN 14348:2005 the tested product **JACLOR®**, batch No: 25, in the concentration 1 tab/2 l, diluted in hard water, and in the contact time 30 min and in the concentration 1 tab/3 l, diluted in hard water, and in the contact time 60 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the membrane filtration method **decreased** the number of viable cells of *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction.

Conclusion:

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

30.10.2018, Hodonín

Gau
.....
Ing. Barbora Stoklášková, Leader of Study

