

DR. F. H. H. BRILL · C/O DR. BRILL + PARTNER GMBH · STIEGSTÜCK 34 · DE-22339 HAMBURG

Romdezimed Production SRL
Sos. Pandurilor Nr.29
RO - Bucuresti, Bl.P2a, ap.31, Sector 5

Hamburg, 08 May 2020

Expert opinion

Bactericidal Activity of **JACLOR** in the quantitative suspension test according to DIN EN 13727:2015 (Phase 2, Step 1)

The disinfectant **JACLOR** was tested and evaluated according to DIN EN 13727:2015 "Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)". The test was accomplished at $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$ test temperature. A test stock solution was prepared by dissolving 1 tab in 5 L WSH.

According to the test report no. L20/0183.1 dated 08/05/2020 of Dr. Brill + Partner GmbH the preparation showed bactericidal activity under clean conditions at $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$ test temperature with a concentration of 25 % of abovementioned stock solution.

JACLOR complies with the requirements of DIN EN 13727:2015 (phase 2, step 1) with the following concentration-time relationship:

Claim	Organic load	Test temperature	Concentration	Contact time
Bactericidal	clean conditions	$30^{\circ}\text{C} \pm 1^{\circ}\text{C}$	1 Tab in 20 l	30 minutes


Dr. Florian H. H. Brill



Test report no L20/0183.1

Quantitative suspension test for the evaluation of bactericidal activity of **JACLOR**
in the medical area according to DIN EN 13727:2015 (Phase 2, step 1)*

In accordance with your order, we tested the preparation **JACLOR** for its activity in the quantitative suspension test according to DIN EN 13727:2015* under clean conditions.

1 General Information and Material

1.1 Client

Client: Romdezimed Production SRL, Mrs Badescu, Sos. Pandurilor Nr.29, RO
- Bucuresti, Bl.P2a, ap.31, Sector 5

Date of order: 28/02/2020

Confirmation no.: 212270

1.2 Identification of Test Laboratory

Location: Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology,
Stiegstück 34, DE-22339 Hamburg, Germany

Study manager: Dipl.-Ing. Dr. rer. nat. Andreas Kampe

Scientific assistant: Dipl.-Biol. Henrik Gabriel

Laboratory technicians: Martina Müller

1.3 Table of Contents

General Information and Material	1
Methods	2
Results	3
Tables	4
List of Abbreviations	10

1.4 Identification of Sample

Name of product: **JACLOR**

Batch no.:

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Germany, Telephone +49. 40. 557631-0, Telefax +49. 40. 557631-11, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results exclusively apply to the tested samples. Information on measurement uncertainty and Version history on request. © Dr. Brill + Partner GmbH 2020



Manufacturer:	Romdezimed Production SRL, RO - Bucuresti, Bl.P2a, ap.31, Sector 5
Date of delivery:	02/03/2020
Storage conditions:	room temperature and darkness
Appearance of product:	white tabs
Odour:	characteristic
Recommended diluent:	Tap water
Diluent used:	water of standardised hardness (WSH, pH 7.0)
pH value, concentrate:	not applicable
Active agents (Manufacturer's data):	78 % Dichloroisocyanurate sodium salt dihydrate

1.5 Test Conditions

Test period:	15/04/ - 20/04/2020
Lab task no.:	L20/0183.1
Product test concentrations:	5.0 + 25 + 50 % of stock solution
Exposure time:	30 + 60 minutes
Test temperature:	30°C ± 1°C
Incubation temperature:	36°C ± 1°C
Organic load:	clean conditions (0.3 g/L bovine albumin)
Neutraliser:	30 g/L polysorbate 80, 30 g/L saponine, 3 g/L lecithin, 1 g/L histidine, 5 g/L sodium thiosulphate (TLSH-Nt)
Test organisms:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442

2 Methods

The tests were carried out according to DIN EN 13727:2015 "Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)".

The test was accomplished at 30°C ± 1°C test temperature. A test stock solution was prepared by dissolving 1 tab in 5 L WSH until no residue was visible. Dilutions of 5 %, 25 % and 50 % were prepared from this stock solution.

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3 Results

The test results based on DIN EN 13727: 2015 are summarised in tables 1.

At $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$ test temperature the test bacteria were sufficiently (RF >5) inactivated with the following concentration-time relationship:

Bactericidal:	clean conditions	25 % of stock solution	30 minutes
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Hamburg, 08/05/2020

Dipl.-Biol. Henrik Gabriel
Head of Laboratory

Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Quality control



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Table 1.1: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR** Batch: -
Test organism: *Staphylococcus aureus* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TLSH-Nt
Contact time: **30 minutes** Lab task no.: L20/0183.1

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Valid. of inactivation (C) Conc.: 50,00 %					
Microbial count			Microbial count		Microbial count		Microbial count		Microbial count		Microbial count		Microbial count			
V _{c1}	70		V _{c1}	80		V _{c1}	54		V _{c1}	75		V _{c1}	75			
V _{c2}	72		V _{c2}	88		V _{c2}	102		V _{c2}	80		V _{c2}	80			
30 ≤ \bar{x} of N _{v0} ≤ 160			Yes		\bar{x} of A(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes		\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes		\bar{x} of C(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	
Suspension for Validation (N _{v8})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?							
			64		86		75		Yes							
Test suspension (N and N ₀)		N	Microbial count				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70 ?					
		1,00E-06	>330		>330		>330	>330	3,70E+08	7,57	Yes					
		1,00E-07	37		37		37	37	8,57							
Concentration of stock solution [%]		N	Microbial count				V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,57)					
5,00		1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,52	≤ 3,05					
		1,00E-01	>330		>330		>330	>330								
25,00		1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 5,42					
		1,00E-01	0		0		<14	<14								
50,00		1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 5,42					
		1,00E-01	0		0		<14	<14								

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Table 1.2: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR** Batch: -
Test organism: *Staphylococcus aureus* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TL5H-Nt
Contact time: **60 minutes** Lab task no.: L20/0183.1

Suspension for validation (N _{v0})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 50,00 %		
Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}
V _{c1}	70	71	V _{c1}	64	77	V _{c1}	54	78	V _{c1}	104	107
V _{c2}	72		V _{c2}	90		V _{c2}	102		V _{c2}	110	
30 ≤ \bar{x} of N _{v0} ≤ 160		Yes	\bar{x} of A(60') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	\bar{x} of C(60') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes
Suspension for Validation (N _{v0})			V _{c1}		V _{c2}	\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?			
			64		86	75		Yes			

Test suspension (N and N ₀)	N	Microbial count			V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70?
	1,00E-06	>330		>330	>330	>330	3,70E+08	7,57	Yes
	1,00E-07	37		37	37	37	8,57		

Concentration of stock solution [%]	N	Microbial count			V _{c1}	V _{c2}	N _a = $\bar{x} \times 10$	lg N _a	lg R (lg N ₀ = 7,57)
		5,00	1,00E+00	>330		>330	>330	>330	>3,30E+04
	1,00E-01	>330		>330	>330	>330			
25,00	1,00E+00	0		0	<14	<14	<1,40E+02	< 2,15	≥ 5,42
	1,00E-01	0		0	<14	<14			
50,00	1,00E+00	0		0	<14	<14	<1,40E+02	< 2,15	≥ 5,42
	1,00E-01	0		0	<14	<14			

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Table 1.3: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR** Batch: -
Test organism: *Enterococcus hirae* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TL5H-Nt
Contact time: **30 minutes** Lab task no.: L20/0183.1

Suspension for validation (N _{v0})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 50,00 %		
Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}
V _{c1}	48	57	V _{c1}	80	81	V _{c1}	62	63	V _{c1}	50	56
V _{c2}	66		V _{c2}	82		V _{c2}	64		V _{c2}	62	
30 ≤ \bar{x} of N _{v0} ≤ 160		Yes	\bar{x} of A(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	\bar{x} of C(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes
Suspension for Validation (N _{v8})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?		
			62		100		81		Yes		
Test suspension (N and N ₀)	N	Microbial count				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70?	
	1,00E-06	156		205	156	205	1,85E+08	7,27	Yes		
	1,00E-07	20		25	20	25	8,27				
Concentration of stock solution [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,27)	
	5,00	1,00E+00	>330		>330	>330	>330	>3,30E+04	> 4,52	≤ 2,75	
		1,00E-01	>330		>330	>330	>330				
25,00	1,00E+00	0		0	<14	<14	<1,40E+02	< 2,15	≥ 5,12		
	1,00E-01	0		0	<14	<14					
50,00	1,00E+00	0		0	<14	<14	<1,40E+02	< 2,15	≥ 5,12		
	1,00E-01	0		0	<14	<14					

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Table 1.4: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR**
Test organism: *Enterococcus hirae*
Organic load: clean conditions
Contact time: **60 minutes**

Batch: -
Temperature: 30°C ± 1°C
Neutraliser: TL5H-Nt
Lab task no.: L20/0183.1

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Valid. of inactivation (C) Conc.: 50,00 %											
Microbial count			x̄		Microbial count		x̄		Microbial count		x̄		Microbial count		x̄							
V _{c1}	48		57		V _{c1}	76		78		V _{c1}	62		63		V _{c1}	42		48				
V _{c2}	66				V _{c2}	80				V _{c2}	64				V _{c2}	54						
30 ≤ x̄ of N _{v0} ≤ 160			Yes		x̄ of A(60') is ≥ 0,5 x x̄ of N _{v0} ?				Yes		x̄ of B is ≥ 0,5 x x̄ of N _{v0} ?				Yes		x̄ of C(60') is ≥ 0,5 x x̄ of N _{v0} ?				Yes	
Suspension for Validation (N _{vB})			V _{c1}		V _{c2}		x̄		30 ≤ x̄ of N _{v0} ≤ 160?													
			62		100		81		Yes													
Test suspension (N and N ₀)		N		Microbial count				V _{c1}	V _{c2}	x̄ _{wm} / lg N		N ₀ =N/10; lg N ₀		7,17 ≤ N ₀ ≤ 7,70?								
		1,00E-06		156		205	156	205	1,85E+08		7,27		Yes									
		1,00E-07		20		25	20	25	8,27													
Concentration of stock solution [%]		N		Microbial count				V _{c1}	V _{c2}	N _a = x̄ x 10		lg N _a		lg R (lg N ₀ = 7,27)								
5,00		1,00E+00		>330		>330	>330	>330	>3,30E+04		> 4,52		≤ 2,75									
		1,00E-01		>330		>330	>330	>330														
25,00		1,00E+00		0		0	<14	<14	<1,40E+02		< 2,15		≥ 5,12									
		1,00E-01		0		0	<14	<14														
50,00		1,00E+00		0		0	<14	<14	<1,40E+02		< 2,15		≥ 5,12									
		1,00E-01		0		0	<14	<14														

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Table 1.5: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR** Batch: -
Test organism: *Pseudomonas aeruginosa* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TLSH-Nt
Contact time: **30 minutes** Lab task no.: L20/0183.1

Suspension for validation (N _{v0})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 50,00 %		
Microbial count			Microbial count			Microbial count			Microbial count		
V _{c1}	68	70	V _{c1}	52	55	V _{c1}	36	39	V _{c1}	46	55
V _{c2}	72		V _{c2}	58		V _{c2}	42		V _{c2}	64	
30 ≤ \bar{x} of N _{v0} ≤ 160			\bar{x} of A(30') is ≥ 0,5 x \bar{x} of N _{v0} ?			\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?			\bar{x} of C(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		
Suspension for Validation (N _{vB})			V _{c1}	V _{c2}	\bar{x}	30 ≤ \bar{x} of N _{v0} ≤ 160?					
			80	84	82	Yes					

Test suspension (N and N ₀)	N	Microbial count		V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70?
	1,00E-06	>330	>330	>330	>330	4,15E+08	7,62	Yes
	1,00E-07	41	42	41	42	8,62		

Concentration of stock solution [%]	N	Microbial count		V _{c1}	V _{c2}	N _a = $\bar{x} \times 10$	lg N _a	lg R (lg N ₀ = 7,62)
5,00	1,00E+00	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 3,10
	1,00E-01	>330	>330	>330	>330			
25,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,47
	1,00E-01	0	0	<14	<14			
50,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,47
	1,00E-01	0	0	<14	<14			

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Table 1.6: Validation, Controls and Evaluation (DIN EN 13727:2015*)

Product name: **JACLOR** Batch: -
Test organism: *Pseudomonas aeruginosa* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TLSh-Nt
Contact time: **60 minutes** Lab task no.: L20/0183.1

Suspension for validation (N _{vo})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 50,00 %		
Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}
V _{c1}	68	70	V _{c1}	52	58	V _{c1}	36	39	V _{c1}	60	62
V _{c2}	72		V _{c2}	64		V _{c2}	42		V _{c2}	64	
30 ≤ \bar{x} of N _{vo} ≤ 160		Yes	\bar{x} of A(60') is ≥ 0,5 x \bar{x} of N _{vo} ?		Yes	\bar{x} of B is ≥ 0,5 x \bar{x} of N _{vo} ?		Yes	\bar{x} of C(60') is ≥ 0,5 x \bar{x} of N _{vo} ?		Yes
Suspension for Validation (N _{vb})			V _{c1}	V _{c2}	\bar{x}	30 ≤ \bar{x} of N _{vo} ≤ 160?					
			80	84	82	Yes					
Test suspension (N and N ₀)	N	Microbial count				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70?	
	1,00E-06	>330	>330	>330	>330	>330	4,15E+08	7,62	Yes		
	1,00E-07	41	42	41	42	8,62					
Concentration of stock solution [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = $\bar{x} \times 10$	lg N _a	lg R (lg N ₀ = 7,62)	
	5,00	1,00E+00	>330	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 3,10	
		1,00E-01	>330	>330	>330	>330					
25,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,47			
	1,00E-01	0	0	<14	<14						
50,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,47			
	1,00E-01	0	0	<14	<14						

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4 List of Abbreviations

A	=	control of test conditions
B	=	control of neutraliser
C	=	validation of method at highest product concentration
N	=	test suspension
N _{vo}	=	suspension for validation
n.t.	=	not tested
N ₀	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in log ₁₀ -steps
V _c	=	viable microbial count per ml
\bar{x}	=	weighted mean of N

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