



CONFIDENTIAL

Test report no L17/0389.1

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

In accordance with your order, we tested the preparation **Globacid AF** 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: Goodpoint Chemicals OÜ, Dr. Kallikorm, Vabaohumuseumi tee 3,
EE – 13522 Talinn
Date of order: 16/06/2017
Confirmation no.: 202231

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.-Biol. Dr. rer. nat. Jan-Hendrik Klock
Scientific assistant: Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Laboratory technicians: Lea Küssner

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: **Globacid AF**
Batch no.: 22052017
Manufacturer: Goodpoint Chemicals OÜ, EE – 13522 Talinn

* 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 2017



CONFIDENTIAL

Date of delivery:	27/06/2017
Storage conditions:	room temperature and darkness
Appearance of product:	liquid
Odour:	characteristic
Product type:	Instrument disinfectant
Recommended diluent:	Product is ready for use
Diluent used:	distilled water (DW, pH 7.0)
pH value, concentrate:	8.0
pH value, 80 % (measured in diluent):	7.6
pH value, 50 % (measured in diluent):	6.5
pH value, 10 % (measured in diluent):	5.9
Active agents (Manufacturer's data):	60 % isopropanol 15 % ethanol

1.5 Test Conditions

Test period:	11/07/ - 14/07/2017
Lab task no.:	L17/0389.1
Product test concentrations:	10 + 50 + 80 %
Exposure time:	30 + 60 seconds
Test temperature:	20°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, (TLSH)
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)".

* 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 2017



DR. BRILL + DR. STEINMANN
INSTITUT FÜR HYGIENE UND MIKROBIOLOGIE

Test report no L17/0389.1
Author AK Version 01 Date 16/08/2017
Replaces Version Date

Name of Product **Globacid AF**
Method DIN EN 13727:2015*

Page 3 of 10

CONFIDENTIAL

3 Results

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

The test bacteria were sufficiently (RF >5) inactivated with the following concentration-time relationship:

Bactericidal: clean conditions 50 % 60 seconds

Hamburg, 16/08/2017

Dipl.-Biol. Henrik Gabriel
Head of Laboratory

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



* 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 2017





CONFIDENTIAL

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

Product name: Globacid AF	Batch: 22052017
Test organism: <i>Staphylococcus aureus</i>	Temperature: 20°C ± 1°C
Organic load: clean conditions	Neutraliser: TLSH
Contact time: 30 seconds	Lab task no.: L17/0389.1

Suspension for validation (N _{v0})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 80,00 %		
Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}
V _{c1}	53	54,5	V _{c1}	53	53,5	V _{c1}	54	55	V _{c1}	60	56
V _{c2}	56		V _{c2}	54		V _{c2}	56		V _{c2}	52	
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 _{vb})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?		
			52		60		56		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	200	220	200	220	2,21E+08	7,35
	1,00E-07	32	35	32	35	8,35		
Productconc. [%]	N	Microbial count		V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,35)
10,00	1,00E+00	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 2,83
	1,00E-01	>330	>330	>330	>330			
50,00	1,00E+00	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 2,83
	1,00E-01	>330	>330	>330	>330			
80,00	1,00E+00	44	37	44	37	<4,05E+02	2,61	4,74
	1,00E-01	11	11	<14	<14			

* 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 2017



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

Product name: **Globacid AF**
Test organism: *Staphylococcus aureus*
Organic load: clean conditions
Contact time: **60 seconds**

Batch: 22052017
Temperature: 20°C ± 1°C
Neutraliser: TLSH
Lab task no.: L17/0389.1

Suspension for validation (N _{v0})		Control of test conditions (A)		Control of neutraliser (B)		Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count	\bar{x}	Microbial count	\bar{x}	Microbial count	\bar{x}	Microbial count	\bar{x}		
V _{c1} 53	54,5	V _{c1} 55	58,5	V _{c1} 54	55	V _{c1} 45	46		
V _{c2} 56		V _{c2} 62		V _{c2} 56		V _{c2} 47			
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 _{vB})	V _{c1}	V _{c2}	\bar{x}	30 ≤ \bar{x} of N _{v0} ≤ 160?					
	52	60	56	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	200	220	200	220	2,21E+08	7,35	Yes	
	1,00E-07	32	35	32	35	8,35			
Productconc. [%]	N	Microbial count		V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,35)	
	10,00	1,00E+00	24	26	24	26	<2,50E+02	2,40	4,95
		1,00E-01	2	1	<14	<14			
50,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,20	
	1,00E-01	0	0	<14	<14				
80,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,20	
	1,00E-01	0	0	<14	<14				

* 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 2017



CONFIDENTIAL

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

Product name: Globacid AF	Batch: 22052017
Test organism: <i>Enterococcus hirae</i>	Temperature: 20°C ± 1°C
Organic load: clean conditions	Neutraliser: TL5H
Contact time: 30 seconds	Lab task no.: L17/0389.1

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}	Microbial count		\bar{x}
V _{c1}	58	58	V _{c1}	47	54	V _{c1}	55	54,5	V _{c1}	54	56	V _{c2}	58	58
V _{c2}	58		V _{c2}	61		V _{c2}	54		V _{c2}	58				
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 _{vB})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?					
			51		56		53,5		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	>660	>660	2,85E+08	7,45	Yes
	1,00E-07	30	27	30	27	8,45				
Productconc. [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = $\bar{x} \times 10$	lg N _a	lg R (lg N ₀ = 7,45)
10,00	1,00E+00	>330	>330	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 2,94
	1,00E-01	>330	>330	>330	>330	>330				
50,00	1,00E+00	>330	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 2,94	
	1,00E-01	>330	>330	>330	>330	>330				
80,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,31		
	1,00E-01	0	0	<14	<14					

* 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 2017



CONFIDENTIAL

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

Product name: Globacid AF	Batch: 22052017
Test organism: <i>Enterococcus hirae</i>	Temperature: 20°C ± 1°C
Organic load: clean conditions	Neutraliser: TLSH
Contact time: 60 seconds	Lab task no.: L17/0389.1

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count			Microbial count		Microbial count		Microbial count		Microbial count		Microbial count			
V _{c1}	58	58	V _{c1}	53	V _{c1}	55	V _{c1}	53	V _{c1}	53	52			
V _{c2}	58		V _{c2}	60	V _{c2}	54	V _{c2}	51						
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			
Suspension for Validation (N _{vB})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?					
			51		56		53,5		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	>660	>660	2,85E+08	7,45	Yes		
	1,00E-07	30	27	30	27	8,45				
Productconc. [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,45)
10,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,31		
	1,00E-01	0	0	<14	<14					
50,00	1,00E+00	1	1	<14	<14	<1,40E+02	< 2,15	≥ 5,31		
	1,00E-01	0	0	<14	<14					
80,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 5,31		
	1,00E-01	0	0	<14	<14					

* 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 2017





CONFIDENTIAL

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

Product name: Globacid AF	Batch: 22052017
Test organism: <i>Pseudomonas aeruginosa</i>	Temperature: 20°C ± 1°C
Organic load: clean conditions	Neutraliser: TLSH
Contact time: 30 seconds	Lab task no.: L17/0389.1

Suspension for validation (N _{v0})		Control of test conditions (A)		Control of neutraliser (B)		Vali. of inactivation (C) Conc.: 80,00 %	
Microbial count	\bar{x}	Microbial count	\bar{x}	Microbial count	\bar{x}	Microbial count	\bar{x}
V _{c1} 51	52,5	V _{c1} 45	45	V _{c1} 58	58,5	V _{c1} 78	74,5
V _{c2} 54		V _{c2} 45		V _{c2} 59		V _{c2} 71	
30 ≤ \bar{x} of N _{v0} ≤ 160		Yes		\bar{x} of A(30') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes	
Suspension for Validation (N _{vB})		V _{c1}	V _{c2}	\bar{x}	30 ≤ \bar{x} of N _{v0} ≤ 160?		
		59	61	60	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	>660	>660	4,55E+08	7,66
	1,00E-07	48	43	48	43	8,66		

Productconc. [%]	N	Microbial count		V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 7,66)
	10,00	1,00E+00	>330	>330	>330	>330	>3,30E+04	> 4,52
1,00E-01		>330	>330	>330	>330			
50,00	1,00E+00	>330	>330	>330	>330	>3,30E+04	> 4,52	≤ 3,14
	1,00E-01	>330	>330	>330	>330			
80,00	1,00E+00	>330	>330	>330	>330	1,57E+04	4,19	3,46
	1,00E-01	160	153	160	153			

* 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 2017





CONFIDENTIAL

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

Product name:	Globacid AF	Batch:	22052017
Test organism:	<i>Pseudomonas aeruginosa</i>	Temperature:	20°C ± 1°C
Organic load:	clean conditions	Neutraliser:	TLSH
Contact time:	60 seconds	Lab task no.:	L17/0389.1

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count		̄	Microbial count		̄	Microbial count		̄	Microbial count		̄	Microbial count		̄
V _{c1}	51	52,5	V _{c1}	43	46	V _{c1}	58	58,5	V _{c1}	70	70,5	V _{c2}	71	
V _{c2}	54		V _{c2}	49		V _{c2}	59		V _{c2}	71				
30 ≤ ̄ of N _{v0} ≤ 160		Yes	̄ of A(60') is ≥ 0,5 x ̄ of N _{v0} ?		Yes	̄ of B is ≥ 0,5 x ̄ of N _{v0} ?		Yes	̄ of C(60') is ≥ 0,5 x ̄ of N _{v0} ?		Yes			
Suspension for Validation (N _{vB})			V _{c1}		V _{c2}		̄		30 ≤ ̄ of N _{v0} ≤ 160?					
			59		61		60		Yes					

Test suspension (N and N ₀)	N	Microbial count				V _{c1}	V _{c2}	̄ _{wm} / lg N	N ₀ =N/10; lg N ₀	7,17 ≤ N ₀ ≤ 7,70 ?
	1,00E-06	>330		>330		>660	>660	4,55E+08	7,66	Yes
	1,00E-07	48		43		48	43	8,66		
Productconc. [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = ̄ x 10	lg N _a	lg R (lg N ₀ = 7,66)
10,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 5,51
	1,00E-01	0		0		<14	<14			
50,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 5,51
	1,00E-01	0		0		<14	<14			
80,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 5,51
	1,00E-01	0		0		<14	<14			

* 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 2017



CONFIDENTIAL

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

* 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 2017