

Test report no L16/0882.1

Quantitative carrier test for the evaluation of fungicidal activity of **Stabimed ultra**
for disinfection of instruments the medical area according to DIN EN 14562:2006 (Phase 2, step 2)*

In accordance with your order, we tested the preparation **Stabimed ultra** for its activity in the quantitative carrier test according to DIN EN 14562:2006* under clean conditions.

1 General Information and Material

1.1 Client

Client: B. Braun Medical AG, Dr. Kurz, Seesatz 17,
CH – 6204 Sempach, Switzerland
Date of order: 09/12/2016
Confirmation no.: 200357

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. Dr. rer. nat. Jan-Hendrik Klock
Laboratory technicians: Carmela Jänicke

1.3 Table of Contents

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1.4 Identification of Sample

Name of product: **Stabimed ultra**
Batch no.: 1606BH0024
Manufacturer: B. Braun Medical AG, Sempach, Switzerland

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Date of delivery:	01/12/2016
Storage conditions:	room temperature and darkness
Appearance of product:	powder
Odour:	characteristic
Recommended diluent:	Tap water
Diluent used:	water of standardised hardness (WSH, pH 7.0)
pH value, concentrate:	not measured
Active agents (Manufacturer's data):	0.16 % peracetic acid in situ (diluted in water 10 g/l)

1.5 Test Conditions

Test period:	10/03/ - 13/03/2017
Lab task no.:	L16/0882.4
Product test concentrations:	1.5 %
Exposure time:	15 + 30 + 45 minutes
Test temperature:	20°C ± 1°C
Incubation temperature:	30°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, 150 g/L sheep blood (TSL-SB)
Test organisms:	<i>Aspergillus brasiliensis</i> (niger) ATCC 16404

2 Methods

The tests were carried out according to DIN EN 14562:2006 "Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)".

The screening was performed with *A. brasiliensis* as single test organism.

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3 Results

The test results based on DIN EN 14562:2006 are summarised in tables 1.

The spores of *Aspergillus brasiliensis* were sufficiently (RF >4) inactivated with the following concentration-time relationship:

<i>Aspergillus brasiliensis</i>	clean conditions	1.5 %	15 minutes
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Hamburg, 25/08/2017

Dipl.-Biol. Dr. rer. nat. Jan Hendrik Klock
Deputy Head of Laboratory

Dipl.-Biol. Henrik Gabriel
Head of Laboratory



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Table 1.1: Validation, Controls and Evaluation (DIN EN 14562:2006*)

Product name: **Stabimed ultra** Batch: 1606BH0024
Test organism: *Aspergillus brasiliensis* Temperature: 20°C ± 1°C
Organic load: clean conditions Neutraliser: TSL-SB
Contact time: **15 minutes** Lab task no.: L16/0882.4

Suspension for validation (N _{v0})				Control of test conditions (A)				Control of Neutraliser (B)				Validation of method (C) Product conc.: 1,50 %			
	cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}
V _{c1}	33		31,5	V _{c1}	21		22,5	V _{c1}	27		24,5	V _{c1}	24		23
V _{c2}	30			V _{c2}	24			V _{c2}	22			V _{c2}	22		
30 ≤ \bar{x} of N _{v0} ≤ 160			Yes	\bar{x} of A(15') 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(15') is ≥ 0,5 x \bar{x} of N _{v0} ?			Yes
Test suspension (N)		N		cell count per plate				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$		8,17 ≤ lg N ≤ 8,70 ?			
		1,00E-06		>165		>165		>330	>330	1,45E+08		Yes			
		1,00E-07		11		18		11	18	8,16					
Water control (N _w)		N		viable count per plate				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$		6,15 ≤ lg N ≤ 6,86 ?			
		1,00E-04		28		17		28	17	2,25E+06		Yes			
		1,00E-05		4		3		4	3	6,35					
Product conc. [%]		N		cell count per plate				V _{c1}	V _{c2}	N _a = \bar{x} x 10		lg N _a		lg R	
														(lg N ₀ =6,35)	
1,50		1,00E+00		26		15		26	15	<2,05E+02		2,31		4,04	
		1,00E-01		5		2		<14	<14						
		1,00E-02		1		1		<14	<14						
		1,00E-03		0		0		<14	<14						

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Table 1.2: Validation, Controls and Evaluation (DIN EN 14562:2006*)

Product name: **Stabimed ultra** Batch: 1606BH0024
Test organism: *Aspergillus brasiliensis* Temperature: 20°C ± 1°C
Organic load: clean conditions Neutraliser: TSL-SB
Contact time: **30 minutes** Lab task no.: L16/0882.4

Suspension for validation (N _{v0})				Control of test conditions (A)				Control of Neutraliser (B)				Validation of method (C) Product conc.: 1,50 %			
	cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}
V _{c1}	33		31,5	V _{c1}	20		21	V _{c1}	27		24,5	V _{c1}	21		24,5
V _{c2}	30			V _{c2}	22			V _{c2}	22			V _{c2}	28		
30 ≤ \bar{x} of N _{v0} ≤ 160			Yes	\bar{x} of A(15') 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(15') is ≥ 0,5 x \bar{x} of N _{v0} ?			Yes
Test suspension (N)	N	cell count per plate				V _{c1}	V _{c2}	$\bar{x}_{wm}/lg N$		8,17 ≤ lg N ≤ 8,70 ?					
	1,00E-06	>165		>165		>330	>330	1,45E+08		Yes					
	1,00E-07	11		18		11	18	8,16							
Water control (N _w)	N	viable count per plate				V _{c1}	V _{c2}	$\bar{x}_{wm}/lg N$		6,15 ≤ lg N ≤ 6,86 ?					
	1,00E-04	21		38		21	38	2,95E+06		Yes					
	1,00E-05	2		4		2	4	6,47							
Product conc. [%]	N	cell count per plate				V _{c1}	V _{c2}	N _a = \bar{x} x 10		lg N _a		lg R (lg N ₀ =6,47)			
	1,50	1,00E+00	0		0		<14	<14	<1,40E+02		< 2,15		≥ 4,32		
1,00E-01	0		0		<14	<14									
1,00E-02	0		0		<14	<14									
1,00E-03	0		0		<14	<14									

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Table 1.3: Validation, Controls and Evaluation (DIN EN 14562:2006*)

Product name: **Stabimed ultra** Batch: 1606BH0024
Test organism: *Aspergillus brasiliensis* Temperature: 20°C ± 1°C
Organic load: clean conditions Neutraliser: TSL-SB
Contact time: **45 minutes** Lab task no.: L16/0882.4

Suspension for validation (N _{v0})				Control of test conditions (A)				Control of Neutraliser (B)				Validation of method (C) Product conc.: 1,50 %			
	cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}		cell count		\bar{x}
V _{c1}	33		31,5	V _{c1}	17		21	V _{c1}	27		24,5	V _{c1}	19		19,5
V _{c2}	30			V _{c2}	25			V _{c2}	22			V _{c2}	20		
30 ≤ \bar{x} of N _{v0} ≤ 160			Yes	\bar{x} of A(15') 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(15') is ≥ 0,5 x \bar{x} of N _{v0} ?			Yes
Test suspension (N)		N	cell count per plate				V _{c1}	V _{c2}	\bar{x}_{wm} /lg N		8,17 ≤ lg N ≤ 8,70 ?				
		1,00E-06	>165		>165		>330	>330	1,45E+08		Yes				
		1,00E-07	11		18		11	18	8,16						
Water control (N _w)		N	viable count per plate				V _{c1}	V _{c2}	\bar{x}_{wm} /lg N		6,15 ≤ lg N ≤ 6,86 ?				
		1,00E-04	51		36		51	36	4,35E+06		Yes				
		1,00E-05	5		3		5	3	6,64						
Product conc. [%]		N	cell count per plate				V _{c1}	V _{c2}	N _a = \bar{x} x 10		lg N _a		lg R (lg N ₀ =6,64)		
1,50		1,00E+00	0		0		<14	<14	<1,40E+02		< 2,15		≥ 4,49		
		1,00E-01	0		0		<14	<14							
		1,00E-02	0		0		<14	<14							
		1,00E-03	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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