

B. Braun Medical AG
CoE Infection Control
Seesatz 17
CH - 6204 Sempach

Bremen, 7. Oktober 2015

Gutachten

Wirksamkeit von Stabimed ultra gegenüber dem Poliovirus Typ 1 im quantitativen Suspensionsversuch nach der EN 14476:2013 unter hoher Belastung

Dieses Gutachten basiert auf dem Prüfbericht B15L0483Pod vom 07.10.2015.

Das Instrumentendesinfektionsmittel Stabimed ultra der B. Braun Medical AG wurde gemäß Auftrag auf seine virusinaktivierenden Eigenschaften gegenüber dem Poliovirus Typ 1 im quantitativen Suspensionsversuch nach der EN 14476:2013 unter hoher Belastung untersucht.

In der EN 14476:2013 wird dann von einer Virus-Wirksamkeit eines Desinfektionsmittels ausgegangen, wenn nach einer bestimmten Einwirkzeit eine Reduktion des initialen Virustiters um $\geq 4 \log_{10}$ Stufen (Inaktivierung $\geq 99,99\%$) erfolgt ist.

Das Instrumentendesinfektionsmittel Stabimed ultra wurde als 1,5 %, 2,0 % und 2,5 % ige Lösungen bei 20 °C untersucht. Die Einwirkzeiten betrugen 10 und 15 Minuten. Nach 10 (2,0 %ige Lösung) bzw. 15 (1,5 %ige Lösung) Minuten war eine ausreichende Reduktion des Virustiters nachweisbar. Deshalb ergibt sich eine Wirksamkeit gegenüber dem Poliovirus Typ 1 wie folgt:

2,0 %	10 Minuten
1,5 %	15 Minuten

Dr. Jochen Steinmann

Stabimed ultra – Gutachten nach EN 14476

B. Braun Medical AG
CoE Infection Control
Seesatz 17
CH - 6204 Sempach

Bremen, 07/10/2015

Expert opinion

Activity of Stabimed ultra against poliovirus type 1 in a quantitative suspension test according to EN 14476:2013 under dirty conditons

This expert opinion is based on the test report B15L0483Pod dating 07.10.2015.

The virus-inactivating properties of the instrument disinfectant Stabimed ultra of B. Braun Medical AG against poliovirus type 1 were investigated by a quantitative suspension test according to EN 14476:2013 under dirty conditions.

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by $\geq 4 \log_{10}$ (inactivation $\geq 99.99\%$).

Stabimed ultra was examined as 1.5 %, 2.0 % and 2.5 % solutions at 20 °C. 10 and 15 minutes were chosen as exposure times. After 10 (2.0 % solution) and 15 (1.5 % soltion) minutes, respectively the virus titre was decreased by $\geq 4 \log_{10}$ steps. Therefore, a virucidal activity against poliovirus type 1 was measured as follows:

2.0 % 10 minutes

1.5 % 15 minutes

Dr. Jochen Steinmann



DR. BRILL + DR. STEINMANN
INSTITUTE FOR HYGIENE AND MICROBIOLOGY



07.10.2015

Test report B15L0483Pod

Evaluation of the effectiveness of
Stabimed ultra

Test virus: poliovirus type 1 strain LSc-2ab

Method: EN 14476:2013

quantitative suspension test for the evaluation
of virucidal activity of chemical disinfectants and
antiseptics used in human medicine

Sponsor:

B. Braun Medical AG
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1. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, DE - 28259 Bremen

2. Identification of sample

Manufacturer	B. Braun Medical AG
Name of product	Stabimed ultra
Product diluent recommended by the manufacturer	-
Batch number	14263M25
Application	instrument disinfection
Production date	
Expiry date	11/2015
Active compound (s) (100 g)	peracetic acid
Appearance, odour	white powder product specific
pH-values (in WSH)	2.5 %: 7.66 (20 °C) 2.0 %: 7.52 (20 °C) 1.5 %: 7.57 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	11.09.2015

3. Materials

3.1 Culture medium and reagents

- Dulbecco's Modified Eagle's Medium (DMEM, Biozym Scientific GmbH, catalogue no. 880021)
- fetal calf serum (Biochrom AG, article no. S 0115)
- 1.4 % formaldehyde solution (Dilution of Roti®-Histofix 4 %, Carl Roth GmbH)
- Aqua bidest. (SG ultrapure water system, type Ultra Clear; serial no. 86996-1)
- PBS (Invitrogen, article no. 18912-014)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153)
- sheep erythrocytes (Fiebig-Nährstofftechnik).

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3.2 Virus and cells

The poliovirus type 1 strain LSc-2ab (Chiron-Behring) was obtained from PD Dr. Olaf Thraenhardt, Eurovir, DE - 14943 Luckenwalde.

BGM cells (buffalo green monkey = permanent monkey kidney cell line; supplied by Prof. Dr. Lindl, Institut für angewandte Zellkultur, DE - 81669 München, Germany) were cultivated in a 175 cm² flask with Dulbecco's Modified Eagle's Medium (DMEM) and 10 % fetal calf serum (FCS).

The cells (passage 26) were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

3.3 Apparatus, glassware and small items of equipment

- CO₂ incubator, Nunc GmbH & Co. KG, model QWJ 350
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)
- Polyesterol 96-well microtitre plate (Nunc GmbH & Co. KG, Wiesbaden)
- Cell culture flask (Nunc GmbH & Co. KG, Wiesbaden)
- Sealed test tubes (Sarstedt AG & Co., Nümbrecht).

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4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	2.5 %, 2.0 %, 1.5 % and 0.5 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	10 and 15 minutes
Interfering substance	3 g/l bovine serum albumin + 3 g/l erythrocytes (dirty conditions, EN 14476:2013)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water of standardised hardness (WSH)
Stability of product in the mix with virus and interfering substance (2.5 % solution)	no flocculation, no precipitation
Virus strain	poliovirus type 1 strain LSc-2ab (Chiron-Behring)
Date of testing	11.09.2015 – 07.10.2015
End of testing	07.10.2015

5. Methods

5.1 Preparation of test virus suspension

For preparation of test virus suspension according to EN 5.4.1 *BGM cells* were infected with a multiplicity of infection of 0.1 at 37 °C. After cells showed a cytopathic effect, they were subjected to a threefold freeze/thaw procedure followed by a low speed centrifugation in order to sediment cell debris. After aliquotation of the supernatant, test virus suspension was stored at -80 °C.

5.2 Preparation of disinfectant (dilutions)

The powder was solved in one litre WSH immediately before the inactivation tests. The test product was tested as 2.5 %, 2.0 %, 1.5 % and 0.5 % solutions under dirty conditions (1 part test virus suspension + 1 part interfering substance + 8 parts disinfectant). Due to the addition of interfering substance and test virus suspension the solutions had to be prepared by the factor 1.25.

These solutions were prepared with water of standardised hardness immediately before the inactivation tests.

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5.3 Infectivity assay

Infectivity was determined as endpoint titration according to EN 5.5 transferring 0.1 ml of each dilution into eight wells of a microtitre plate to 0.1 ml of freshly trypsinised *BGM cells* ($10\text{--}15 \times 10^3$ cells per well), beginning with the highest dilution. Microtitre plates were incubated at 37 °C in a 5 % CO₂-atmosphere. The cytopathic effect was read by using an inverted microscope after seven days. Calculation of the infective dose TCID₅₀/ml was calculated with the method of Spearman (2) and Kärber (3) with the following formula:

$$-\log_{10}\text{TCID}_{50} = X_0 - 0.5 + \sum r/n$$

meaning

X_0 = log₁₀ of the lowest dilution with 100 % positive reaction

r = number of pos. determinations of lowest dilution step with 100 % positive and all higher positive dilution steps

n = number of determinations for each dilution step.

5.4 Calculation and verification of virucidal activity

The virucidal activity of the test disinfectant was evaluated by calculating the decrease in titre in comparison with the control titration without disinfectant. The difference is given as reduction factor (RF).

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by four log₁₀ steps within the recommended exposure period. This corresponds to an inactivation of $\geq 99.99\%$.

5.5 Inactivation assay

Determination of virucidal activity has been carried out in accordance to EN 5.5. The test product was examined as 2.5 %, 2.0 %, 1.5 % and 0.5 % (demonstration of non-active range) solutions in WSH at 20 °C according to EN 14476:2013. 10 and 15 minutes were chosen as contact times.

Immediately at the end of a chosen contact time, activity of the disinfectant was stopped by dilution to 10⁻⁸.

Titration of the virus control were performed after the longest exposure time (EN 5.5.7).

Furthermore, a cell control (only addition of medium) was incorporated.

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Inactivation tests were carried out in sealed test tubes in a water bath at $20\text{ °C} \pm 1.0\text{ °C}$. Aliquots were retained after appropriate exposure times, and residual infectivity was determined.

5.6 Determination of cytotoxicity

Determination of cytotoxicity was performed according to EN 5.5.4.1.

5.7 Cell sensitivity to virus

For the control of cell sensitivity to virus two parts by volume hard water were mixed with eight parts by volume of the lowest apparently non-cytotoxic dilution of the product. This mixture or PBS as control was added to a volume of double concentrated cell suspension. After 1 h at 37 °C the cells were centrifuged and re-suspended in cell culture medium (EN 5.5.4.2b).

Finally, a comparative titration of the test virus suspension was performed on the pre-treated (disinfectant) and non-pre-treated (PBS) cells as described above.

5.8 Control of efficacy for suppression of disinfectant's activity

Furthermore, a control of efficiency for suppression of disinfectant's activity was included (EN 5.5.5).

5.9 Reference virus inactivation test

As reference for test validation a 0.7 % formaldehyde solution according to EN 5.5.6 was included. 5, 15, 30 and 60 minutes were chosen as contact times. In addition, cytotoxicity of formaldehyde test solution was determined following EN 5.5.6.2 with dilutions up to 10^{-5} .

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6. Verification of the methodology

The following criteria as mentioned in EN 5.7 were fulfilled:

- a) The titre of the test virus suspension allowed the determination of a $\geq 4 \log_{10}$ reduction (maximal virus reduction $\geq 5.13 \pm 0.27$).
- b) The difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test (see 6.6.7) was 2.00 ± 0.67 (between 0.5 - 2.5) after 30 min and 2.50 ± 0.64 (between 2.0 - 4.5) after 60 min for poliovirus type 1.
- c) The test product (2.5 %) showed cytotoxicity in the 1:100 dilutions thus allowing the detection of a $4 \log_{10}$ reduction of virus titre.
- d) The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) *BGM cells* showed no significant difference ($< 1 \log_{10}$; EN 5.7) of virus titre: 8.13 ± 0.45 (PBS) versus 8.38 ± 0.53 (1:1,000 dilutions of disinfectant, 2.5 %) $\log_{10}\text{TCID}_{50}/\text{ml}$ and also 8.13 ± 0.45 (PBS) versus 8.25 ± 0.44 (1:100 dilutions of disinfectant, 1.5 %) $\log_{10}\text{TCID}_{50}/\text{ml}$.
- e) The control of efficacy for suppression of disinfectant's activity (2.5 %) showed no decrease ($< 0.5 \log_{10}$; EN 5.5.5.1) in virus titre (8.00 ± 0.27 versus $7.75 \pm 0.33 \log_{10}\text{TCID}_{50}/\text{ml}$).
- f) One concentration demonstrated a $4 \log_{10}$ reduction and (at least) one concentration demonstrated a \log_{10} reduction of less than 4.

Since all criteria according EN 5.7 were fulfilled, examination with poliovirus type 1 according to EN 14476:2013 is valid.

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7. Results

Results of examination are shown in tables 1 to 9. Tables 1 to 8 demonstrate the raw data, whereas table 9 (a+b) gives a summary of results.

The test product as 2.5 % and 2.0 % was able to inactivate poliovirus type 1 after 10 minutes in this quantitative suspension test (Tables 1 and 2). The reduction factor was $\geq 4.50 \pm 0.27$ for both concentrations. This corresponded to an inactivation of ≥ 99.99 %.

The test product as 1.5 % solution was able to inactivate poliovirus type 1 after 15 minutes in this quantitative suspension test (Table 3). The reduction factor was $\geq 5.13 \pm 0.27$ at this time point. This corresponded to an inactivation of ≥ 99.999 %.

The test product as 0.5 % solution was not active against the poliovirus type 1 after 15 minutes of incubation time in this quantitative suspension test (Table 4).

8. Conclusion

The instrument disinfectant Stabimed ultra tested as 2.0 % solution demonstrated effectiveness against poliovirus type 1 after an exposure time of 10 minutes under dirty conditions. Tested as 1.5 % solution, Stabimed ultra demonstrated effectiveness against poliovirus type 1 after an exposure time of 15 minutes under dirty conditions.

Therefore, the instrument disinfectant Stabimed ultra can be declared as active against poliovirus type 1 as follows:

dirty conditions 2.0 % 10 minutes

dirty conditions 1.5 % 15 minutes

Bremen, 07.10.2015

- Dr. Jochen Steinmann -
Scientific Director

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9. Quality control

The Quality Assurance of the results was maintained by performing the determination of the virus-inactivating properties of the disinfectant in accordance with Good Laboratory Practice regulations:

- 1) Chemicals Act of Germany, Appendix 1, dating of 01.08 1994 (BGBl. I, 1994, page 1703). Appendix revised at 14. 05. 1997 (BGBl. I, 1997, page 1060).
- 2) OECD Principles of Good Laboratory Practice (revised 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. Environment Directorate, Organization for Economic Co-operation and Development, Paris 1998.

The plausibility of the results was additionally confirmed by controls incorporated in the inactivation assays.

10. Records to be maintained

All testing data, protocol, protocol modifications, the final report, and correspondence between Dr. Brill + Partner GmbH and the sponsor will be stored in the archives at Dr. Brill + Partner GmbH.

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The test results in this test report relate only to the items examined.

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11. Literature

1. EN 14476:2013: Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemicals disinfectants and antiseptics in human medicine test - Test method and requirements (phase 2, step 1)
2. Spearman, C.: The method of 'right or wrong cases' (constant stimuli) without Gauss's formulae.
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Appendix:

Legend to the Tables

Table 1:	Raw data for Stabimed ultra (2.5 %) tested against poliovirus type 1
Table 2:	Raw data for Stabimed ultra (2.0 %) tested against poliovirus type 1
Table 3:	Raw data for Stabimed ultra (1.5 %) tested against poliovirus type 1
Table 4:	Raw data for Stabimed ultra (0.5 %) tested against poliovirus type 1
Table 5:	Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1
Table 6:	Raw data for control of efficacy for suppression of disinfectant's activity (2.5 %)
Table 7:	Raw data (poliovirus type 1) for cell sensitivity (2.5 %)
Table 8:	Raw data (poliovirus type 1) for cell sensitivity (1.5 %)
Table 9 (a+b):	Summary of results with Stabimed ultra and poliovirus type 1

Legend to the Figures

Figure 1:	Virus-inactivating properties of Stabimed ultra (2.0 %)
Figure 2:	Virus-inactivating properties of formaldehyde (0.7 %)

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Table 1: Raw data for Stabimed ultra (2.5 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (4101)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log ₁₀)								
				1	2	3	4	5	6	7	8	9
test product	2.5%	dirty conditions	10	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			20	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	2.5%	dirty conditions	n.a.	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 4444	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4404 0004	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 2: Raw data for Stabimed ultra (2.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (4101)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log ₁₀)								
				1	2	3	4	5	6	7	8	9
test product	2.0%	dirty conditions	10	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			20	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	2.0%	dirty conditions	n.a.	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 4444	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4404 0004	0000 0000	0000 0000

n.a. = not applicable
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0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 3: Raw data for Stabimed ultra (1.5 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (4101)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log ₁₀)								
				1	2	3	4	5	6	7	8	9
test product	1.5%	dirty conditions	10	tttt tttt	4444 4444	4444 4444	4444 4444	0000 4440	0000 0040	0000 0000	n.d. 0000	n.d. 0000
			15	tttt tttt	0040 4040	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d. 0000	n.d. 0000
			20	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	1.5%	dirty conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 4444	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4404 0004	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 4: Raw data for Stabimed ultra (0.5 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (4101)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log ₁₀)								
				1	2	3	4	5	6	7	8	9
test product	0.5%	dirty conditions	10	4444	4444	4444	4444	4444	4444	0040	n.d.	n.d.
				4444	4444	4444	4444	4444	4444	0000	n.d.	n.d.
			15	4444	4444	4444	4444	4444	4444	0000	n.d.	n.d.
				4444	4444	4444	4444	4444	4044	0040	n.d.	n.d.
			20	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.5%	dirty conditions	n.a.	0000	0000	0000	0000	0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444	4444	4444	4444	4444	4444	4400	0000	0000
			60	4444	4444	4444	4444	4444	4444	4404	0000	0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 5: Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (4101)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log ₁₀)								
				1	2	3	4	5	6	7	8	9
formaldehyde	0.7% (m/V)	PBS	5	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	4444 0444	0440 0400	n.d.	n.d.
			15	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	4404 0444	0004 0004	n.d.	n.d.
			30	tttt tttt	tttt tttt	4444 4444	4444 4444	4044 4444	0440 0000	0000 0000	n.d.	n.d.
			60	tttt tttt	tttt tttt	4444 4444	4444 4444	4400 0444	0000 0000	0000 0000	n.d.	n.d.
formaldehyde cytotoxicity	0.7% (m/V)	PBS	n.a.	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	PBS	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 0300	0044 4042	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 6: Raw data for control of efficacy for suppression of disinfectant's activity (2.5 %) (4101)

Product	Interfering substance	dilutions (log ₁₀)								
		1	2	3	4	5	6	7	8	9
test product	PBS	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	clean conditions	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	dirty conditions	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	0004 0004	0000 0000	n.d.

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 7: Raw data (poliovirus type 1) for cell sensitivity (2.5 %) (4101)

Product	Dilution	Dilutions (log ₁₀)								
		1	2	3	4	5	6	7	8	9
PBS	-	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 0400	0400 0000	n.d.
test product	1:10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:100	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:1,000	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4404 0004	4000 4040	n.d.

n.a. = not applicable

n.d. = not done

0 = no virus present; t = cytotoxic

1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 8: Raw data (poliovirus type 1) for cell sensitivity (1.5 %) (4101)

Product	Dilution	Dilutions (log ₁₀)								
		1	2	3	4	5	6	7	8	9
PBS	-	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 0400	0400 0000	n.d.
test product	1:10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:100	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 4440	0400 0000	n.d.
test product	1:1,000	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable

n.d. = not done

0 = no virus present; t = cytotoxic

1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 9a: Summary of results with Stabimed ultra and poliovirus type 1

Product	Con- centration	Interfering substance	Level of cytotoxicity	log ₁₀ TCID ₅₀ /ml aftermin					> 4 log ₁₀ reduction after ... min
				10	15	20	30	60	
test product	2.5%	dirty conditions	3.50	≤3.50±0.00	≤3.50±0.00	n.d.	n.d.	n.d.	10 (RF ≥ 4.50±0.27)
test product	2.0%	dirty conditions	3.50	≤3.50±0.00	≤3.50±0.00	n.d.	n.d.	n.d.	10 (RF ≥ 4.50±0.27)
test product	1.5%	dirty conditions	2.50	6.00±0.44	≤2.88±0.37	n.d.	n.d.	n.d.	15 (RF ≥ 5.13±0.27)
test product	0.5%	dirty conditions	1.50	7.63±0.25	7.50±0.35	n.d.	n.d.	n.d.	> 15

n.a. = not applicable n.d. = not done

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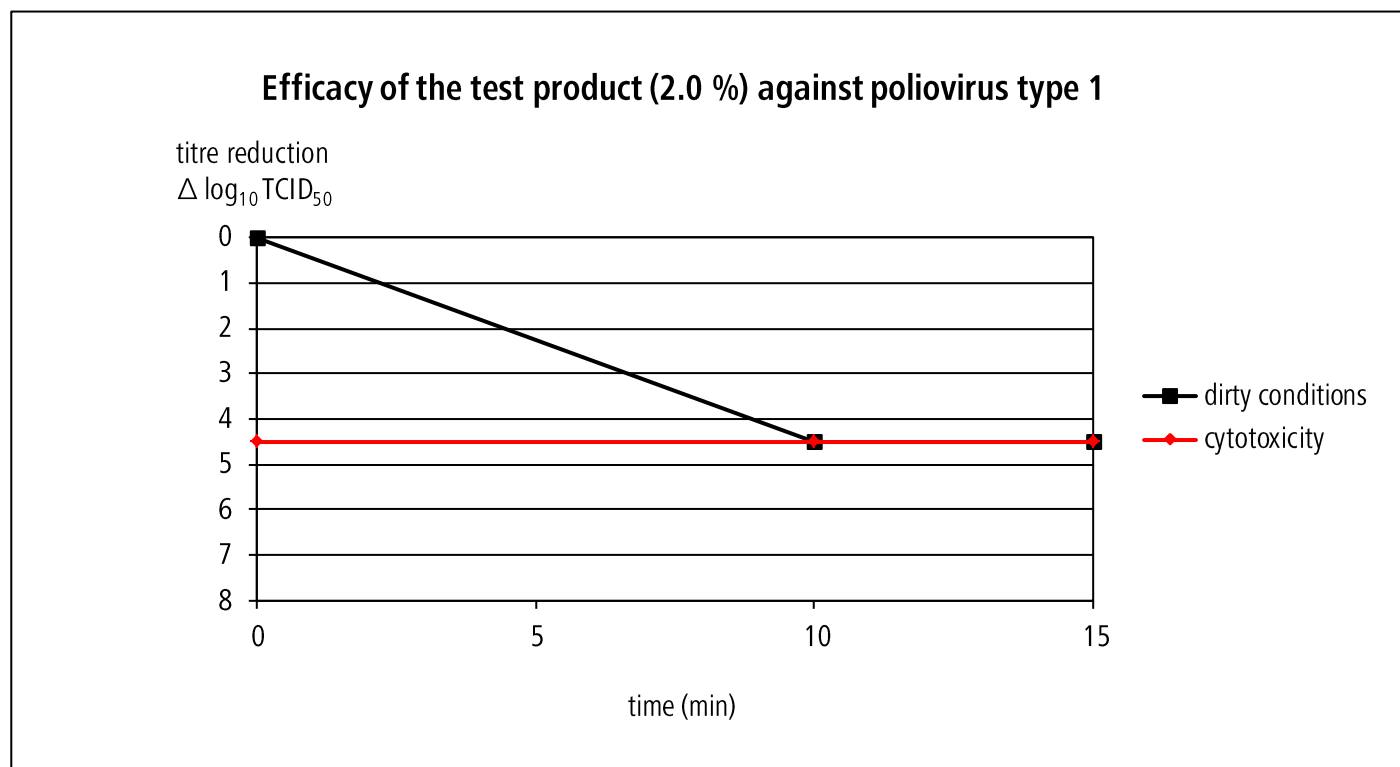
Table 9b: Summary of results with Stabimed ultra and poliovirus type 1

Product	Con- centration	Interfering substance	Level of cytotoxicity	log ₁₀ TCID ₅₀ /ml aftermin					> 4 log ₁₀ reduction after ... min
				0	5	15	30	60	
formaldehyde	0.7% (w/v)	PBS	3.50	n.d.	7.75±0.44	7.50±0.46	6.63±0.41	6.13±0.37	> 60
virus control	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	8.63±0.53	n.a.
virus control	n.a.	dirty conditions	n.a.	8.25±0.33	n.d.	n.d.	n.d.	8.00±0.38	n.a.
suppression control	2.5%	dirty conditions	3.50	n.d.	n.d.	n.d.	7.75±0.33	n.d.	n.a.
sens.control PBS	n.a.	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.13±0.45	n.a.
sens. control test product	2.5% → 1:1,000	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.38±0.53	n.a.
sens. control test product	1.5% → 1:100	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.25±0.44	n.a.

n.a. = not applicable n.d. = not done sens. = sensitivity

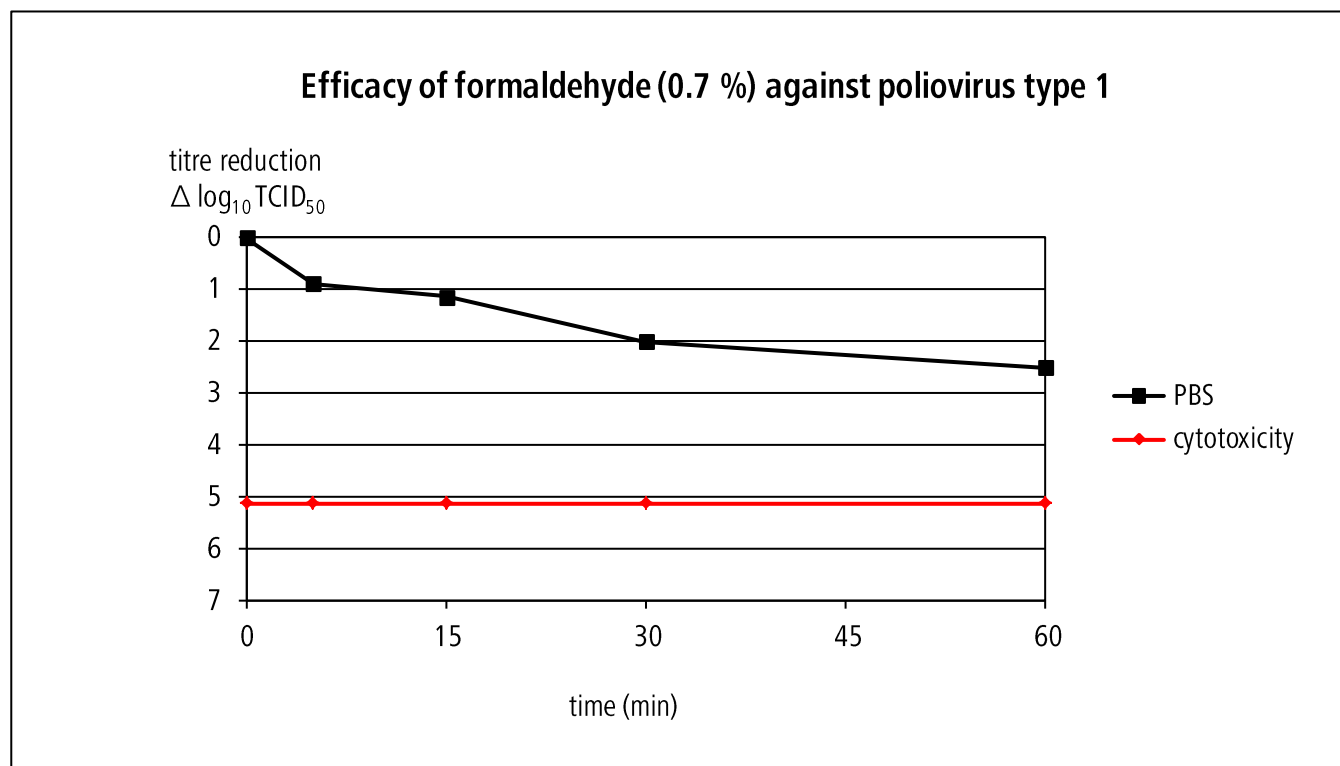
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Figure 1: Virus-inactivating properties of Stabimed ultra (2.0 %)



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Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)



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