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Expert Opinion

on the efficacy of

Stabimed Ultra

against

Adenovirus

EN 17111:2018

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Akkreditiert nach DIN EN ISO/IEC 17025



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B. Braun Medical AG

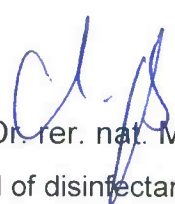
Seesatz 17
CH-6204 Sempach

2020-10-08

Expert opinion

The efficacy of the product **Stabimed Ultra** against Adenovirus type 5 strain Adenoid 75 was tested in a quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area according to the European standard EN 17111:2018. The efficacy of the disinfectant was evaluated under clean conditions (0.3 g/l BSA) as interfering substance and a temperature of $20\text{ °C} \pm 1.0\text{ °C}$. **Stabimed Ultra** was tested as a 0.1%, 1.0% and 2.0% concentration. The exposure times were 5, 10 and 15 minutes. This expert opinion refers to the test report LI-020-315.

In conclusion, the 1.0% and 2.0% concentration of the product Stabimed Ultra is effective against Adenovirus type 5 strain Adenoid 75 at 20 °C under clean conditions (0.3 g/l BSA) as interfering substance with an application time of 10 minutes.


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Head of disinfectant testing

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Test report

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Seesatz 17
CH-6204 Sempach

2020-10-08

Efficacy of Stabimed Ultra against Adenovirus type 5 strain Adenoid 75 in the quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area

Test report

Stabimed Ultra was tested for its efficacy against Adenovirus type 5 strain Adenoid 75 in the quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area according to the European standard EN 17111:2018. Under this standard, the product performance is tested against model viruses under defined test conditions, including temperature, contact time, or interfering substances, and the product should demonstrate at least a four log reduction in the titre of the test strain. **Stabimed Ultra** was examined as a 0.1%, 1.0% and 2.0% concentration under clean conditions (0.3 g/l BSA). The contact times were 5, 10 and 15 minutes.

Laboratory

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Germany

Identification of the sample

| | |
|---|---|
| Laboratory project identification number | LI-020-315 |
| Sample name | Stabimed Ultra |
| Batch number | 1903BH0014 |
| Manufacturer | B. Braun Medical AG |
| Appearance of the undiluted product | white fine powder |
| Date of manufacture | not specified |
| Expiry date | 2021-03 |
| Date of delivery | 2020-04-20 |
| Opened on | 2020-04-27 |
| Storage conditions | 20.0°C, dark |
| pH value undiluted | – |
| Active compounds in 100 g | According to Manufacturer: 0.16% peracetic acid (in 1.0% product solution) per 100 g |

Experimental conditions

| | |
|---|---|
| Test period | 2020-04-28 – 2020-05-05 2020-06-23 – 2020-06-30 2020-09-04 – 2020-09-11 |
| Test temperature | 20.0°C ± 1.0°C |
| Product test concentrations, pH value | 0.1% (pH 7.33), 1.0% (pH 7.93 / 8.26), 2.0% (pH 7.78 / 8.09) |
| Contact times | 5, 10 and 15 minutes |
| Interfering substance | clean conditions (0.3 g/l BSA) |
| Diluent used for product test solution | hard water |
| Appearance of product dilutions | clear, blue, liquid |
| Stability and appearance of the mixture during procedure | no changes |
| Temperature of incubation | 37.0°C ± 1.0°C, CO ₂ Incubator (5.0% CO ₂) |
| Virus | Adenovirus type 5 strain Adenoid 75 |
| Virus source | Virus bank of the DVV (Prof. Dr. A. Sauerbrei/University of Jena) |
| Virus charge | 230219 |
| Virus, number of passage | 5P/1 |
| Cell line | A549 cells (human lung adenocarcinoma epithelial cell line) |
| Cell line, source | ATCC (American Type Culture Collection) |
| Cell line, number of passage | 121 / 21 |

Test strain virus and cell culture line

As test virus Adenovirus type 5 strain Adenoid 75 was used. A549, a cell line established from human lung adenocarcinoma epithelial cells, were used for virus cultivation and the suspension test. The host cells were cultivated at 37.0°C in a humid atmosphere under 5.0% CO₂. The cells were feed with Minimum Essential Medium (MEM) supplemented with heat inactivated fetal calf serum (FCS) and with non essential amino acids. For virus cultivation confluent monolayers with an age of maximum 2 days were used.

The stock virus suspension was produced according to the directive. Cell debris was separated by low speed centrifugation at 2500 rpm for 10 minutes. Aliquots of the virus suspension were stored at -70.0°C.

Inactivation assay

The test product **Stabimed Ultra** was tested as a 0.1%, 1.0% and 2.0% concentration under clean conditions (0.3 g/l BSA) as interfering substance. The contact times were 5, 10 and 15 minutes. The test assays were mixed in the following way:

Frosted glass carriers (15 mm x 60 mm x 1 mm, one surface sandblasted were inoculated with a 50 µl virus mixture plus interfering solution [clean conditions (0.3 g/l BSA)]. Then, after drying, the carriers were placed in 10 ml disinfectant. Two carriers were tested for each test solution, control and contact time. The water control was carried out in parallel with the test solutions. Immediately after the contact time (within 10 seconds), the carrier was transferred into 5 ml medium. Each carrier was visually examined for complete elution. Then the virus suspensions were serially diluted 10-fold. Six wells of a microtitre plate containing a confluent monolayer were inoculated with 0.1 ml of each dilution, and the cells were incubated at 37.0°C in a humidified atmosphere under 5.0% CO₂. After the incubation time, the cell cultures were stained with 50 µl crystal violet per well. The cells were examined microscopically for cytopathic effects (CPE).

The cell culture results were recorded as "0" for no CPE and "1" (25.0% CPE) to "4" (100% CPE) depending on degree of the cell damage. The viral titre was calculated using the Spearman-Kärber-method (Br. J. Psychol. 2 (1908): 227-42, Arch. exp. Path. Pharmac. 162 (1931): 480-87).

Calculation of the virucidal activity of the products

Reduction of virus titre was calculated from by logarithmic titre differences between those treated with disinfectant and those treated with hard water at the chosen contact time ($\Delta \log_{10} \text{TCID}_{50}/\text{ml}$).

Cytotoxic effect

To check for possible morphological alteration of cells by the disinfectant, 45 μl MEM +2 % FCS + 5 μl of interfering substance were inoculated on a carrier and dried. The inoculated carrier was immersed immediately after the drying process has been finished in 10 ml of one of the product test solutions. The tube was placed in a water bath controlled at the chosen test temperature. At the end of the contact time, the carrier was transferred into a tube filled with 5 ml of medium. As the virus suspensions a series of ten-fold dilutions was prepared and the dilutions were inoculated on cell culture. After incubation the titre of virus was calculated.

Interference control

The comparative virus titration was performed on cells that had been treated with disinfectants to check the reduction in the sensitivity to the virus as follows: Cells were incubated for 1 hour with the lowest apparently non-cytotoxic dilution of the test product based on the results of the cytotoxicity test. After 1 h at 37.0°C the test solution was removed, and the cells were infected with the titrated control virus. The assay is only valid if the virus control of mock-treated cells (no disinfectant) minus the virus control of cells pre-treated with the test product resulted in less than a log difference.

Control of efficiency of suppression of product's activity

100 μl of the undiluted test product and 850 μl of ice-cold medium with 2.0% FCS were mixed. Afterwards 50 μl of the virus inoculum were added and the mixture is incubated in an ice-bath for 30 min \pm 10 s. A serial dilution in \log_{10} steps was prepared and cell cultures were inoculated with the dilutions. The titre was determined. The difference between the titre of the suppression of virucidal activity (SVA) control and the titre of virus control should not exceed 0.50 \log_{10} according to EN 14476.

Reference virus inactivation assay

A control of the test system with glutardialdehyde as a reference was included.

Results

The product **VP4078/51** was tested as a 0.1%, 1.0% and 2.0% concentration under clean conditions (0.3 g/l BSA) as interfering substance and following exposure times of 5, 10 and 15 minutes.

Validity of the test

The test product dilutions caused no cytotoxic effects (Table 1). As shown in Table 2, the comparative virus titration on cells treated with test mixture dilution or without resulted in a difference of less than one log. The after-effect control, which measures the efficiency of suppression of product's activity, shall be ≤ 0.50 lg. As shown in Table 3, the control was 0.00 lg.

The results of the reference virus inactivation using glutardialdehyde (Glutaral, 1,5-Pentanedial, CAS Number 111-30-8) are given in Table 4, and the reduction was in the acceptable range (≥ 4 lg within 5 min).

Test results

The data of the virucidal efficacy of **Stabimed Ultra** is presented in Tables 5 and 6. With the 0.1 % concentration of **Stabimed Ultra** no virucidal efficacy was obtained. The inactivation assay with the 1.0% and 2.0% concentration of the test product could not demonstrate a 4 log₁₀ reduction due to the cytotoxicity of the test product. Therefore, the Large Volume Plating (LVP) method was performed. In LVP, a high volume of the lowest apparently non-cytotoxic dilution of the inactivation assay test mixture is added to the detector cell line and the cultures are monitored for virus-specific effects. After detoxification, the 1.0 % and 2.0% concentration of **Stabimed Ultra** showed excellent virucidal activity against the Adenovirus type 5 strain Adenoid 75 at 20 °C within 10 minutes.

Table 1: Cytotoxic factor of VP4078/51

| Concentration | Interfering substance | Dilution (log ₁₀) | | | | | | |
|---------------|-----------------------|-------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| | | 10 ⁻⁰ | 10 ⁻¹ | 10 ⁻² | 10 ⁻³ | 10 ⁻⁴ | 10 ⁻⁵ | 10 ⁻⁶ |
| 0.1% | clean conditions | – | – | – | – | – | – | – |
| 1.0% | clean conditions | + | – | – | – | – | – | – |
| 2.0% | clean conditions | + | – | – | – | – | – | – |

Table 2: Comparative virus titration on cells treated with the test mixture dilution

| Concentration | Interfering substance | Titre of the virus control (log ₁₀ TCID ₅₀ /ml) PBS | Titre of the comparative virus titration (log ₁₀ TCID ₅₀ /ml) | Difference in virus titre (log ₁₀ TCID ₅₀ /ml) |
|---------------|-----------------------|---|---|--|
| 2.0% | clean conditions | 7.67 +/- 0.33 | 7.67 +/- 0.33 | 0.00 |

Table 3: Control of efficiency of suppression of product's activity

| Concentration | Titre of the virus control (log ₁₀ TCID ₅₀ /ml) | Titre of the after effect control titration (log ₁₀ TCID ₅₀ /ml) | Difference in virus titre (log ₁₀ TCID ₅₀ /ml) |
|---------------|---|--|--|
| 2.0% | 7.00 +/- 0.45 | 7.00 +/- 0.45 | 0.00 |

Table 4: Reference virus inactivation of Adenovirus type 5 strain Adenoid 75 with glutardialdehyde (Glutaral, 1,5-Pentanedial) CAS Number 111-30-8

| Concentration / Contact time | Interfering substance | Level of cyto-toxicity | Titre of the virus control (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Titre of the “residual virus” inactivation (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Reduction factor |
|------------------------------|-----------------------|------------------------|--|---------------------|---------------------|--|---------------------|---------------------|-----------------------------------|
| | | | Carrier 1 | Carrier 2 | Mean value | Carrier 1 | Carrier 2 | Mean value | Mean value ± 95.0% CI |
| 3500 ppm / 5 min | clean conditions | — | 5.33 +/- 0.33 | 5.33 +/- 0.33 | 5.33 +/- 0.33 | 0.67 +/- 0.33 | 0.67 +/- 0.33 | 0.67 +/- 0.33 | 4.66 +/- 0.47 |

CI confidence interval

Table 5: Virucidal activity of Stabimed Ultra against Adenovirus type 5 strain Adenoid 75

| Concentration / contact time | Interfering substance | Level of cyto- toxicity | ° C | Titre of the virus control at (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Titre of the “residual virus” inactivation (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Reduction factor (RF) |
|---------------------------------|--------------------------|-------------------------------|------|---|---------------------|---------------------|--|-----------------------|-----------------------|-------------------------------------|
| | | | | Carrier 1 | Carrier 2 | Mean value | Carrier 1 | Carrier 2 | Mean value | Mean value RF 95.0% CI |
| 0.1% 5 min | clean conditions | | 20.0 | 5.33 +/- 0.33 | 5.33 +/- 0.33 | 5.33 +/- 0.33 | 4.33 +/- 0.54 | 4.50 +/- 0.00 | 4.42 +/- 0.27 | 0.92 +/- 0.43 |
| 1.0% 5 min | clean conditions | 1.50 | 20.0 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≥ 2.17 +/- 0.33 |
| 1.0% 10 min | clean conditions | 1.50 | 20.0 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≥ 2.17 +/- 0.33 |
| 2.0% 10 min | clean conditions | 1.50 | 20.0 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≥ 2.17 +/- 0.33 |
| 2.0% 15 min | clean conditions | 1.50 | 20.0 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | 3.67 +/- 0.33 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≤ 1.50 +/- 0.00 | ≥ 2.17 +/- 0.33 |

Table 5: Virucidal activity of Stabimed Ultra against Adenovirus type 5 strain Adenoid 75 after detoxification with the LVP method

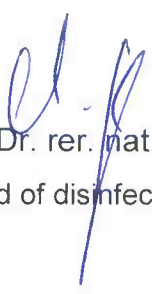
| Concentration / contact time | Interfering substance | Level of cyto- toxicity | °C | Titre of the virus control at (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Titre of the “residual virus” inactivation (log ₁₀ TCID ₅₀ /ml) with 95.0% confidence interval | | | Reduction factor (RF) |
|---------------------------------|--------------------------|-------------------------------|------|---|---------------------|---------------------|--|-----------|---------------|---------------------------------|
| | | | | Carrier 1 | Carrier 2 | Mean value | Carrier 1 | Carrier 2 | Mean value | Mean value RF 95.0% CI |
| 1.0% 5 min | clean conditions | – | 20.0 | 5.33 +/- 0.33 | 5.50 +/- 0.47 | 5.42 +/- 0.40 | 2.82 | 2.82 | 2.82 | 2.60 +/- 0.40 |
| 1.0% 10 min | clean conditions | – | 20.0 | 5.33 +/- 0.33 | 5.50 +/- 0.47 | 5.42 +/- 0.40 | 0.66 | 0.66 | 0.66 | 4.76 +/- 0.40 |
| 2.0% 10 min | clean conditions | – | 20.0 | 5.33 +/- 0.33 | 5.50 +/- 0.47 | 5.42 +/- 0.40 | 0.66 | 0.66 | 0.66 | 4.76 +/- 0.40 |
| 2.0% 15 min | clean conditions | – | 20.0 | 5.33 +/- 0.33 | 5.50 +/- 0.47 | 5.42 +/- 0.40 | 0.66 | 0.66 | 0.66 | 4.76 +/- 0.40 |

Conclusion

Stabimed Ultra efficiently inactivates Adenovirus type 5 strain Adenoid 75 under clean conditions (0.3% BSA) within 10 minutes exposure time.

The following concentrations and exposure times is active against Adenovirus type 5 strain Adenoid 75:

| Concentration | Temperature [°C] | Contact time |
|---------------|------------------|--------------|
| 1.0 % | 20.0 | 10 min |
| 2.0 % | 20.0 | 10 min |



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Head of disinfectant testing

Archiving: The raw data with respect to this test and a copy of the report will be stored in the archive of Labor Enders MVZ.

Information: The test results exclusively refer to the samples described above. Account of extracts of this test report is only possible by written approval from Labor Enders MVZ.

The assessment of medical devices is not covered by accreditation.

Raw data for the test product Stabimed ultra tested against Adenovirus type 5 strain Adenoid 75 under clean conditions (quantal test; 6 wells)

2020-04-28 – 2020-05-05

| Control | Interfering substance | Contact time | Dilution (log ₁₀) | | | | | | | |
|--------------------|-----------------------|--------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Suspension control | | 0 min | 444 | 444 | 444 | 444 | 444 | 222 | 001 | 000 |
| | | | 444 | 444 | 444 | 444 | 444 | 222 | 010 | 000 |

2020-04-28 – 2020-05-05

| Product | Con- centra- tion | Interfering substance | Contact time | Dilution (log ₁₀) | | | | | | | |
|-----------------------------|-------------------------|--------------------------|---------------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Stabimed ultra | 1.0% | clean conditions | Carrier 1 5 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 5 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 1 10 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 10 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| Virus control hard water | | clean conditions | Carrier 1 10 min | 444 | 444 | 333 | 213 | 100 | 000 | 000 | 000 |
| | | | | 444 | 444 | 334 | 322 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 10 min | 444 | 444 | 444 | 222 | 001 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 000 | 000 | 000 | 000 |
| Cytotoxicity | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |

1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)

0 no virus present

n. a. not applicable

n. d. not done

x cytotoxic

Raw data for the test product Stabimed ultra tested against Adenovirus type 5 strain Adenoid 75 under clean conditions (quantal test; 6 wells)

2020-04-28 – 2020-05-05

| Product | Con- centra- tion | Interfering substance | Contact time | Dilution (log ₁₀) | | | | | | | |
|-----------------------------|-------------------------|--------------------------|---------------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Stabimed ultra | 2.0% | clean conditions | Carrier 1 10 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 10 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 1 15 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 15 min | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| Virus control hard water | | clean conditions | Carrier 1 15 min | 444 | 444 | 333 | 213 | 100 | 000 | 000 | 000 |
| | | | | 444 | 444 | 334 | 322 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 15 min | 444 | 444 | 444 | 222 | 001 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 000 | 000 | 000 | 000 |
| Cytotoxicity | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | xxx | 000 | 000 | 000 | 000 | 000 | 000 | 000 |

1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)

0 no virus present

n. a. not applicable

n. d. not done

x cytotoxic

Raw data for the test product Stabimed ultra (1.0%) tested against Adenovirus type 5 strain Adenoid 75 under clean conditions, inactivation assay according to LVP

2020-06-23 – 2020-06-30

| Concentration | Interfering substance | Contact time | Line | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|----------------|-----------------------|--------------|-------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 1.0% Carrier 1 | clean conditions | 5 min | plate 1 / 1 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4440 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 |
| 1.0% Carrier 2 | clean conditions | 5 min | plate 1 / 1 | 4444 4444 | 4404 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 | 4444 4444 |
| Virus control | | | | 444 444 | 444 444 | 443 433 | 312 120 | 000 000 | 000 000 | – – | – – | – – | – – | – – | – – |
| Virus control | | | | 444 444 | 444 444 | 334 343 | 220 212 | 000 010 | 000 000 | – – | – – | – – | – – | – – | – – |
| Cytotoxicity | | | | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |

| Concentration | Interfering substance | Contact time | Line | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|----------------|-----------------------|--------------|-------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 1.0% Carrier 1 | clean conditions | 10 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| 1.0% Carrier 2 | clean conditions | 10 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| Virus control | | | | 444 444 | 444 444 | 443 433 | 312 120 | 000 000 | 000 000 | – – | – – | – – | – – | – – | – – |
| Virus control | | | | 444 444 | 444 444 | 334 343 | 220 212 | 000 010 | 000 000 | – – | – – | – – | – – | – – | – – |
| Cytotoxicity | | | | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |

1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)

0 no virus present

Raw data for the test product Stabimed ultra (2.0%) tested against Adenovirus type 5 strain Adenoid 75 under clean conditions, inactivation assay according to LVP

2020-06-23 – 2020-06-30

| Concentration | Interfering substance | Contact time | Line | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|----------------|-----------------------|--------------|-------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 2.0% Carrier 1 | clean conditions | 10 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| 2.0% Carrier 2 | clean conditions | 10 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| Virus control | | | | 444 444 | 444 444 | 443 433 | 312 120 | 000 000 | 000 000 | – | – | – | – | – | – |
| Virus control | | | | 444 444 | 444 444 | 334 343 | 220 212 | 000 010 | 000 000 | – | – | – | – | – | – |
| Cytotoxicity | | | | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |

| Concentration | Interfering substance | Contact time | Line | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|----------------|-----------------------|--------------|-------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 2.0% Carrier 1 | clean conditions | 15 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| 2.0% Carrier 2 | clean conditions | 15 min | plate 1 / 1 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |
| Virus control | | | | 444 444 | 444 444 | 443 433 | 312 120 | 000 000 | 000 000 | – | – | – | – | – | – |
| Virus control | | | | 444 444 | 444 444 | 334 343 | 220 212 | 000 010 | 000 000 | – | – | – | – | – | – |
| Cytotoxicity | | | | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 | 0000 0000 |

1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)

0 no virus present

Raw data for the product Stabimed Ultra tested against Adenovirus type 5 strain Adenoid 75 under clean conditions (quantal test; 6 wells)

2020-09-04 – 2020-09-11

| Control | Interfering substance | Contact time | Dilution (log ₁₀) | | | | | | | |
|---|-----------------------|--------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Suspension control | | 0 min | 444 | 444 | 444 | 444 | 433 | 212 | 102 | 000 |
| | | | 444 | 444 | 444 | 444 | 333 | 222 | 000 | 000 |
| Cell sensitivity to virus after preincubation with the test product | clean conditions | | 444 | 444 | 444 | 444 | 344 | 132 | 000 | 000 |
| | | | 444 | 444 | 444 | 444 | 444 | 222 | 010 | 000 |
| Cell sensitivity to virus after preincubation with PBS | | | 444 | 444 | 444 | 444 | 444 | 121 | 000 | 000 |
| | | | 444 | 444 | 444 | 444 | 434 | 122 | 002 | 000 |
| After-effect control without product | | 30 min | 444 | 444 | 444 | 444 | 433 | 221 | 000 | 000 |
| | | | 444 | 444 | 444 | 444 | 323 | 222 | 200 | 000 |
| After-effect control with product | | 30 min | 444 | 444 | 444 | 444 | 333 | 002 | 000 | 000 |
| | | | 444 | 444 | 444 | 444 | 333 | 120 | 000 | 000 |

Raw data for the product Stabimed Ultra tested Adenovirus type 5 strain Adenoid 75 under clean conditions (quantal test; 6 wells)

2020-09-04 – 2020-09-11

| Product | Con- centra- tion | Interfer- ing sub- stance | Contact time | Dilution (log ₁₀) | | | | | | | |
|---------------------------------------|-------------------------|------------------------------------|--------------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Reference control Glutaraldehyde | 3500 ppm | clean conditions | Carrier 1 5 min | 001 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 5 min | 100 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| Virus control hard water 20.0°C | | clean conditions | Carrier 1 2 min | 444 | 444 | 444 | 323 | 122 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 122 | 000 | 000 | 000 |
| | | | Carrier 2 2 min | 444 | 444 | 444 | 233 | 212 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 112 | 000 | 000 | 000 |

- 1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)
 0 no virus present
 x cytotoxic

Raw data for the product Stabimed Ultra tested against Adenovirus type 5 strain Adenoid 75 under clean conditions (quantal test; 6 wells)

2020-09-04 – 2020-09-11

| Product | Con- centra- tion | Interfering substance | Contact time | Dilution (log ₁₀) | | | | | | | |
|-----------------------------|-------------------------|--------------------------|--------------------|-------------------------------|-----|-----|-----|-----|-----|-----|-----|
| | | | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Stabimed Ultra | 0.1% | clean conditions | Carrier 1 5 min | 444 | 444 | 433 | 322 | 020 | 000 | 000 | 000 |
| | | | | 444 | 444 | 333 | 020 | 000 | 000 | 000 | 000 |
| | | | Carrier 2 5 min | 444 | 444 | 343 | 121 | 000 | 000 | 000 | 000 |
| | | | | 444 | 444 | 333 | 212 | 000 | 000 | 000 | 000 |
| Virus control hard water | | clean conditions | Carrier 1 5 min | 444 | 444 | 444 | 323 | 122 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 122 | 000 | 000 | 000 |
| | | | Carrier 2 5 min | 444 | 444 | 444 | 233 | 212 | 000 | 000 | 000 |
| | | | | 444 | 444 | 444 | 333 | 112 | 000 | 000 | 000 |
| Cytotoxicity | | | | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| | | | | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |

1–4 virus present, degree of CPE in cell culture units (6 wells of microtitre plates)

0 no virus present

x cytotoxic