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Requirements and Methods for VAH Certification of Chemical Disinfection Procedures

Edited by VAH Disinfectants Commission

Annex V (Requirements for virucidal efficacy):
As of 1 November 2021

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*DVV: German Association for Control of Viral Diseases

RKI: Robert Koch Institute

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ANNEX V

V1A Hygienic hand disinfection

Requirements

For the conformity assessment procedure two independent expert opinions (assessments), including test reports, confirming the efficacy in the claimed concentration-time relation must be submitted.

To that effect, expert opinions compiled in accordance with the DVV/RKI Guideline 2008 [1] or 2015 [2] may be submitted. Expert opinions based on DVV/RKI Guideline 2005 [3] may need to be supplemented with additional tests in order to comply with the requirements of DVV/RKI Guideline 2015 or 2008 [1,2]. Alternatively, expert opinions based on DIN EN 14476 [4] may also be submitted.

Furthermore, for tests based on a European standard the use concentration must be confirmed in the respective test report in a second independent test batch and, as controls, must include the virus control, cytotoxicity test and reference test. The mean confidence interval for two independent tests must each be ≤ 0.5 lg.

The bactericidal and yeasticidal activity confirmed by the VAH by means of a conformity assessment procedure or confirmed additionally during this procedure is a prerequisite for certification. This also includes activity within the claimed concentration and contact time (exposure time) in the simulated-use test with *E. coli* based on Method 11 or DIN EN 1500 [5].

The concentration-time relation for activity against viruses featured in the VAH List must not be shorter than that specified for the VAH-listed bactericidal and yeasticidal efficacy.

The test concentrations and contact times must be selected such that the relationship between the disinfectant virucidal activity and the concentration and contact time is evident from the test results (kinetics).

Obligatory

– *Determination of the virucidal efficacy (activity spectrum: activity against enveloped viruses) in the quantitative suspension test (method based on DVV/RKI 2008 or 2015 [1,2] or DIN EN 14476 [4]*

  The test product must reduce the virus titre of the test viruses listed in Table V1.1 under the specified conditions within the stipulated contact time(s) at 20 °C by at least 4 lg levels.

Optional:

– *Determination of the virucidal efficacy (limited spectrum virucidal activity or virucidal activity) in the quantitative suspension test (method based on DVV/RKI 2008 or 2015 [1,2] or DIN EN 14476 [4]*

The test product must reduce the virus titre of the test viruses listed in Table V1.1 under the specified conditions within the stipulated contact time(s) at 20 °C by at least 4 lg levels.

Table V1.1: Test conditions in the quantitative suspension test.

Activity spectrum	Test organisms	Test method	Interfering substance [1]/ Test concentrations[2]	Test temperature [°C]	Contact times[3]
Active against enveloped viruses	*Vaccinia virus BVDV*[4]	DVV/RKI [1 and 2] or DIN EN 14476 [4][5]	DVV/RKI dirty or clean conditions (EN) / undiluted	20 ± 1	15 s, 30 s, 1 min
Limited virucidal activity	*Adenovirus Norovirus*	DVV/RKI [1, 2 and 3] or DIN EN 14476 [4][5]	RKI/DVV dirty or clean conditions (EN) / undiluted	20 ± 1	15 s, 30 s, 1 min, 1.5 min, 2 min
Virucidal activity	*Poliovirus Adenovirus Norovirus SV40*	DVV/RKI [1, 2 and 3] or DIN EN 14476 [4][5]	RKI/DVV dirty or clean conditions (EN) / undiluted	20 ± 1	15 s, 30 s, 1 min, 1.5 min, 2 min

[1]The interfering substances based on DVV/RKI are 10 % FCS (foetal calf serum) and distilled water or based on DIN EN 14476 the use of a lower amount of interfering substance consisting of 0.3 % BSA (bovine serum albumin).
[2]To record the efficacy limits at least two concentrations (use concentration and an ineffective concentration) must be tested.
[3]At least three of the listed contact times must be tested, including the claimed contact times. The contact times should be between 15 s and 2 min. A maximum contact time of 60 s should be aspired to.
[4]Additionally for products with oxidative activity
[5]Test reports based on EN 14476:2013 continue to be valid

- If available, test reports based on prDIN EN 17430 (simulated use-test with the murine norovirus) may also be submitted for the virucidal efficacy (*limited spectrum virucidal activity and/or virucidal activity*) [6]. Such test reports must meet the following requirements:

  To compare the results of the test procedure and reference procedure and evaluate the test procedure, the following requirements must be met:

  - Exploitable results must be available for at least 18 subjects.
  - The total mean value of the prevalues for the reference product and test product must be at least 4 lg.

- For the reference product no more than three individual lg reductions may be < 2 and the absolute difference of the mean differences between the lg reductions of the reference product group → test product and test product group → reference product must be less than 2.
- The test product must not be inferior to the reference product (Hodges-Lehmann) p = 0.025.
- The limit for inferiority = 0.35 lg units.

Test viruses as per DVV/RKI guidelines and DIN EN 14476

Adenovirus	=	Adenovirus type 5, Adenoid 75 strain
BVDV	=	Bovine Viral Diarrhea Virus, NADL strain
Norovirus	=	Murine norovirus, S99 Berlin (MNV) strain
Poliovirus	=	Poliovirus vaccination type 1 strain, LSc-2ab strain
SV40	=	Polyomavirus (SV 40), 777 strain
Vaccinia virus	=	Modified vaccinia virus Ankara (MVA) or vaccinia virus, Elstree strain

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2. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. Dezember 2014. Bundesgesundheitsbl 2015;58:493–504.
3. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten e.V. und des Robert Koch-Instituts zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin (Fassung vom 15. Juni 2005). Bundesgesundheitsbl 2005;48:1420–1426.
4. DIN EN 14476:2019-10. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2, Stufe 1); Deutsche Fassung EN 14476:2013+A2:2019. DIN Deutsches Institut für Normung e.V.: 1–42.
5. DIN EN 1500:2017-10. Chemische Desinfektionsmittel und Antiseptika – Hygienische Händedesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 1500:2013.
6. DIN EN 17430:2019-09 Entwurf. Chemische Desinfektionsmittel und Antiseptika – Viruzide hygienische Händedesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche und Englische Fassung prEN 17430:2019.

Note: VAH certificates based on the prEN version continue to be valid.

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V2A Surface disinfection

Requirements

For the conformity assessment procedure two independent expert opinions, including test reports, confirming the efficacy in the claimed concentration-time relation in quantitative suspension tests and simulated-use tests must be submitted.

To that effect, expert opinions compiled in accordance with DVV/RKI Guideline 2008 [1] or 2015 [2] may be submitted. Expert opinions based on DVV/RKI Guideline 2005 [3] may need to be supplemented with additional tests in order to comply with the requirements of DVV/RKI Guideline 2015 or 2008 [1,2]. Alternatively, expert opinions based on DIN EN 14476 [4] may also be submitted.

The simulated-use surface tests must be performed in accordance with the DVV guideline 2012 [5] and EN 16777 [6].

Furthermore, for tests based on a European standard the use concentration must be confirmed in the respective test report in a second independent test batch and, as controls, must include the virus control, cytotoxicity test and reference test. The mean confidence interval for two independent tests must each be ≤ 0.5 lg.

The bactericidal and yeasticidal (levoricidal) activity confirmed by the VAH by means of a conformity assessment procedure or confirmed additionally during this procedure is a prerequisite for certification.

The concentration-time relation for activity against viruses featured in the VAH List must not be shorter than that specified for the VAH-listed bactericidal and yeasticidal efficacy.

The test concentrations and contact times must be selected such that the relationship between the disinfectant virucidal activity and the concentration and contact time is evident from the test results (kinetics).

Obligatory

- *Determination of the virucidal efficacy (activity against enveloped viruses, limited spectrum virucidal activity and/or virucidal activity) in the quantitative suspension test (method based on DVV/RKI 2008 or 2015 [1,2] or DIN EN 14476 [4]*
- *Determination of the virucidal efficacy (activity against enveloped viruses, limited spectrum virucidal activity and/or virucidal activity) in the simulated-use surface test (DVV guideline 2012 [5] and EN 16777 [6]), whereby limited spectrum virucidal activity corresponds to the low-level virucidal activity spectrum and virucidal activity corresponds to the high-level virucidal activity spectrum of the DVV*

*guideline, provided that the test viruses listed in **Table V 2.2** are used.*

The test product must reduce the virus titre of the test viruses listed in **Table V2.1** under the specified conditions within the stipulated contact time(s) at the test temperature by at least 4 lg levels.

Table V2.1: Test conditions in the quantitative suspension test.

Activity spectrum	Test organisms	Test method	Interfering substance[1]/ Test concentrations [2]	Test temperature [°C]	Contact times[3]
Active against enveloped viruses	*Vaccinia virus BVDV*[4]	DVV/RKI [1, 2] or DIN EN 14476 [4][5]	DVV/RKI or clean or dirty/ use concentration[2]	20 ± 1	1, 5, 15, 30, 60
Limited virucidal activity	*Adenovirus Norovirus*	DVV/RKI [1, 2] or DIN EN 14476 [4][5]	DVV/RKI or clean or dirty/ use concentration[2]	20 ± 1	
Virucidal activity	*Poliovirus Adenovirus Norovirus SV40*	DVV/RKI [1, 2] or DIN EN 14476 [4][5]	DVV/RKI or clean or dirty/ use concentration[2]	20 ± 1	

[1]The interfering substances based on DVV/RKI are 10 % FCS (foetal calf serum) and distilled water. Based on DIN EN 14476, the test batch with a lower amount of interfering substance consisting of 0.3 % BSA (bovine serum albumin) is considered to be under clean conditions and the test batch with 3% BSA and 3% sheep erythrocytes is considered to be under dirty conditions

[2]To record the efficacy limits at least two concentrations (use concentration and an ineffective concentration) must be tested (for gradations, see Chapter 5).

[3]At least three of the listed contact times must be tested, including the claimed contact times. The test must also take into account the contact time that is directly below the claimed contact time.

[4]Additionally for products with oxidative activity

[5]Test reports based on EN 14476:2013 continue to be valid

Table V2.2: Test conditions in the simulated-use test.

Activity spectrum	Test organisms	Test method	Interfering substance[1]/ Test concentrations[2]	Test temperature [°C]	Contact times [min][3]
Active against enveloped viruses	*Vaccinia virus*	DVV guideline 2012 [5] or EN 16777 [6][4]	Clean or dirty/ use concentration[2]	22 ± 3	1, 5, 15, 30, 60
Limited virucidal activity (corresponds to low-level virucidal [5])	*Adenovirus Norovirus*	*DVV guideline 2012 [5] or EN 16777 [6][4]*	Clean or dirty/ use concentration[2]	22 ± 3	
Virucidal activity (corresponds to high-level virucidal ([5])	*Adenovirus* Norovirus* Parvovirus*	DVV guideline 2012 [5] or EN 16777 [6][4]	Clean or dirty/ use concentration[2]	22 ± 3	

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[1]The test with 0.3% BSA (bovine serum albumin) is considered to be under clean conditions and the test with 3% BSA and 3% sheep erythrocytes is considered to be under dirty conditions..
[2]To record the efficacy limits at least two concentrations (use concentration and an ineffective concentration) must tested. (For gradations see Chapter 5).
[3] The test contact times are based on Table V2.3. The test must also take into account the contact time that is directly below the claimed contact time.
[4] Test reports based on the prEN version continue to be valid.
* If efficacy has not already been demonstrated for the limited virucide PLUS activity spectrum.

Table V2.3: Contact times to be selected in the individual test runs for simulated-use testing of surface disinfectants.

Claimed contact time	1st Test run	2nd Test run
Surface disinfection without mechanical action		
1 min	0.5 min, 1 min	1 min
5 min	1 min, 5 min	5 min
15 min	5 min, 15 min	15 min
30 min	15 min, 30 min	30 min
60 min	30 min, 60 min	60 min

The simulated-use tests must be performed in all cases in two independent test runs:

1. Test run: In each case at least two test surfaces per concentration-time relation (see **Table V2.2** and **V2.3**), virus control (before and after drying), sustained effect check, interference test, cytotoxicity test and reference test

2. Test run: In each case at least two test surfaces per claimed concentration-time relation, virus control (before and after drying), cytotoxicity test and reference test

Test viruses as per DVV/RKI guidelines and DIN EN 14476 or DIN EN 16777

Adenovirus = Adenovirus type 5, Adenoid 75 strain
BVDV = Bovine Viral Diarrhea Virus, NADL strain
Norovirus = Murine norovirus, S99 Berlin (MNV) strain
Parvovirus = Murine parvovirus (minute virus of mice, rodent protoparvovirus 1) (MVM)
Poliovirus = Poliovirus vaccination type 1 strain, LSc-2ab strain
SV40 = Polyomavirus (SV 40), 777 strain
Vaccinia virus = Modified vaccinia virus Ankara (MVA) or vaccinia virus, Elstree strain

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1. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. August 2008. Bundesgesundheitsbl 2008;51:937–945.

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3. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten e.V. und des Robert Koch-Instituts zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin (Fassung vom 15. Juni 2005). Bundesgesundheitsblatt 2005;48:1420–1426.

4. DIN EN 14476:2019-10. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2, Stufe 1); Deutsche Fassung EN 14476:2013+A2: 2019.

5. DVV. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e. V. Quantitative Prüfung der viruziden Wirksamkeit chemischer Desinfektionsmittel auf nicht-porösen Oberflächen (Anwendung im Bereich Humanmedizin). HygMed 2012;37(3):78–85.

6. DIN EN 16777:2019-03. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Versuch auf nicht porösen Oberflächen ohne mechanische Einwirkung zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2); Deutsche Fassung EN 16777:2018.

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V3A Instrument disinfection (as immersion disinfection)

Requirements

For the conformity assessment procedure two independent expert opinions, including test reports, confirming the efficacy in the claimed concentration-time relation in quantitative suspension tests and simulated-use tests must be submitted.

To that effect, expert opinions compiled in accordance with DVV/RKI Guideline 2008 [1] or 2015 [2] may be submitted. Expert opinions based on DVV/RKI Guideline 2005 [3] may need to be supplemented with additional tests in order to comply with the requirements of DVV/RKI Guideline 2015 or 2008 [1,2]. Alternatively, expert opinions based on DIN EN 14476 [4] may also be submitted.

The simulated-use surface tests must be performed in accordance with EN 17111 [5].

Furthermore, for tests based on a European standard the use concentration must be confirmed in the respective test report in a second independent test batch and, as controls, must include the virus control, cytotoxicity test and reference test. The mean confidence interval for two independent tests must each be ≤ 0.5 lg.

The bactericidal and yeasticidal (levoricidal) activity confirmed by the VAH by means of a conformity assessment procedure or confirmed additionally during this procedure is a prerequisite for certification.

The concentration-time relation for activity against viruses featured in the VAH List must not be shorter than that specified for the VAH-listed bactericidal and yeasticidal efficacy.

The test concentrations and contact times must be selected such that the relationship between the disinfectant virucidal activity and the concentration and contact time is evident from the test results (kinetics).

Obligatory

- *Determination of the virucidal efficacy (activity against enveloped viruses and/or virucidal) in the quantitative suspension test (method based on DVV/RKI 2008 or 2015 [1,2] or DIN EN 14476 [4]*
- *Determination of the virucidal efficacy (activity against enveloped viruses and/or virucidal) in the simulated-use test as per DIN EN 17111 [5].*

  The test product must reduce the virus titre of the test viruses listed in **Table V3.1 and V3.2** under the specified conditions within the stipulated contact time(s) at the test temperature by at least 4 lg levels.

Table V3.1: Test conditions in the quantitative suspension test.

Activity spectrum	Test organisms	Test method	Interfering substance[1]/ Test concentrations[2]	Test temperature [°C]	Contact times [min][3]
Activity against enveloped viruses*	*Vaccinia virus BVDV* [4]	DVV/RKI [1, 2] or in accordance with DIN EN 14476 [4][5]	DVV/RKI or under clean or dirty conditions/ use concentration	20 ± 1	1, 5, 15, 30, 60
Virucidal instrument disinfection at < 40 °C	*Poliovirus Adenovirus Norovirus SV40*	DVV/RKI [1, 2] or DIN EN 14476 [4][5]	DVV/RKI or under clean or dirty conditions/ use concentration	20 ± 1 to < 40 ± 1	
Virucidal instrument disinfection at ≥ 40 °C	*Parvovirus*	DVV/RKI [1, 2] or DIN EN 14476 [4][5]	DVV/RKI or under clean or dirty conditions/ use concentration	≥ 40 ± 1 to ≤ 70 ± 1	

* For combined detergent/disinfectant precleaning products, suitable methods must be used to demonstrate the absence of protein-fixing properties (e.g. Amido black stain).

[1] The interfering substances based on DVV/RKI are 10 % FCS (foetal calf serum) and distilled water. Based on DIN EN 14476, the test with a lower amount of interfering substance consisting of 0.3 % BSA (bovine serum albumin) is considered to be under clean conditions and the test with 3% BSA and 3% sheep erythrocytes is considered to be under dirty conditions

[2] To record the efficacy limits at least two concentrations (use concentration and an ineffective concentration) must be tested. (For gradations, see Chapter 5).

[3] At least three of the listed contact times must be tested, including the claimed contact times.

[4] Additionally for products with oxidative activity

[5] Test reports based on EN 14476:2013 continue to be valid

Table V3.2: Test conditions in the simulated-use test.

Activity spectrum	Test organisms	Test method	Interfering substance[1]/ Test concentrations[2]	Test temperature [°C]	Contact times [min][3]
Activity against enveloped viruses*	*Vaccinia virus*	EN 17111 [5][4]	Under clean or dirty conditions/ use concentration	20 ± 1	1, 5, 15, 30, 60
Virucidal instrument disinfection at < 40 °	*Adenovirus Norovirus SV40*	EN 17111 [5] [4]	Under clean or dirty conditions/ use concentration	20 ± 1 to < 40 ± 1	
Virucidal instrument disinfection at ≥ 40 °C	*Parvovirus*	EN 17111 [5] [4]	Under clean or dirty conditions/ see footnote[2]	≥ 40 ± 1 to ≤ 70 ± 1	

* For combined detergent/disinfectant precleaning products, suitable methods must be used to demonstrate the absence of protein-fixing properties (e.g. Amido black stain.

[1] The Interfering substance based on EN 17111 with 0.3% BSA (bovine serum albumin) is considered to be under clean conditions and the test with 3% BSA and 3% sheep erythrocytes is considered to be under dirty conditions.

[2] To record the efficacy limits at least two concentrations (use concentration and an ineffective concentration) must a be tested. (For gradations see Chapter 5).

[3] The test contact times are based on Table V3.3.

[4] Test reports based on EN 14476:2013 continue to be valid.

Table V3.3: Contact times to be selected in the individual test runs for simulated-use testing of instrument disinfectants.

Claimed contact time	1st Test run	2nd Test run
5 min	1 min, 5 min	5 min
15 min	5 min, 15 min	15 min
30 min	15 min, 30 min	30 min
60 min	30 min, 60 min	60 min

The simulated-use tests must be performed in all cases in two test runs:

1. Test run: In each case at least two test surfaces per concentration-time relation (see **Table V3.2** and **V3.3**), virus control (before and after drying), sustained effect check, interference test, cytotoxicity test and reference test.
2. Test run: In each case at least two test surfaces per claimed concentration-time relation, virus control (before and after drying), cytotoxicity test and reference test

In the 2nd test run in processes < 40ºC only test resistant viruses from the 1st test run need be tested;

Test viruses as per DVV/RKI guidelines and DIN EN 14476 or DIN EN 16777

Adenovirus = Adenovirus type 5, Adenoid 75 strain

BVDV = Bovine Viral Diarrhea Virus, NADL strain

Norovirus = Murine norovirus, S99 Berlin (MNV) strain

Parvovirus = Murine parvovirus (minute virus of mice, rodent protoparvovirus 1) (MVM)

Poliovirus = Poliovirus vaccination type 1 strain, LSc-2ab strain

SV40 = Polyomavirus (SV 40), 777 strain

Vaccinia virus = Modified vaccinia virus Ankara (MVA) or vaccinia virus, Elstree strain

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1. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. August 2008. Bundesgesundheitsbl 2008;51:937–945.
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4. DIN EN 14476:2019-10. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2, Stufe 1); Deutsche Fassung EN 14476:2013+A2: 2019.

5. DIN EN 17111. Quantitativer Keimträgerversuch zur Prüfung der viruziden Wirkung für Instrumente im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2); Deutsche Fassung EN 17111:2018.

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V4A Chemothermal textile disinfection

Requirements

For the conformity assessment procedure two independent expert opinions, including test reports based on DIN EN 14476[1], confirming the efficacy in the claimed concentration-time relation in quantitative suspension tests must be submitted.

In addition, details of controls must be provided to demonstrate the quality of the test viruses and the validity of the test. Since at present these controls are not adequately described in DIN EN 14476 or are missing in some cases, controls must be performed as per DVV/RKI guideline 2015 [2] Subpara. 5.1 and 7.6 or DVV/RKI guideline 2008 [3] Subpara. 5.1 and 7.7.

The use concentration must be confirmed in the respective test report in a second independent test batch and, as controls, must include the virus control, cytotoxicity test and reference test. The mean confidence interval for two independent tests must each be ≤ 0.5 lg.

The bactericidal and yeasticidal activity confirmed by the VAH by means of a conformity assessment procedure or confirmed additionally during this procedure is a prerequisite for certification. The procedural sequence (e.g. time disinfectant added) should be taken into account in the virus tests as far as possible.

The concentration-time relation for activity against viruses featured in the VAH List must not be shorter than that specified for the VAH-listed bactericidal and yeasticidal efficacy.

The test concentrations and contact times must be selected such that the relationship between the disinfectant virucidal activity and the concentration and contact time is evident from the test results (kinetics).

Obligatory:

- *Determination of the virucidal activity (virucidal activity spectrum in the quantitative suspension test as per DIN EN 14476 [1]).*

  To that effect, the method must be tested with the complete procedure (i.e. all components* of the procedure in one test batch) at 20 °C ± 1 °C and at the specified process temperature. The virus titres must also be determined at 20 °C ± 1°C and at the process temperature.

* It is not necessary to test the individual components, e.g. detergent, laundry cleaning booster, disinfectant (in cases where the procedure concerned is a multi-component procedure)

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The test product must reduce the virus titre of the test viruses listed in **Table V4.1** under the specified conditions within the stipulated contact time(s) at the test temperature by at least 4 lg levels.

Table V4.1: Test conditions in the quantitative suspension test.

Activity spectrum	Test organisms	Test method	Interfering substance[1]/ Test concentrations[2]	Test temperature [°C]	Contact times [min]
Virucidal temperature ≥ 30 °C – ≤ 70 °C	*Murine parvovirus*[3] *(MVM)*	DIN EN 14476, controls as per DVV/RKI [2, 3]	Under clean or dirty conditions/ see footnote[2]	≥ 30 ± 1 to ≤ 70 ± 1	5, 10, 15, 20

[1] Based on DIN EN 14476, the test with 3% BSA and 3% sheep erythrocytes is considered to be under dirty conditions.
The lower amount of interfering substance – 0.3% BSA (bovine serum albumin)- may only be used for testing if the procedure includes a pre-wash step
[2]To record the efficacy limits at least two concentration-time relations (use concentration and an ineffective concentration) must be tested
[3] Test reports with the bovine parvovirus continue to be valid if they meet the requirements set out here.

Table V4.2: Test conditions (test batch and controls).

Virus titre	Temperature		
	20 °C ± 1 °C	Process temperature	60 °C ± 1 °C
Virus control with low amount of interfering substance[1]	X	X	
Virus control with high amount of interfering substance	X	X	
Test batch with all components	X	X	
Reference substance * (peracetic acid 0.005%/10 min)			X

[1] Only required if the procedure includes a pre-wash step.

* Alternatively, testing as per DVV/RKI guideline 2008 [3], Subpara. 5.1 and 7.7 may also be recognized to demonstrate the quality of the test viruses (control with pH value of the wash process at 20 °C and at the process temperature).

Test viruses as per DVV/RKI guidelines and DIN EN 14476

Parvovirus = Murine parvovirus (minute virus of mice, rodent protoparvovirus 1) (MVM)

References

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2. DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. Dezember 2014. Bundesgesundheitsbl 2015;58:493–504.
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