SLOVENSKI STANDARD
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Kemična razkužila in antiseptiki - Kvantitativni preskus na neporoznih površinah za vrednotenje virucidnega delovanja kemičnih razkužil in antiseptikov v veterini - Preskusna metoda in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer nicht-poröser Oberflächenversuch zur Bestimmung der viruziden Wirkung chemischer Desinfektionsmittel und Antiseptika für den Veterinärbereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface non-poreuse pour l'évaluation de l'activité virucide des antiseptiques et désinfectants chimiques utilisés dans le domaine vétérinaire - Méthode d'essai et prescriptions - Phase 2, étape 2

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Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements - Phase2, step2

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Contents

Page

Foreword 4
Introduction 5
1 Scope 6
2 Normative references 6
3 Terms and definitions 6
4 Requirements 8
4.1 Requirements for virucidal activity on surfaces 8
5 Test method 9
5.1 Principle 9
5.2 Materials and reagents 10
5.2.1 Test virus 10
5.2.2 Culture media and reagents 10
5.2.3 Test surface 14
5.2.4 General 14
5.2.5 Usual microbiological laboratory equipment and, in particular, the following 14
5.3 Product test solutions 15
5.4 Procedure for assessing the virucidal activity of the product 16
5.4.1 General 16
5.4.2 Infectivity assay 17
5.4.3 Plaque assay 17
5.4.4 Virucidal test – preparation 17
5.4.5 Test method 18
5.4.6 Control of efficiency for suppression of disinfectant activity 18
5.4.7 Dilution in ice-cold medium 18
5.4.8 Filtration technique 18
5.5 Calculation and expression of results 19
5.5.1 Protocol of the CPE results 19
5.5.2 Calculation of virus titre 19
5.5.3 Calculation of PFU 19
5.6 Verification of the methodology 19
5.7 Calculation of the virucidal activity of products 19
5.7.1 Test virus reference inactivation test 19
5.8 Expression of results 20
5.8.1 Activity on non-porous surfaces 20
5.9 Test report 20
Annex A (informative) Referenced strains of national collections 22
Annex B (normative) Cytotoxicity, reference inactivation test and test virus titration and detoxification of test mixtures 23
B.1 Cytotoxicity caused by product solutions 23
Elimination of cytotoxicity 23
B.2 Reference inactivation test 24

B.3 Titration of test virus suspension **24**
B.4 Detoxification of text mixtures by molecular sieving **24**
B.4.1 Molecular sieving with SephadexTM LH 20 ..... **24**
B.4.2 Molecular sieving using MicroSpinTM S 400 HR **26**
Annex C (informative) **Calculation of virus infectivity titre** **27**
C.1 Calculation of the viral infectivity titre **27**
C.2 Calculation of plaque-forming units (PFU) **27**
Annex D (informative) **Example of a typical test report** **29**
Bibliography **31**

Foreword

This document (prEN 17083:2017) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

Introduction

This European Standard describes a surface test method for establishing whether a product proposed as a disinfectant in the fields described in Clause 1 has or does not have virucidal activity on non-porous surfaces.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, virus on surfaces ...) reflect parameters which are found in practical situations including conditions which may influence the action of disinfectants.

Each use concentration found from this test corresponds to defined experimental conditions. The conditions are intended to cover general purposes and to allow reference between laboratories and product types. However for special applications the recommendations of use of a product can differ and therefore additional test conditions might be needed, which cannot be covered by this European Standard.

1 Scope

This European Standard specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water, or – in the case of ready-to-use-products – with water.

This European Standard applies to products that are used in the veterinary area on non-porous surfaces without mechanical action i.e. in the breeding, husbandry, production, veterinary care facilities, transport and disposal of all animals except when in the food chain following death and entry to the processing industry.

EN 14885 specifies in detail the relationship of the various tests to one another and to "use recommendations".

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a Phase 2 Step 2 test.

NOTE 3 Using this European Standard, it is possible to determine the virucidal activity of the undiluted product.

NOTE 4 This standard uses Porcine Parvovirus because Bovine Enterovirus Type 1 (ECBO) virus used in the suspension test EN 14675 cannot be used for surface testing because of its loss of titre during drying. Porcine Parvovirus has comparable resistance to ECBO virus.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 14885, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 together with the following apply.

3.1
cytotoxicity
morphological alteration of cells and/or their destruction or their reduced sensitivity to virus multiplication caused by the product

3.2
interfering substances
protein solutions that are added to a test virus suspension to demonstrate any influence of protein and erythrocytes on the virucidal activity of the product test solution

3.3
plaque forming units (PFU)
number of infectious virus particles per unit volume (ml)

3.4
reference virus inactivation test
test with a defined reagent (e.g. formalin) instead of a product for the internal control of the test Results of reference virus inactivation test shall be within limits for validating the method

3.5
reference virus suspension
virus suspension of a defined virus strain which is not passaged more than 10 times, is maintained in national culture collection centres and kept in small volumes (less than 1 ml) at a temperature of −70 °C or preferably at 196 °C under liquid nitrogen

NOTE to entry: Stock virus suspensions are prepared from reference virus suspensions.

3.6
stock virus suspension
virus suspension of a defined strain that is multiplied on a large scale to obtain a virus suspension of the same characteristics as the reference virus suspension and kept in a small volume at a temperature of below 70 °C or preferably at 196 °C over liquid nitrogen

3.7
test virus suspension
virus suspension that is used in the virucidal testing of the disinfectant

3.8
tissue culture infecting dose ($TCID_{50}$)
50 % infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE (3.9) in 50 % of cell culture units virus dose that gives rise to cytopathic change (CPE) in 50 % of the inoculated cell cultures

3.9
viral cytopathic effect (CPE)
morphological alteration of cells and/or their destruction as a consequence of virus multiplication

3.10
viral plaque
area of lysis formed in a cell monolayer under semisolid medium due to infection by and multiplication of a single infectious virus particle

3.11
virus titre
amount of infectious virus per unit volume present in a cell culture lysate or in a solution

4 Requirements

4.1 Requirements for virucidal activity on surfaces

The product, when diluted in hard water (see 5.2.2.2) and tested in accordance with Table 1 and Clause 5, shall demonstrate at least a log reduction in virus titre of 4.

Note 1 Full virucidal activity means activity against enveloped and un-enveloped viruses.

Note 2 Limited virucidal activity means activity against enveloped viruses.

Table 1 — Obligatory and additional test conditions

A: Full virucidal activity

	Obligatory conditions	Additional conditions
Test organism	Porcine Parvovirus, Strain NADL2	Not applicable
Test temperature	10 °C	4 °C, 20 °C or 40 C
Contact time	30 min	1, 5, 60, 120 min
Interfering substance–low level soiling	3,0 g/l bovine albumin	Not applicable
Interfering substance–high level soiling	10 g/l yeast extract and 10 g/l bovine albumin	Not applicable

B: Limited virucidal activity

	Obligatory conditions	Additional conditions
Test organism	Feline Coronavirus, Strain Munich	Not applicable
Test temperature	10°C	4 °C, 20 °C or 40 °C
Contact time	30 min	1, 5, 60, 120 min
Interfering substance–low level soiling	3,0 g/l bovine albumin	Not applicable
Interfering substance–high level soiling	10 g/l yeast extract and 10 g/l bovine albumin	Not applicable

5 Test method

5.1 Principle

A test suspension of virus mixed interfering substance is inoculated onto the test surface and dried. After a drying time, 0,1 ml of the product is transferred to the surface, in a manner which covers the dried film. The surface is maintained at a specified temperature for a defined period of time, as specified in Clause 4 and 5.5.1.1. At the end of that contact time remaining virus is recovered by washing with ice-cold DMEM with 3 % FCS. The titre of the virus recovered from the surface is determined.

The titre of the virus on a surface treated with hard water in place of the disinfectant is also determined and the reduction in virus titre attributed to the product is calculated by difference.