Keemilised desinfektsioonivahendid ja antiseptikumid. Kvantitatiivne suspensioonikatse meditsiini valdkonnas, meditsiinilised instrumendid kaasa arvatud, kasutatava keemiliste desinfektantide müobakteritsiidse toime Määramiseks. Katsemeetodid ja nõuded (faas 2, etapp 1)

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 14348:2005 sisaldab Euroopa standardi EN 14348:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 22.02.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14348:2005 consists of the English text of the European standard EN 14348:2005. This document is endorsed on 22.02.2005 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This document specifies a test method and the minimum requirements for mycobactericidal (or tuberculocidal) activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water - or in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less as some dilution is always produced by adding the test organisms and interfering substance.	**Scope:** This document specifies a test method and the minimum requirements for mycobactericidal (or tuberculocidal) activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water - or in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less as some dilution is always produced by adding the test organisms and interfering substance.

ICS 11.080.20

Võtmesõnad: bactericides, dis, disinfection, effects, efficiency, evaluations, human medicine, hygiene, instrument disinfection, medical sciences, medicine, microbiology, mycobacteriaceae, specification (approval), specifications, suspensions (chemical), testing, weighting level

EUROPEAN STANDARD

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English version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)

Désinfectants chimiques - Essai quantitatif de suspension pour l'evaluation de l'activité mycobactéricide des désinfectants chimiques utilisés en médecine y compris les désinfectants pour instruments - Méthode d'essai et prescriptions (phase 2, étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der mykobakteriziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich einschließlich der Instrumentendesinfektionsmittel - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 22 November 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This document (EN 14348:2005) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2005, and conflicting national standards shall be withdrawn at the latest by July 2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Medical Devices Directive 93/42.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

A collaborative trial has been undertaken and will be evaluated to provide a precision annex to this document.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical area are in preparation.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This document describes a suspension test for establishing whether a chemical disinfectant has or does not have a mycobactericidal activity in the area defined in the scope.

This laboratory test takes into account practical conditions of application of the product ,including contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence its action in practical situations.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each concentration of the chemical disinfectant found by this test corresponds to the chosen experimental conditions. However, for some applications the instructions of use of a product may differ and therefore additional test conditions need to be used.

1 Scope

This document specifies a test method and the minimum requirements for mycobactericidal (or tuberculocidal) activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water - or in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products that are used in the medical area including those that are covered by the EEC/93/42 Directive on Medical Devices.

This document applies to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

in hospitals, in community medical facilities and in dental institutions;

in clinics of schools, of kindergartens and of nursing homes;

and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

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 1 test (see Annex E).

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 microbial strains used for the determination of bactericidal and fungicidal activity.*

EN 14820, *Single-use containers for human venous blood specimen collection.*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
product
chemical agent or formulation used as a chemical disinfectant or antiseptic

3.2
mycobactericide
product which kills mycobacteria under defined conditions

NOTE The adjective derived from “mycobactericide” is “mycobactericidal”.

3.3
mycobactericidal activity
capability of a product to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions