

Biotehnoloogia. Aparatuur. Juhend puhtuse kontrollimise protseduurideks

Biotechnology - Equipment - Guidance on testing
procedures for cleanability

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 12296:1999 sisaldab Euroopa standardi EN 12296:1998 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 12296:1999 consists of the English text of the European standard EN 12296:1998.</p> <p>This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: Käesolev Euroopa standard annab juhendi biotehnoloogilistes protsessides kasutatava aparatuuri (üksikaparaatide ja nende osade) puhtuse hindamise üldisteks protseduurideks.</p>	<p>Scope:</p>
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ICS 07.080

Võtmesõnad: biotehnoloogia, desinfitseerimine, hügieeninõuded, kahjulikud mikroorganismid, keskkonnakaitse, kontroll, meditsiiniaparatuur, mikroorganismid, ohutus, puhastamine, saastumine, testimine, tööohutus, õnnetuste vältimine

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Descriptors: Biotechnology, cleaning, equipment, testing.

English version

Biotechnology – Equipment

Guidance on testing procedures for cleanability

Biotechnologie – Equipement – Guide
des procédures d'essai pour le
contrôle de la capacité au nettoyage

Biotechnik – Geräte und Aus-
rüstungen – Leitfaden für Verfahren
zur Prüfung der Reinigbarkeit

This European Standard was approved by CEN on 1998-03-02.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", 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 September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

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

Introduction

The cleaning of plant and equipment is an essential element of biotechnology processes in order to protect the safety of people and the environment and to avoid harmful operational effects through the accumulation of soil.

Testing procedures should be developed and documented to ensure that relevant information on cleanability is available. Standards (e.g. EN ISO 9000 series, see annex C [9]), guidelines (e.g. Good Manufacturing Practice (GMP) see annex C [10]) state general procedures of good practice which facilitate high quality manufacturing if followed. This European Standard refers to assessing the cleanability of equipment used in biotechnology, where additional specific requirements related to safety and to special features of biotechnological processes are required. It should be read in association with the more general standards and guidelines as mentioned above. In particular this European Standard states the principles on which test methodology is based. Informative guidance on selection of test methods is provided in annex A.

The extent to which it is necessary to remove soil from equipment and plant varies substantially with the process. In some cases abundant residues after cleaning do not harm people or the environment or do not cause difficulties in the process. In others very low residues are essential. The complete removal of soil on surfaces cannot be achieved, because for example all surfaces are adsorptive to some degree.

1 Scope

This European Standard gives guidance on general testing procedures to assess the cleanability of equipment (components and units of equipment) used in biotechnological processes.

This European Standard applies primarily if the intended use of equipment includes the use of potentially hazardous microorganisms. This European Standard also applies to non-hazardous microorganisms and/or to residual soil which can adversely affect sterilization processes or which can cause cross-contamination of products or processes.