SLOVENSKI STANDARD
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Biotehnologija - Merila za sestavne dele filtrov in montažo priprave za filtracijo

Biotechnology - Performance criteria for filter elements and filtration assemblies

Biotechnik - Leistungskriterien für Filterelemente und Filtrationseinrichtungen

Biotechnologie - Criteres de performance pour les éléments filtrants et les filtres

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Biotechnology - Performance criteria for filter elements and filtration assemblies

Biotechnologie - Critères de performance pour les éléments filtrants et les filtres

Biotechnik - Leistungskriterien für Filterelemente und Filtrationseinrichtungen

This European Standard was approved by CEN on 25 September 1999.

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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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

Filter elements by nature are not intended to prevent the passage of fluids, but to remove or reduce the microorganism load to acceptable levels, by retention of the target microorganisms within the filter medium. Leaktightness in this context refers to the ability of the filtration assembly to retain the target microorganism.

Use of this European Standard will aid the equipment manufacturer in the classification of filter elements and filtration assemblies with regard to biosafety performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the competent authorities.

1 Scope

This European Standard specifies performance criteria for filter elements and filtration assemblies used in biotechnological processes with respect to the potential risks of microorganisms in use for the worker and the environment.

This European Standard applies where the intended use of the filter elements or filtration assemblies includes hazardous or potentially hazardous microorganisms used in biotechnological processes and/or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

This European Standard applies to sterilizability and cleanability of filter assemblies and to leakage of microorganisms through the housing of a filtration assembly and to leakage of microorganisms through filter elements for dead-end filtration and cross-flow filtration.

This European Standard does not apply to filter elements and filtration assemblies used to avoid contamination of bioreactors for example by sterilizing inlet air or feedstream.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1672-2	Food processing machinery - Basic concepts - Part 2 : Hygiene requirements
EN 12296	Biotechnology - Equipment - Guidance on testing procedures for cleanability
EN 12297	Biotechnology - Equipment - Guidance on testing procedures for sterilizability
EN 12298	Biotechnology - Equipment - Guidance on testing procedures for leaktightness

EN 12460	Biotechnology - Large-scale process and production - Guidance on equipment selection and installation in accordance with the biological risk
EN ISO 4287	Geometrical Product Specifications (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters (ISO 4287:1997)
EN ISO 4288	Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and Procedures for the assessment of surface texture (ISO 4288:1996)

3 Terms and definitions

For the purposes of this standard, the following definitions apply :

3.1
arithmetical mean deviation of the profile (R_a)

the arithmetical mean of the absolute values of the profile departures within the sampling length [EN ISO 4287].

3.2
cartridge

disposable filter element.

3.3
cross-flow filtration

filtration characterized by a flow alongside the filter medium surface (retentate) and a flow crossing the filter medium (permeate).

NOTE Examples of cross-flow filtration are reversed osmosis, dialysis, microfiltration, ultrafiltration and nanofiltration.

3.4
cut-off

smallest particle size or molecular weight components retained at a given reduction efficiency.

3.5
dead-end filtration

filtration characterized by a feed forced through the filter medium depositing retentate in or on the filter medium.

NOTE Examples of dead-end filtration are filtration by means of sand filters, wounded cartridges, high efficiency particulate air (HEPA) filters, sintered glass filters and sterilizing membrane cartridges.

3.6
direct test method (in biotechnology)

test method which employs microorganisms for quantification.

3.7
feed

incoming fluid.

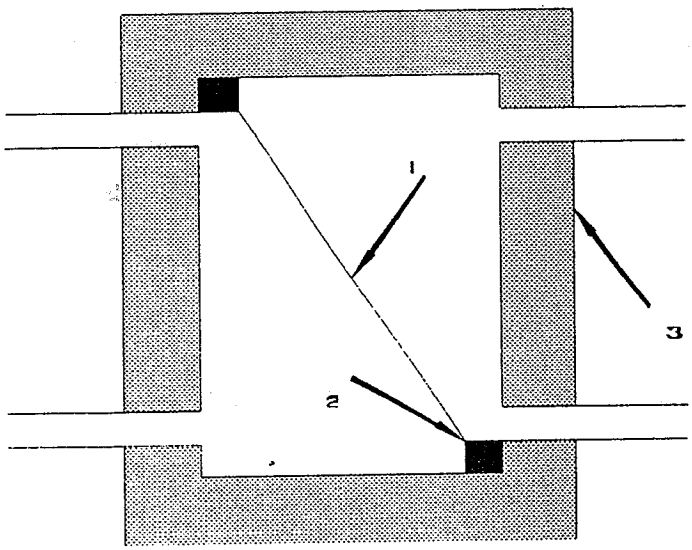
3.8
filtration assembly

filter element mounted into a filter housing.

NOTE 1 A filtration assembly is sometimes called a module.

NOTE 2 The filter housing can include for example valves, pumps, couplings and monitoring devices that enable a filtration operation.

NOTE 3 An example of how a filter assembly is made up of a filter element and filter housing is given in figure 1.



1 = Filter medium
2 = Supporting construction
3 = Filter housing
1+2 = Filter element
1+2+3 = Filtration assembly

Figure 1- Example of a filtration assembly

3.9
filter element

combination of a filter medium and its supporting construction.

NOTE A filtration assembly will normally consist of several filter elements. The first filter element (prefilter element) will retain the bulk of the particles in the gas- or liquid in order to give the final filter element(s) a longer lifetime. The prefilter elements will usually have a lower reduction efficiency than the final filter element(s).

3.10
filter medium

physical barrier consisting of a membrane or any porous material.

3.11
filtrate; permeate

part of the feed passing through the filter medium.

3.12
filtration

separation technique using a filter medium.

NOTE Filtration can be done in dead-end operating mode or in cross-flow operating mode.

3.13
hazard

intrinsic property or ability of something (e.g. agent, equipment, material or process) to cause harm [EN 1620].

NOTE Harm is an injury or damage to health of people and/or the environment.

3.14
indirect test method (in biotechnology)

test method which employs physical and/or chemical means for quantification

3.15
integrity test

test to verify conformity with respect to specifications of the filter element characteristics.

NOTE An integrity test for a filter element usually refers to a non-destructive indirect test for assessment of for example the retention rate.

3.16
leakage

egress from equipment.

3.17
log reduction value (L_{rv})

logarithm to the base 10 of the ratio of the concentration of target microorganisms in the feed and the concentration of target microorganisms in the permeate, expressed as :

$$L_{rv} = lg \frac{C_f}{C_p}$$

where :

C_f is the concentration of target microorganisms in the feed, expressed in numbers per millilitre ;

C_p is the concentration of target microorganisms in the permeate, expressed in numbers per millilitre.

NOTE 1 Sometimes the term titer reduction value T_r is used instead of L_{rv}.

NOTE 2 log reduction values of the filter elements in filtration assemblies can be added in order to get the total log reduction value.

3.18
membrane

barrier separating retentate and permeate.

3.19
microorganism

any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which can be able to provoke any infection, allergy or toxicity.

3.20
process microorganism

microorganism used for production purposes in a biotechnological process or constituting (part of) the product itself.

3.21
reduction efficiency

efficiency of a device (for example a filter element) to decrease the number of viable microorganisms passing it measured by the log reduction value L_{rv}.

NOTE In practice the term removal efficiency is also used.

3.22
retentate

part of the feed not passing through the filter medium.

3.23
risk

a combination of the probability and the degree of the possible injury or damage to health in a hazardous situation [EN 1070].

3.24
soil

any unwanted matter (including product residues, microorganisms, dust and debris) [ISO/CD 14159].

3.25
sterile

state of being free from viable microorganisms.

NOTE 1 In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.26
sterilizability

ability of components of equipment, units of equipment or plants to be made sterile.

3.27
sterilization

process used to reach a sterile state.