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BIOTECHNOLOGY - PERFORMANCE CRITERIA FOR VESSELS - PART 6: CHROMATOGRAPHY COLUMNS

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Biotechnologie - Critères de performance des récipients - Partie 6: Colonnes de chromatographie

Biotechnik - Leistungskriterien für Behälter - Teil 6: Chromatographiesäulen

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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 Management Centre 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by September 2001, and conflicting national standards shall be withdrawn at the latest by September 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This standard is one of a series of European Standards concerned with performance criteria for vessels. These standards are :

EN 13311-1, *Biotechnology - Performance criteria for vessels - Part 1: General performance criteria.*

EN 13311-2, *Biotechnology - Performance criteria for vessels - Part 2: Pressure protection devices.*

EN 13311-3, *Biotechnology - Performance criteria for vessels - Part 3: Glass pressure vessels.*

EN 13311-4, *Biotechnology - Performance criteria for vessels - Part 4: Bioreactors.*

EN 13311-5, *Biotechnology - Performance criteria for vessels - Part 5: Kill tanks.*

EN 13311-6, *Biotechnology - Performance criteria for vessels - Part 6: Chromatography columns.*

Annex A is informative.

This standard includes a bibliography.

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

Chromatography columns are containers filled with a stationary phase called chromatography medium, used for a separation of components from the feed stream. They are used in a wide variety of biotechnological processes, and vary considerably in scale and function. Materials used for filling chromatography columns are chromatography media such as dextrane, agarose, coated glass and polymer beads whereas chromatography column walls, top and bottom plates may be made of glass, stainless steel, polymers or combinations hereof.

Use of this European Standard will aid the equipment manufacturer in the classification of chromatography columns with regard to safe performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the regulatory authorities.

1 Scope

This European Standard specifies performance criteria for chromatography columns used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

This European Standard applies where the intended use of chromatography columns includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

When substantial parts of the chromatography column are made of glass or from other materials, this standard should be used in conjunction with other relevant standards.

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 revision 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 (including amendments).

EN 13311-1:2001, *Biotechnology - Performance criteria for vessels - Part 1 : General performance criteria.*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13311-1:2001 apply.

4 Hazards

The following hazards shall be taken into account.