BRITISH STANDARD

BS EN
13311-6:2001

Biotechnology — Performance criteria for vessels —

Part 6: Chromatography columns

The European Standard EN 13311-6:2001 has the status of a British Standard

ICS 07.080

National foreword

This British Standard is the official English language version of EN 13311-6:2001.

The UK participation in its preparation was entrusted to Technical Committee CII/ 58, Biotechnology, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 May 2001

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 8, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 37601 X

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13311-6

March 2001

ICS 07.080; 07.100.01

English version

Biotechnology - Performance criteria for vessels - Part 6: Chromatography columns

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

Biotechnik - Leistungskriterien für Behälter - Teil 6: Chromatographiesäulen

This European Standard was approved by CEN on 4 February 2001.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents **Page**

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.

- Release of microorganisms caused by improper connection of bottom plates and/or adapter to the column house wall.

- Release of microorganisms caused by dissolution of joints or sealings resulting from the use of aggressive chemicals or solvents.

- Release of microorganisms caused by rupture of the housing resulting from swelling of the chromatography medium.

5 Performance classes

5.1 General

The chromatography columns shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 of EN 13311-1:2001.

5.2 Leaktightness

For the use of this European Standard, 5.2 of EN 13311-1:2001 applies.

NOTE For chromatography columns leaktightness refers to the leaktightness of the housing, its connections, such as rubber or silicone piping, and the leaktightness of the sealing gaskets.

5.3 Cleanability

For the use of this European Standard, 5.3 of EN 13311-1:2001 applies.

NOTE For chromatography columns cleanability refers to the housing, its connections and sealing gaskets and to the sanitation of the chromatography media.

5.4 Sterilizability

For the use of this European Standard, 5.4 of EN 13311-1:2001 applies.

NOTE 1 For chromatography columns sterilizability refers to the housing, its connections and sealing gaskets and the chromatography media.

NOTE 2 Sterilization of chromatography columns containing chromatography media is usually carried out with chemicals.

5.5 Use of performance classes in equipment selection

The selection of the appropriate class for performance of a chromatography column shall be made in accordance with 5.5 of EN 13311-1:2001.

6 Classification and verification of performance

The chromatography column shall conform to the general requirements given in clause 6 of EN 13311-1:2001.

NOTE Leaktightness of the adaptor seal can generally be detected by visual examination.

Guidance on test methods for determining leaktightness of chromatography columns is given in annex A.

7 Marking and packaging

The chromatography column shall conform to the requirements given in clause 7 of EN 13311-1:2001 applies.

8 Documentation

The chromatography column shall conform to the requirements given in clause 8 of EN 13311-1:2001 applies.

Annex A
(informative)

Guidance on test methods for determining leaktightness of chromatography columns

A list of test methods for leaktightness is given in table A.1 of EN 12298 (see [1]). From that list suitable test methods to the testing of chromatography columns are given in table A.1.

Table A.1 - Suitable alternative leaktightness test methods for chromatography columns

Number	Test method
1	Pressure loss - gas/air
2	Pressure loss - liquid
3	Helium probe
4	SF_6, e.g. Freon[a] probe
5	Thermal conductivity
6	Ultrasonics
8	Tracer-liquid dyes
11	Electronic particle counting
12	Tracer aerosol (NaCl)
14	Qualitative bioaerosol monitoring
15	Quantitative bioaerosol monitoring
16	Surface swabbing
17	Surface conductivity
19	Bacteria tightness

NOTE Restrictive use of SF_6 should be considered due to environment protection

a Freon is an example of a suitable product available commercially. This information is given for the convenience of the user of this Standard and does not constitute an endorsement of CEN of these products.

Bibliography

[1] EN 12298:1998, *Biotechnology - Equipment - Guidance on testing procedures for leaktightness.*

[2] *Druckbehälterverordnung, In: Bundesgesetzblatt 1, (1989), Nr. 20, S. 843-869. Bundersanzeigerverlag.*

[3] *Technical Note 211: "Sanitization of BioProcess Glass Columns with Sodium Hydroxide", Pharmacia Biotech 1993.*

[4] *Sofer & Nyström: "Process Chromatography, A Practical Guide", 1989, p 93-105, Academic Press, London (containing further references).*

[5] *P. Meyer in "Bioprocess Engineering, Systems, Equipment and Facilities", ed. Lydersen et al., 1994, p 191-214 (general considerations on vessels, surface finish etc.).*

[6] *P.W. Thomson in "Bioprocess Engineering, Systems, Equipment and Facilities", ed. Lydersen et al., 1994, p 473-497 (cleaning).*

[7] *T. Oakley in "Bioprocess Engineering, Systems, Equipment and Facilities", ed. Lydersen et al., 1994, p 500-521 (sterilization).*

[8] *Brunhow et al., "Cleaning and cleaning validation", A Biotechnology Perspective, PDA, 1996.*

blank

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: 020 8996 9000. Fax: 020 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: 020 8996 9001. Fax: 020 8996 7001. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: 020 8996 7111. Fax: 020 8996 7048.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: 020 8996 7002. Fax: 020 8996 7001. Further information about BSI is available on the BSI website at http://www.bsi-global.com.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL