SLOVENSKI STANDARD
SIST EN 13312-5:2002

01-januar-2002

Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 5. del: Ventili

Biotechnology - Performance criteria for piping and instrumentation - Part 5: Valves

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 5: Ventile

Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 5: Robinetterie

Ta slovenski standard je istoveten z: **EN 13312-5:2001**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
23.060.01	Ventili na splošno	Valves in general

SIST EN 13312-5:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13312-5

February 2001

ICS 07.080; 07.100.01

English version

Biotechnology - Performance criteria for piping and instrumentation - Part 5: Valves

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 5: Robinetterie

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 5: Ventile

This European Standard was approved by CEN on 13 January 2001.

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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
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of an identical text or by endorsement, at the latest by August 2001, and conflicting national standards shall be withdrawn at the latest by August 2001.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 piping and instrumentation. These standards are:

EN 13312-1, *Biotechnology - Performance criteria for piping and instrumentation - Part 1 : General performance criteria.*

EN 13312-2, *Biotechnology - Performance criteria for piping and instrumentation - Part 2 : Couplings.*

EN 13312-3, *Biotechnology - Performance criteria for piping and instrumentation - Part 3 : Sampling and inoculation devices.*

EN 13312-4, *Biotechnology - Performance criteria for piping and instrumentation - Part 4 : Tubes and pipes.*

EN 13312-5, *Biotechnology - Performance criteria for piping and instrumentation - Part 5 : Valves.*

EN 13312-6, *Biotechnology - Performance criteria for piping and instrumentation - Part 6 : Equipment probes.*

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

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

1 Scope

This European Standard specifies performance criteria for valves 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 the valves 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.

This European Standard applies to the sterilizability and cleanability of valves and to microbial leaktigtness of valves breaching the physical containment of the intended closed system in an unwanted manner.

NOTE This implies both leakage to the environment as well as within compartments of the process system.

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 (including amendments).

EN 13312-1:2001, *Biotechnology - Performance criteria for piping and instrumentation - Part 1: General performance criteria.*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13312-1:2001 apply.

4 Hazards

The following hazards shall be taken into account.

a) Release of microorganisms caused by an inappropriate selection of a valve. In general valves in which the operating mechanism is not in contact with process material are applied when the equipment needs to be sterilized and leaktightness is required.

b) Release of microorganisms and/or cross-contamination caused by an accumulation of soil due to lack of circulation of cleaning media. This accumulation of soil can affect mechanical functioning and/or sterilizability of the valve.

c) Release or backflow of microorganisms caused by inadequate information on the actual position of the valve.

NOTE It is advisable to use fail safe actuators for automatically controlled systems.

d) Release of microorganisms caused by repeated overtightening of valves that can result in damage the membrane seal.

e) Release of microorganisms caused by inappropriate installation of the valve for example so that it is not self-draining and cannot be cleaned adequately.

f) Release of microorganisms caused by a loss of component integrity resulting from deterioration of non-metallic materials by excessive thermal or chemical exposure, or ageing, and inappropriate maintenance .

5 Performance classes

The valves shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 to 5.4 of EN 13312-1:2001.

The selection of the appropriate class for performance of a valve shall be made in accordance with 5.5 of EN 13312-1:2001.

6 Classification and verification of performance

The valves shall conform to the general requirements given in clause 6 of EN 13312-1:2001.

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

Guidance on materials, design and manufacture is given in annex B.

7 Marking and packaging

The valves shall conform to the requirements given in clause 7 of EN 13312-1:2001.

8 Documentation

The valves shall conform to the requirements given in clause 8 of EN 13312-1:2001.

Annex A (informative)

Guidance on test methods for determining leaktightness, cleanability and sterilizability of valves

A list of test methods for leaktightness is given in table A.1 of EN 12298:1998 (see [4]). From that list suitable test methods to the testing of valves are given in table A.1.

Table A.1 - Suitable alternative leaktightness test methods for valves

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
8	Tracer-liquid dyes
11	Electronic particle counting
12	Tracer aerosol (NaCl)
13	Product aerosol (non-microbial)
14	Qualitative bioaerosol monitoring
15	Quantitative bioaerosol monitoring
16	Surface swabbing
18	Visual inspection (only qualitative)
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.	

Annex B (informative)

Guidance on materials, design and manufacture

B.1 Materials

The material should be appropriate for the intended use, depending upon the properties of the process and cleaning fluids and any coupling or welding requirements. The material most commonly used is stainless steel and should be in accordance with EN 10088-1 (see [3]) or similar but valves for biotechnological process applications are made from a wide range of materials including non-ferrous metals and plastics such as PVC and polypropylene.

Elastomeric materials commonly used for seals and diaphragms include EPDM (Ethylene-propylene-diene-monomer), NBR (Acryle-nitrile-butadiene-rubber), CSM (chlorosulphonated polyethylene), VMQ (vinyl-methyl-polysiloxane e.g. silicone rubber) and FKM (Fluor-caoutchouc e.g. viton). Silicone rubber and viton are suitable for high temperature usage (up to 180 °C). Other inert materials can be used.

The material should be chemically inert and resistant, and thermally stable, retaining its integrity and principal working properties during the specified lifespan.

B.2 Design

There should be access for cleaning and visible inspection. Dead spaces or gaps in which soil could accumulate should be avoided. Gap length to width ratios should be sufficiently large to allow free flow of cleaning fluid. Bolt holes, blind holes and other dead ends should be avoided. Exposed threads should be avoided. The design and orientation of the valve and fittings should be such that they are self-draining.

Internal surfaces should have a surface roughness of R_a = 0,2 µm to R_a = 1,6 µm and be free from crevices. Further design criteria are specified in Part 1 of this European Standard.

The body of the valve should be equipped with couplings for welding or pipe couplings which comply with the criteria laid down for couplings used in biotechnological processes as given in EN 13312-2:2001. Orbital welding methods are preferred.

O-ring seals should be fitted as close as possible to the product area to avoid gaps. Rotating seals should be selected in accordance with the guidance given in EN 12690:1999 (see [2]).

The manufacturer or supplier should indicate the seals used and how to replace them.

B.3 Manufacture and control over suitability of product

Manufacturing methods should be selected at the discretion of the manufacturer to meet the needs of the application as defined by the manufacturer and end user together.

The control over the product's suitability may consist of checking the quality of the manufacturer production system, or conducting practical tests.