SLOVENSKI STANDARD
SIST EN ISO 8871:2000/A1:2000

01-julij-2000

Deli iz elastomera za vodne paranteralne farmacevtske oblike (ISO 8871:1997/AM:1999)

Elastomeric parts for aqueous parenteral preparations (ISO 8871:1997/AM1:1999)

Elastomere Teile für wässerige parenterale Zubereitungen (ISO 8871:1997/AM1:1999)

Eléments en élastomere pour préparations aqueuses parentérales (ISO 8871:1997/AM1:1999)

Ta slovenski standard je istoveten z: **EN ISO 8871:1997/A1:1999**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 8871:2000/A1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8871:1997/A1

March 1999

ICS 11.040.20

English version

Elastomeric parts for aqueous parenteral preparations (ISO 8871:1997/AM1:1999)

Eléments en élastomère pour préparations aqueuses parentérales (ISO 8871:1997/AM1:1999)

Elastomere Teile für wässrige parenterale Zubereitungen (ISO 8871:1997/AM1:1999)

This amendment A1 modifies the European Standard EN ISO 8871:1997; it was approved by CEN on 19 February 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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.

This amendment 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 Central Secretariat 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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

NOTE:
This first amendment to the EN ISO 8871: 1997 has two purposes.
One is to incorporate Amendment 1: 1995 to the second edition of ISO 8871: 1990 into the EN ISO 8871: 1997, the text of the amendment being taken over from Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" of the International Standards Organization (ISO) by Technical Committee CEN/TC 205 "Non-active medical equipment", the secretariat of which is held by BSI. This has been achieved by amending the Foreword and Endorsement notice of EN ISO 8871: 1997.
The other purpose is to add the A-deviation requested by the Swedish member body of CEN, and this has been achieved by adding a new annex ZB.

REVISED TEXT

Foreword
Add a new paragraph as follows:
"Attention is drawn to annex ZB (informative), concerning A-deviations. Annexes N and P form an integral part of this standard."

Endorsement notice
Add a new sentence as follows:
"The text of Amendment 1: 1995 to the International standard ISO 8871: 1990 has been approved by CEN as an amendment to the European Standard without any modification."

Annex ZB
Add a new annex ZB as follows:

"**Annex ZB (informative)**
A-deviations
A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of CEN/CENELEC member:

This European Standard falls under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

NOTE (from CEN/CENELEC IR Part 2, **3.1.9**): Where standards fall under EC Directives it is the view of the Commission of the European Communities (OJ No G 59, 9.3, 1982) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovitch (European Court Reports 1980, p.3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

The European Standard is not in agreement with the European Pharmacopoeia 2nd edition VI.2.3.1, which is mandatory in Sweden, by LVFS 1996:16."

INTERNATIONAL STANDARD

ISO 8871

Second edition
1990-08-01

AMENDMENT 1
1995-10-01

Elastomeric parts for aqueous parenteral preparations

AMENDMENT 1

Éléments en élastomère pour préparations aqueuses parentérales

AMENDEMENT 1

Reference number
ISO 8871:1990/Amd.1:1995(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Amendment 1 to International Standard ISO 8871:1990 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

Annexes N and P form an integral part of ISO 8871.

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Elastomeric parts for aqueous parenteral preparations

AMENDMENT 1

Page iv

Add the following to the list of contents:

Annex N Determination of visible particles on elastomeric parts

Annex P Determination of subvisible particles on elastomeric parts

Page v

Amend the last paragraph of the foreword to include annexes N and P as forming an integral part of this International Standard.

Page vi

Beneath the existing introduction, add the following text:

The pharmaceutical industry requires to an increasing extent concrete details from the rubber manufacturer about the presence of particles the closures may release to the injectable where elastomeric closures are used as primary packaging materials in direct contact with pharmaceutical preparations. This request has been taken into account by preparing annexes N and P.

Page 15

After this page, insert the following two new annexes.

Annex N
(normative)

Determination of visible particles on elastomeric parts

N.1 Principle

Elastomeric closures may be superficially contaminated with particles visible to the naked eye.

Such particles may be transferred to pharmaceutical preparations in contact with the elastomeric parts, and deteriorate the quality of such preparations.

This method serves to evaluate contamination of this kind by collecting and counting the particles, detached from the elastomeric parts by rinsing.

N.2 Classification

For the purposes of this method, particles are divided in categories as follows, using the longest visible dimension as the classifying parameter:

Class I: larger than 25 µm and smaller than or equal to 50 µm

Class II: larger than 50 µm and smaller than or equal to 100 µm

Class III: larger than 100 µm

N.3 Apparatus and reagents

N.3.1 Shaking machine, moving in a horizontal circle of 12 mm ± 1 mm diameter at 300 min^{-1} to 350 min^{-1}.

N.3.2 Membrane filters, with maximum pore size of 0,8 µm, provided with grid lines at 3 mm × 3 mm.

NOTE 6 The colour of the filter may significantly affect the test results.

In case no specific agreements have been made between parties, the colour should be medium grey, and meet the following coordinate ranges in the CIE system:

L* between 60 % and 70 %

a* between −4,7 % and −3,7 %

b* between −4,7 % and −3,7 %

These specifications are valid for measurements on the grid-imprinted face of the filter, assuming a 3 mm square grid in green colour.

N.3.3 Clean, wide-mouth Erlenmeyer flasks, of capacity 300 ml.

N.3.4 Rinse fluid, prepared by dissolving 3 g of commercially available highly concentrated sodium *N*-methyl-*N*-oleyltaurate powder[1)] in 10 l of purified water as specified in ISO 3696, grade 1 or grade 2.

N.3.5 Equipment to supply the rinse fluid under adequate pressure, using a final filter with maximum pore size of 1,2 µm.

N.3.6 Microscope, magnification about × 50, with appropriate object illumination, incident angle with the object stage between 0° and 10°.

N.4 Preparations

N.4.1 Provide the apparatus and reagents as specified in N.3.

N.4.2 Ensure such an environment for carrying out all operations that no extraneous particles can interfere. This involves wearing suitable garments and gloves, and using a suitable clean air workstation, for example providing laminar airflow to Class 100[2)] as well as suitably decontaminated tools and handling means.

N.4.3 Carry out a blank preparation, as follows.

N.4.3.1 In an Erlenmeyer flask, place 50 ml of prefiltered rinse fluid

1) Sodium salt of *N*-methyl-*N*-oleylmethylaminoethanesulfonic acid.

2) As specified in USA Federal Standard 209E.

N.4.3.2 Shake for 20 s.

N.4.3.3 Immediately filter the fluid over a membrane filter.

N.4.3.4 Add another 50 ml portion of rinse fluid to the flask, shake, and filter in the same way.

N.4.3.5 Store the filter suitably.

N.4.3.6 Count the particles on the filter by means of the microscope.

N.4.3.7 No more than five particles of Class I nor more than one particle of Class II shall be found; no particle of Class III shall be present.

N.4.3.8 If these requirements are not met, investigate the possible causes for the failure, improve, and repeat the test until satisfactory results are obtained.

NOTE 7 Only when satisfactory blank values have been obtained, both before and after a test series on parts, are the results of the part tests considered valid.

N.5 Test

N.5.1 Place the number of intact elastomeric parts to be tested, with a total surface of approximately 100 cm^2, in an Erlenmeyer flask.

N.5.2 Add 50 ml of prefiltered rinse fluid.

N.5.3 Shake for 20 s.

N.5.4 Immediately filter the fluid over a membrane filter.

N.5.5 Add another 50 ml portion of rinse fluid to the flask, shake and filter in the same way.

N.5.6 Store the filter suitably.

N.5.7 Count the particles on the filter by means of the microscope.

N.6 Expression of results

For each test, report the following:

a) total surface tested, and number of whole parts tested;

b) total count of particles in each of the three classes;

c) counts in each of the three classes for at least one of the blank tests performed;

d) average count of particles in each class per 10 cm^2 of tested surface, rounded to one decimal.