INTERNATIONAL STANDARD

ISO 8871-1

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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 1: Extractables in aqueous autoclavates

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique —

Partie 1: Substances extractibles par autoclavage en milieu aqueux

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Contents

Page

Foreword ... iv
Introduction ... v
1 Scope ... 1
2 Normative references ... 1
3 Classification ... 2
4 Requirements ... 2
5 Sampling ... 2
6 Apparatus and reagents ... 3
7 Preparation of test solutions ... 4
Annex A (normative) **Appearance of solution** ... 5
Annex B (normative) **Acidity or alkalinity** ... 9
Annex C (normative) **Absorbance** ... 10
Annex D (normative) **Reducing substances** ... 11
Annex E (normative) **Extractable heavy metals** ... 12
Annex F (normative) **Extractable zinc** ... 14
Annex G (normative) **Extractable ammonia** ... 15
Annex H (normative) **Residue on evaporation** ... 16
Annex I (normative) **Volatile sulfides** ... 17
Annex J (informative) **Conductivity** ... 18
Bibliography ... 19

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8871-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

Together with the other parts (see below), this part of ISO 8871 cancels and replaces ISO 8871:1990, which has been technically revised.

ISO 8871 consists of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

— *Part 1: Extractables in aqueous autoclavates*

— *Part 2: Identification and characterization*

— *Part 3: Determination of released-particle count*

— *Part 4: Biological requirements and test methods*

— *Part 5: Functional requirements and testing*

Introduction

The elastomeric parts specified in the various parts of this International Standard are produced from a material which is usually called “rubber”. However, rubber is not a unique entity, since the composition of rubber materials may vary considerably. The base elastomer and the type of vulcanization have a major influence on the principle characteristics of an individual rubber material, as do additives such as fillers, softeners and pigments. These may have a significant effect on the overall properties. The effectiveness, purity, stability and safe handling of a drug preparation may be affected adversely during manufacture, storage and administration if the rubber part used has not been properly selected and validated (approved).

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 1:
Extractables in aqueous autoclavates

1 Scope

1.1 This part of ISO 8871 defines procedures for classifying elastomeric parts for primary packs and medical devices used in direct contact with preparations for parenteral use, including both aqueous preparations and dry preparations which have to be dissolved before use.

It specifies a series of comparative test methods for chemical evaluation by the determination of extractables in aqueous autoclavates (see Clause 4) and describes the various fields of application for elastomeric parts. Dimensions and functional characteristics are specified in the relevant International Standards. Required properties as specified in this part of ISO 8871 are regarded as minimum requirements.

1.2 This part of ISO 8871 is applicable for the categories of elastomeric parts given in Clause 3; specific requirements, however, are laid down in the relevant International Standards dealing with the items or devices listed in Clause 3.

Elastomeric parts for empty syringes for single use are excluded from the scope of this part of ISO 8871 as they are not in contact with the injected preparation for a significant length of time.

1.3 Compatibility studies with the intended preparation have to be performed before the approval for final use can be given; however, this part of ISO 8871 does not specify procedures for carrying out compatibility studies.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8362-2:1988, *Injection containers for injectables and accessories — Part 2: Closures for injection vials*

ISO 8362-5:1995, *Injection containers for injectables and accessories — Part 5: Freeze drying closures for injection vials*

ISO 8536-2:2001, *Infusion equipment for medical use — Part 2: Closures for infusion bottles*

ISO 8536-6:1995, *Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles*

ISO 11040-2:1994, *Prefilled syringes — Part 2: Plungers and discs for dental local anaesthetic cartridges*

ISO 11040-5:2001, *Prefilled syringes — Part 5: Plungers for injectables*

3 Classification

Elastomeric parts exist in various designs and sizes depending on the intended end-use. These parts serve different purposes depending on the item or device in which they are incorporated. Elastomeric parts have, therefore, been classified into the following categories:

— elastomeric parts for injection vials (see ISO 8362-2);

— elastomeric parts for infusion bottles (see ISO 8536-2);

— elastomeric parts for prefilled syringes (see ISO 11040-2 and ISO 11040-5);

— elastomeric parts for medical devices for pharmaceutical use (excluding gloves and probes);

— elastomeric parts for freeze-dried products (see ISO 8362-5 and ISO 8536-6).

4 Requirements

4.1 Resistance to steam sterilization

Elastomeric parts shall not lose their required biological, chemical and physical properties after being sterilized twice in saturated steam at (121 ± 2) °C for 30 min each time.

4.2 Chemical requirements

Elastomeric parts shall comply with the chemical requirements specified in Table 1.

Elastomers are divided into the following types:

— Type I elastomer: this meets the strictest requirements and is the preferred type.

— Type II elastomer: this does not meet these severe requirements as a result of its different chemical composition which is necessary to give the mechanical properties required for special applications (e.g. multiple piercing).

The methods to be used to determine the chemical characteristics of the elastomeric parts are specified in Annex A to Annex J.

5 Sampling

Take a random sample of the elastomeric parts which is representative of each delivery, with the parts in their original state. The number of elastomeric parts taken shall be as specified in the relevant International Standards (see Clause 3).

Table 1 — Chemical requirements for testing aqueous autoclavates

Characteristic	Requirements	Test as described in Clause/Annex
Turbidity	Type I: Not more turbid than reference suspension II	A.1
	Type II: Not more turbid than reference suspension III	
Colour	Type I and II: Not more intensely coloured than reference solution GY_5	A.2
Acidity/alkalinity	Type I and II: $\leqslant$ 0,3 ml sodium hydroxide solution, c(NaOH) = 0,01 mol/l or $\leqslant$ 0,8 ml hydrochloric acid, c(HCl) = 0,01 mol/l	B
Absorbance	Type I: $\leqslant$ 0,2 AU across the whole range from 220 nm to 360 nm	C
	Type II: $\leqslant$ 4,0 AU across the whole range from 220 nm to 360 nm	
Reducing substances	Type I: $\leqslant$ 3,0 ml sodium thiosulfate solution, $c(Na_2S_2O_3)$ = 0,01 mol/l	D
	Type II: $\leqslant$ 7,0 ml sodium thiosulfate solution, $c(Na_2S_2O_3)$ = 0,01 mol/l	
Extractable heavy metals	Type I and II: $\leqslant$ 2,0 mg/l	E
Extractable zinc	Type I and II: $\leqslant$ 5,0 mg/l	F
Extractable ammonia	Type I and II: $\leqslant$ 2,0 mg/l	G
Residue on evaporation	Type I: $\leqslant$ 2,0 mg/50 ml	H
	Type II: $\leqslant$ 4,0 mg/50 ml	
Volatile sulfides	Type I and II: Black stain on acetate paper shall not be larger or darker than reference (0,154 mg Na_2S for every 20 cm^2 of stopper surface area.)	I
Conductivity (optional)	Type I: $\leqslant$ 15 µS/cm	J
	Type II: $\leqslant$ 30 µS/cm	
A blank may be prepared where appropriate for system control, but correction of the result using the blank result is only allowed if mentioned in the corresponding annex.		

6 Apparatus and reagents

6.1 Use only reagents of recognized analytical grade. For the preparation of standard solutions, see the relevant annex.

6.2 Use purified water prepared by distillation or by any other suitable means.

Its conductivity shall be less than 3,0 µS/cm.

NOTE Purified water as specified in various national pharmacopoeias corresponds to grade 1 and grade 2 water as specified in ISO 3696.

6.3 Glassware shall be made from borosilicate glass.

7 Preparation of test solutions

7.1 Closures shall be processed in the as-delivered condition.

7.2 Place a suitable number of complete elastomeric parts in a wide-necked flask and add 300 ml of purified water for every 150 cm^2 of surface area of the elastomeric parts. Cover the mouth of the flask, e.g. with aluminium foil or an inverted borosilicate glass beaker. Weigh the flask plus contents. Heat in an autoclave so that a temperature of (121 ± 2) °C is reached within 20 min to 30 min and maintain this temperature for 30 min. Cool to room temperature over about 30 min. Make up to the original mass with purified water if necessary (if tightly closed containers are not used).

Shake this solution (solution S_1) and immediately separate it from the elastomeric parts. Shake solution S_1 before each test.

7.3 Prepare a blank solution (solution S_0) in the same way as for solution S_1 except that 300 ml of purified water are used without the elastomeric parts.

7.4 Use solutions S_1 and S_0 obtained as described to carry out the chemical tests.

Annex A
(normative)

Appearance of solution

A.1 Turbidity of solution S_1

A.1.1 General

The determination may be carried out instrumentally using a turbidimeter or by visual comparison.

A.1.2 Visual comparison with standards

A.1.2.1 Reagents

A.1.2.1.1 Hydrazine sulfate solution

Dissolve 1,0 g of hydrazine sulfate in water and dilute to 100 ml with water. Allow to stand for 4 h to 6 h.

A.1.2.1.2 Hexamethylenetetramine solution

Dissolve 2,5 g of hexamethylenetetramine in 25,0 ml of water in a glass-stoppered 100 ml flask.

A.1.2.1.3 Stock suspension

To the solution of hexamethylenetetramine in the flask add 25,0 ml of hydrazine sulfate solution. Mix and allow to stand for 24 h. This suspension is stable for 2 months, provided it is stored in a glass container free from surface defects. Discard if the suspension adheres to the glass. Mix well before use.

A.1.2.1.4 Standard suspension

Dilute 15,0 ml of the stock suspension to 1 000 ml with water. This suspension shall be freshly prepared and may not be stored for longer than 24 h.

A.1.2.1.5 Reference suspensions

Prepare reference suspensions in accordance with Table A.1. Mix well before use.

Table A.1

	I	II	III
Standard suspension	5,0 ml	10,0 ml	30,0 ml
Water	95,0 ml	90,0 ml	70,0 ml

A.1.2.2 Procedure

Use identical test tubes made of colourless, transparent, neutral glass, and with a flat base and an internal diameter of 15 mm to 25 mm. Fill one tube to a depth of 40 mm with solution S_1 and three others to the same depth with the reference suspensions (see Table A.1). Compare the solutions in diffuse daylight 5 min after preparation of the reference suspensions, viewing vertically against a black background. The light conditions shall be such that reference suspension I can be readily distinguished from water, and that reference suspension II can be readily distinguished from reference suspension I.

A.1.3 Instrumental determination by turbidimeter

The reference suspensions prepared in A.1.2.1.5 represent the following limits:

Reference suspension II: 6 FTU[1)] (type I elastomers)

Reference suspension III 18 FTU (type II elastomers)

Check the instrument on a regular basis to ensure that it defines these limits correctly.

A.1.4 Expression of results

Report the result as “complies”/“does not comply” with type I or type II requirements (see Table 1).

A.2 Colouration of solution S_1

A.2.1 Reagents

A.2.1.1 Stock yellow solution

Dissolve 46 g of ferric chloride in about 900 ml of a mixture of 25 ml of concentrated hydrochloric acid (~ 36 %) and 975 ml of water and make up to 1 000 ml with the same mixture. Titrate (see A.2.1.2) and adjust the concentration of the solution to 45,0 mg of $FeCl_3 \cdot 6H_2O$ per millilitre by adding the same mixture. Protect the solution from light.

A.2.1.2 Titration

Into a 250 ml conical flask fitted with a ground-glass stopper, place 10,0 ml of the stock solution, 15 ml of water, 5 ml of concentrated hydrochloric acid and 4 g of potassium iodide. Close the flask, allow to stand in the dark for 15 min and then add 100 ml of water. Titrate the liberated iodine with 0,1 mol/l sodium thiosulfate, using 0,5 ml of starch solution (A.2.1.8), added towards the end of the titration, as indicator.

1 ml of 0,1 mol/l sodium thiosulfate is equivalent to 27,03 mg of $FeCl_3 \cdot 6H_2O$.

A.2.1.3 Stock red solution

Dissolve 60 g of cobalt chloride in about 900 ml of a mixture of 25 ml of concentrated hydrochloric acid and 975 ml of water and make up to 1 000 ml with the same mixture. Titrate (see A.2.1.4) and adjust the concentration of the solution to 59,5 mg of $CoCl_2 \cdot 6H_2O$ per millilitre by adding the same mixture.

1) Formazine turbidity units.

A.2.1.4 Titration

Into a 250 ml conical flask fitted with a ground-glass stopper, place 5,0 ml of the stock solution, 5 ml of dilute hydrogen peroxide solution and 10 ml of a 300 g/l solution of sodium hydroxide. Boil gently for 10 min, allow to cool and add 60 ml of dilute sulfuric acid (A.2.1.7) and 2 g of potassium iodide. Close the flask and dissolve the precipitate by shaking gently. Titrate the liberated iodine with 0,1 mol/l sodium thiosulfate, using 0,5 ml of starch solution (A.2.1.8), added towards the end of the titration, as indicator. The end-point is reached when the solution turns pink.

1 ml of 0,1 mol/l sodium thiosulfate is equivalent to 23,79 mg of $CoCl_2 \cdot 6H_2O$.

A.2.1.5 Stock blue solution

Dissolve 63 g of copper sulfate in about 900 ml of a mixture of 25 ml of concentrate hydrochloric acid and 975 ml of water and make up to 1 000 ml with the same mixture. Titrate (see A.2.1.6) and adjust the concentration of the solution to 62,4 mg of $CuSO_4 \cdot 5H_2O$ per millilitre by adding the same mixture.

A.2.1.6 Titration

Into a 250 ml conical flask fitted with a ground-glass stopper, place 10,0 ml of the stock solution, 50 ml of water, 12 ml of dilute acetic acid (~ 12 %) and 3 g of potassium iodide. Titrate the liberated iodine with 0,1 mol/l sodium thiosulfate, using 0,5 ml of starch solution (A.2.1.8), added towards the end of the titration, as indicator. The end-point is reached when the solution shows a slight pale-brown colour.

1 ml of 0,1 mol/l sodium thiosulfate is equivalent to 24,97 mg of $CuSO_4 \cdot 5H_2O$.

A.2.1.7 Sulfuric acid, dilute

Prepare a solution containing 98 g of sulfuric acid per litre of water.

A.2.1.8 Starch solution

Triturate 1,0 g of soluble starch with 5 ml of water and, whilst stirring, pour the mixture into 100 ml of boiling water containing 10 mg of mercuric iodide.

A.2.1.9 Standard solution

From the three stock solutions, prepare a standard solution as follows:

Table A.2 — Standard solution GY

Volumes in millilitres

Standard solution	Stock yellow solution	Stock red solution	Stock blue solution
GY (greenish-yellow)	9,6	0,2	0,2

A.2.1.10 Reference solution

From the standard solution, prepare a reference solution as follows:

Table A.3 — Reference solution GY_5

Volumes in millilitres

Reference solution	Standard solution GY	Hydrochloric acid (10 g/l HCl)
GY_5	3,0	97,0

Prepare the reference solution immediately before use.

A.2.2 Procedure

Use identical test tubes made of colourless, transparent, neutral glass, and with a flat base and an internal diameter of 15 mm to 25 mm. Fill one tube to a depth of 40 mm with solution S_1 and another to the same depth with the reference solution (see Table A.3). Compare the solutions in diffuse daylight, viewing vertically against a white background.

Using identical tubes of colourless, transparent, neutral glass with a flat base and an external diameter of 15 mm to 25 mm, compare the liquid to be examined with the reference solution (see Table A.3). The depth of the layer being 40 mm. Compare the colours in diffuse daylight, viewing vertically against a white background.

A.2.3 Expression of results

Report the result as “complies”/“does not comply” with the requirement (see Table 1).

Annex B
(normative)

Acidity or alkalinity

B.1 General

Depending on their composition, some types of closure formulation contain ingredients which may act as acids or alkalis. If acidic or alkaline material is extracted, a change in the pH-value, which may adversely affect the stability of a pharmaceutical product, may occur. Such a change in the pH-value can be determined by potentiometric measurement of the aqueous extract using a pH electrode. However, the potentiometric determination may lead to misleading results when measurements are performed in unbuffered systems around pH 7. Therefore, it is recommended that a titration method be used to determine acidity or alkalinity.

B.2 Reagents

B.2.1 Bromothymol blue solution

Dissolve 50 mg of bromothymol blue in a mixture of 4 ml of 0,02 mol/l sodium hydroxide and 20 ml of ethanol (~ 96 %) and dilute to 100 ml with water.

B.2.2 Colour change

From pH 5,8 (yellow) to pH 7,4 (blue) or *vice versa*.

B.2.3 Test for sensitivity

To 0,3 ml of bromothymol blue solution add 100 ml of carbon-dioxide-free water. The solution shall be yellow. Not more than 0,1 ml of 0,02 mol/l sodium hydroxide shall be required to change the colour to blue.

B.3 Procedure

Add 0,1 ml of bromothymol blue solution to 20 ml of test solution S_1. Titrate against 0,01 mol/l sodium hydroxide or 0,01 mol/l hydrochloric acid.

Calculate the result as the number of millilitres of sodium hydroxide or hydrochloric acid consumed by 20 ml of test solution S_1 (to one place of decimals). Not more than 0,3 ml of 0,01 mol/l sodium hydroxide or 0,8 ml of 0,01 mol/l hydrochloric acid shall be required to obtain a blue or yellow colour, respectively.

B.4 Expression of results

Report the result as “complies”/“does not comply” with the requirement (see Table 1).

Annex C
(normative)

Absorbance

C.1 General

The ultraviolet (UV) spectrum obtained on extracts of elastomeric materials is primarily a function of the kind of accelerator or antioxidant present in the individual elastomeric formulation. This type of test is applicable to all vulcanized rubber products and is usually performed using an aqueous extract.

C.2 Procedure

Carry out the test within 5 h of preparation of solution S_1.

Filter test solution S_1 through a membrane filter (pore size approx. 0,45 µm) if necessary to filter out particles which could cause stray light interference. Place the solution in a 1 cm quartz cell in a scanning UV spectrometer, with a blank solution S_0 in the reference cell, and obtain the spectrum over the wavelength range from 220 nm to 360 nm.

If dilution is necessary, record the dilution factor.

Use this factor when estimating compliance.

C.3 Expression of results

Report the result as the recorded curve showing the absorbance (extinction coefficient) plotted versus the wavelength and also as “complies”/“does not comply” with type I or type II requirements (see Table 1).

Annex D
(normative)

Reducing substances

D.1 General

When subjected to extraction processes in aqueous media, a given elastomeric material may release oxidizable matter, depending on its composition. Probably the most common of the possible extractables from elastomeric parts are the vulcanizing agents, the accelerators and their reaction products. This category of materials might include one or more of the following constituents: sulfur, thiurams, sulfenamides, thiazoles, dithiocarbamates, complex organic amines, phenolic resins and organic peroxides.

The extraction of the reducing matter is performed under conditions which simulate those to which elastomeric parts are usually exposed during sterilization in a steam autoclave.

D.2 Reagents

D.2.1 Sulfuric acid, dilute

Prepare a solution containing 98 g of sulfuric acid per litre of water.

D.2.2 Starch solution

Triturate 1,0 g of soluble starch with 5 ml of water and, whilst stirring, pour the mixture into 100 ml of boiling water containing 10 mg of mercuric iodide.

D.3 Procedure

Carry out the test within 4 h of preparation of solution S_1. To 20,0 ml of solution S_1, add 1 ml of dilute sulfuric acid and 20,0 ml of 0,002 mol/l potassium permanganate. Boil for 3 min. Cool. Add 1 g of potassium iodide or 2 ml of 10 % potassium iodide solution in water and titrate immediately with 0,01 mol/l sodium thiosulfate, using 0,25 ml of starch solution as indicator. Also carry out a titration using 20,0 ml of blank solution S_0.

Calculate the result as the difference, in millilitres, between the volumes of titrant required by solution S_1 and solution S_0 (to one place of decimals).

D.4 Expression of results

Report the result as “complies”/“does not comply” with type I or type II requirements (see Table 1).

Annex E
(normative)

Extractable heavy metals

E.1 General

The extraction of metal ions, due to the presence of mineral fillers and certain metal oxides used as cure boosters, is common. The levels of these metals can be controlled by the rubber manufacturer by careful selection of material and thorough inspection of supplies.

The extraction of the heavy metals is performed under conditions which simulate those to which elastomeric parts are usually exposed during sterilization in a steam autoclave.

E.2 Reagents

E.2.1 Standard lead solution

Prepare an aqueous solution containing 2,0 mg/l of Pb from lead nitrate [$Pb(NO_3)_2$].

E.2.2 Thioacetamide reagent

To 0,2 ml of a 40 g/l thioacetamide solution in water, add 1 ml of a mixture of 5 ml of water, 15 ml of 1 mol/l sodium hydroxide and 20 ml of glycerol (85 %). Heat in a water-bath for 20 s. Prepare immediately before use.

E.2.3 Buffer solution, pH 3,5

Dissolve 25,0 g of ammonium acetate in 25 ml of water and add 38,0 ml of hydrochloric acid (E.2.4). Adjust the pH if necessary with dilute hydrochloric acid (E.2.5) or dilute ammonia (E.2.6). Dilute to 100 ml with water.

E.2.4 Hydrochloric acid

Dilute 70 g of concentrated hydrochloric acid [35,0 % to 37,0 % (by mass) of HCl] to 100 ml with water.

E.2.5 Hydrochloric acid, dilute

Dilute 20 g of concentrated hydrochloric acid [35,0 % to 37,0 % (by mass) of HCl] to 100 ml with water.

E.2.6 Ammonia, dilute

Dilute 41 g of concentrated ammonia [25,0 % to 30,0 % (by mass) of ammonia] to 100 ml with water.

E.3 Procedure

To 12 ml of solution S_1, add 2 ml of pH 3,5 buffer solution (E.2.3). Mix and add to 1,2 ml of thioacetamide reagent (E.2.2). Mix immediately. Prepare a reference solution in the same manner by mixing 10 ml of standard lead solution (E.2.1), as prescribed, and 2 ml of solution S_1.

After 2 min, any brown colour in the test solution shall not be more intense than that of the reference solution, which corresponds to a heavy metal concentration of 2 mg/l.

E.4 Expression of results

Report the result as “complies”/“does not comply” with the requirement (see Table 1).

Annex F
(normative)

Extractable zinc

F.1 Procedure

Most rubber formulations require a small portion of zinc oxide to support the vulcanization process and to improve certain physical characteristics. Consequently zinc ions may be extracted by aqueous fluids.

F.2 Procedure

F.2.1 Add 1 ml of 0,01 mol/l hydrochloric acid to 20 ml of solution S_1.

F.2.2 Prepare at least three calibration solutions from a standard zinc solution (1 g/l Zn) by diluting with 0,1 mol/l hydrochloric acid and water to give an acid concentration similar to that in the test solution. Prepare calibration solutions of concentrations which span the expected zinc concentration in the test solution.

F.2.3 Measure the absorbance of the test solution and the calibration solutions at 213,9 nm using a zinc hollow-cathode lamp as the radiation source and an air/acetylene flame.

If dilution of the test solution is necessary, record the dilution factor.

Consider the dilution factor, if applicable, in the calculation of the results.

Calculate the result as mg/l of Zn in solution S_1 (to one place of decimals).

F.3 Expression of results

Report the result as “complies”/“does not comply” with the requirement (see Table 1).