International Standard 7864

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Sterile hypodermic needles for single use

Aiguilles hypodermiques stériles, non réutilisables

First edition — 1984-09-01

UDC 615.473.2 **Ref. No. ISO 7864-1984 (E)**

Descriptors: medical equipment, hypodermic needles, specifications, dimensions, packing, colour marking, tests.

Price based on 7 pages

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. Every 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7864 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*.

Printed in Switzerland

Contents

Sterile hypodermic needles for single use

0 Introduction

This International Standard deals with products primarily intended for use with humans and provides performance requirements, but permits some variation of design and of methods of packaging and sterilization by individual manufacturers.

Materials to be used for the construction of hubs for sterile needles for single use are not specified in detail as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids included in relevant pharmacopoeiae.

The majority of injections are in aqueous media. Such media are not known to give problems. It is usual for non-aqueous injections to be formulated in either ester type solvent or the active ingredient itself may be fluid.

Tests for freedom from pyrogenic material, abnormal toxicity and certain chemical tests for extractable material are included in clauses 6, 7 and 9 respectively.

Annexes A, B, C and D form an integral part of this International Standard.

In some countries national pharmacopoeia or other government regulations are legally binding and their requirements may take precedence over this International Standard.

Hypodermic needles specified in this International Standard are intended for use with hypodermic syringes specified in ISO 595 and ISO 7886. The 6 % taper conical fitting (Luer) specified is in conformity with ISO 594.

1 Scope and field of application

This International Standard specifies requirements for sterile hypodermic needles for single use.

2 References

ISO 594, *Conical fitting with 6 % (Luer) taper for syringes, needles and certain other medical equipment —*

Part 1 : General requirements.[1]

Part 2 : Luer lock fittings[1]

ISO 595, *Syringes for medical use.*[2]

ISO 683/13, *Heat treated steels, alloy steels and free-cutting steels — Part 13 : Wrought stainless steels.*

ISO 6009, *Hypodermic needles for single use — Colour coding for identification.*

ISO 7886, *Sterile hypodermic syringes for single use.*

3 Nomenclature

The nomenclature of components of hypodermic needles for single use is illustrated in the figure.

1) At present at the stage of draft. (Revision of ISO/R 594-1967.)

2) At present at the stage of draft. (Revision of ISO/R 595-1967.)

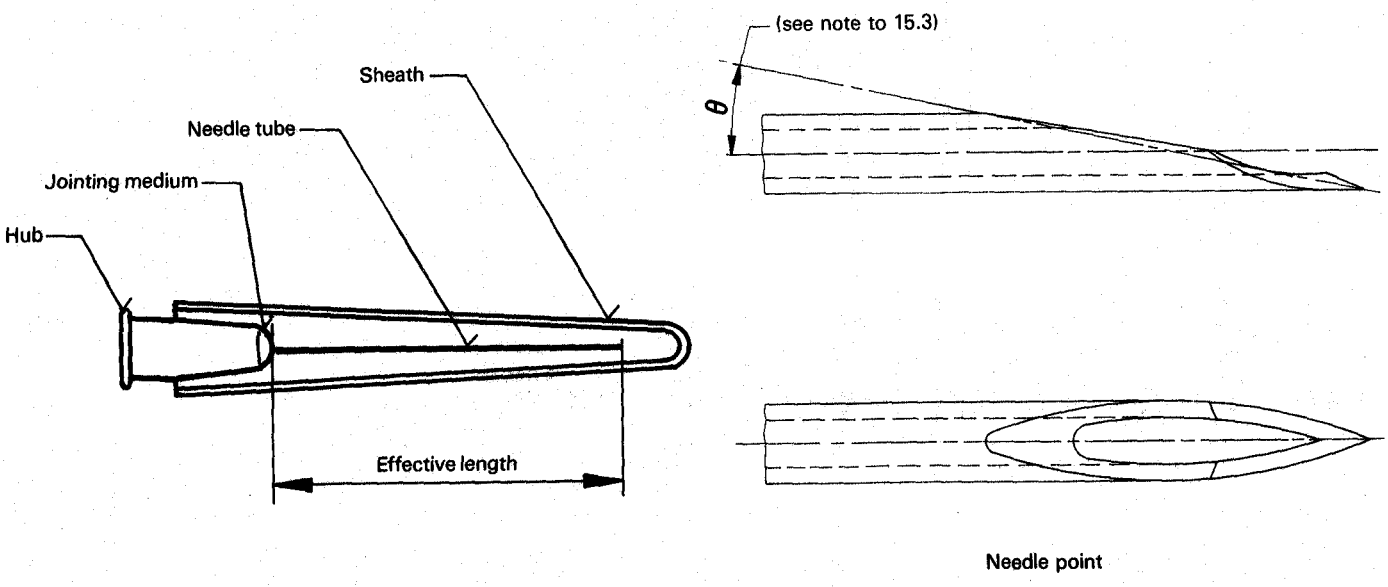

Figure — Typical hypodermic needle for single use

NOTE — The drawing is intended to illustrate the nomenclature of a typical hypodermic needle, but does not otherwise form part of the specification.

4 Materials

4.1 Materials used in the construction of hypodermic needles shall be suitable for their intended use and the process to be used for sterilization.

4.2 Materials used in the construction of hypodermic needles shall not cause them to be detrimentally affected, physically or chemically, by the normal use of injectable preparations.

4.3 Materials used in the construction of hypodermic needles shall not cause them to yield, under conditions of normal use, significant amounts of toxic substances and shall permit them to satisfy the requirements for freedom from pyrogenic materials (see clause 6), abnormal toxicity (see clause 7) and tests for extractable matter (see clause 9).

5 Manufacture

Hypodermic needles shall be manufactured in accordance with recognized national or international codes of good manufacturing practice and shall be substantially free from defects affecting appearance, safety and serviceability for the intended use.

6 Freedom from pyrogenic materials

Hypodermic needles shall be capable of satisfying the test for freedom from pyrogenic materials in accordance with the relevant national pharmacopoeia.

The extract to be used in the test shall be prepared as described in clause A.2.

7 Test for abnormal toxicity

Hypodermic needles shall be capable of satisfying the test for abnormal toxicity specified in the relevant national pharmacopoeia.

The extract to be used in the test shall be prepared as described in clause A.2.

8 Freedom from extraneous matter

The surface of the hypodermic needle shall be clean and free from extraneous matter when viewed by normal or corrected vision without magnification.

9 Limits for extractable matter

9.1 General

Hypodermic needles shall be capable of satisfying the chemical tests for extractable matter in accordance with the relevant national pharmacopoeia.

9.2 Limits for acidity or alkalinity

The pH value of the needle extract prepared as described in clause A.3 shall be determined with a laboratory potentiometric pH meter and using a general purpose electrode, and shall be within one unit of pH of that of the control fluid.

9.3 Limits for extractable metals

An extract prepared as described in clause A.3 shall contain not more than a combined total of 5 mg/kg of lead, tin, zinc and

iron when tested by a recognized micro-analytical method, for example by an atomic absorption method. The cadmium content of the extract shall be less than 0,1 mg/kg.

10 Lubrication of hypodermic needles

10.1 If the exterior surface of the hypodermic needle tube is lubricated, the lubricant shall not adversely affect compliance with the requirements of clause 4.

10.2 The quantity of lubricant used shall be minimal and shall not be visible as drops of fluid on the exterior surface of the hypodermic needle tube or in the bore.

11 Size designation

The size of hypodermic needle shall be designated by the following :

a) nominal external diameter of needle tube expressed in millimetres;

b) nominal effective length of needle expressed in millimetres where the length is measured from the tip of the point to the joint with the hub, including the adhesive if present (see the figure).

The size shall be expressed, in millimetres, in accordance with the following example :

0,8 × 40

NOTE — If the needle is made of thin-walled tubing, this may be stated.

12 Range of sizes

The diameter of hypodermic needles shall be in accordance with table 1.

The preferred range of nominal effective lengths of hypodermic needles shall be in accordance with table 1.

The nominal diameter of hypodermic needles shall be identified by colour coding in accordance with ISO 6009 and as shown in table 1, applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath.

13 Needle hub

13.1 Conical fitting

The conical socket of the hypodermic needle hub shall comply with the requirements of ISO 594.

When mated with a reference steel male conical fitting in accordance with ISO 594/1 the socket shall make a leak-proof union when subjected to the test described in annex B.

13.2 Colour of hub

The hub shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with clause 12.

13.3 Finish

The surface of the hub shall be free from functional and substantially free from visual defects.

When examined under X 2,5 magnification with adequate illumination, the hub socket shall be free from particles and other extraneous matter.

14 Sheath

If a separate needle sheath is provided, it shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with clause 12.

15 Needle tube

15.1 Material

The needle tube shall be made from austenitic stainless steel having properties capable of satisfying the tests for mechanical strength and corrosion resistance in 15.5, 15.6 and 15.7.

NOTE — Suitable needle tubing may be manufactured from steel having composition in accordance with ISO 683/13 types 10, 11, 16, 20, 21 and 23.

15.2 Dimensions of needle tube

The external diameter and minimum bore of the needle tube shall be as given in table 2.

The actual length of the needle tube shall be as given in table 3.

15.3 Needle point

The needle point shall be sharp, free from feather edges, burrs, hooks and other defects.

NOTE — The needle point, as illustrated by the angle shown in the figure, usually has a bevel with an angle of 12 ± 2°. Alternatively a "short" bevel with an angle of 18 ± 2° or other nominal angle subject to a tolerance of ± 2° may be supplied.

15.4 Freedom from defects

The needle tube shall be straight, of regular cross-section and wall thickness and free from manufacturing defects. The external surface of the tube shall be smooth.

15.5 Resistance to corrosion

The needle tube shall not show corrosion when tested by the procedure given in annex C.

15.6 Stiffness

The needle tube, after removal of the hub if necessary, shall not show a deflection greater than that given for the appropriate nominal diameter when loaded centrally between two supports under the conditions defined in table 4.

15.7 Resistance to breakage

When tested by the method given in annex D, the needle tube shall withstand 20 complete cycles of reversal of force without breaking.

16 Test requirements for needle assembly

16.1 Bond between hub and needle tube

The union of the hub and needle tube shall not be broken by a force of the magnitude given in table 5 applied as push or pull in the direction of the axis of the needle.

16.2 Patency of lumen

A stainless steel stylet of the appropriate diameter selected from table 6 shall pass through the needle.

Alternatively, the lumen shall satisfy a water flow rate test in which the flow rate shall be not less than 80 % of that of a needle of equivalent diameter and length with a minimum bore in accordance with table 2. The water pressure during the test shall not exceed 1×10^5 Pa (≈ 1 atm).

17 Packaging

17.1 Unit container

Each hypodermic needle shall be sealed in a unit container. The material and design of this container shall be such as to ensure

a) visible colour coding to denote nominal external diameter of the needle tube in accordance with the requirements of table 1;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

c) minimum risk of contamination of the contents during removal from the container;

d) adequate protection of the contents during normal handling, transit and storage.

17.2 Outer container

A convenient number of unit containers shall be packaged in an outer container which shall be sufficiently robust to protect the contents during handling, transit and storage.

18 Sterility

The contents of the unit container (see 17.1) shall be sterile.

NOTE — National regulatory authorities in many countries may require conformance with pharmacopoeia tests or national regulations.

19 Marking of containers

19.1 Unit container

The unit container shall be marked to include the following :

a) description of contents, including the size designated in accordance with clause 11;

b) the word "STERILE";

c) the name and/or trade mark of the manufacturer or supplier;

d) an identification reference to the batch or the date of manufacture.

19.2 Outer container

Outer containers shall be marked to include the following :

a) description of contents, including the size designated in accordance with clause 11, the type or angle of bevel (see 15.3) and the word "STERILE";

b) the words "FOR SINGLE USE" or equivalent;

NOTE — Use of the term "disposable" is not acceptable.

c) warning to check the integrity of each unit container;

d) identification reference to the batch [to accord with 19.1 d)] and date (month and year) of sterilization;

e) the name and address of the manufacturer or supplier.

Annex A

Preparation of extracts

(This annex forms part of this International Standard.)

A.1 Method

Immerse 25 needles in 250 ml of extraction fluid in a suitable container made from boro-silicate glass. Maintain the fluid at a temperature of 37 $^{+3}_{0}$ °C for 1 h. Remove the needles.

A.2 Extract for tests for pyrogenicity and abnormal toxicity

Prepare the extract as detailed in clause A.1, using a sterile, pyrogen-free saline solution containing 9 g/l of sodium chloride of recognized analytical quality in freshly prepared distilled water as the extraction fluid.

A.3 Extract and control fluid for tests for acidity/alkalinity and extractable metals

Prepare the extract as detailed in clause A.1, using freshly prepared sterile distilled water as the extraction fluid.

Prepare the control fluid by following the procedure given in clause A.1, but omitting the needles.

Annex B

Testing of conical fitting for integrity of needle assembly on aspiration

(This annex forms part of this International Standard.)

B.1 Procedure

The test shall be conducted as follows :

B.1.1 Connect the hub to a reference steel male conical fitting as specified in ISO 594/1, both components being dry. Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a value of torque not exceeding 0,1 N·m to give rotation not exceeding 90°.

B.1.2 Connect the reference male conical fitting via a leak-proof joint of minimum volume to a syringe, the latter having previously passed the test for air leakage past the piston during aspiration given in ISO 594/1.

B.1.3 Draw into the syringe through the needle hub and reference male conical fitting a volume of recently boiled and cooled water exceeding 25 % of the nominal graduated capacity of the syringe. Avoid wetting the hub/reference male conical fitting union.

B.1.4 Expel the air, except for a small residual air bubble.

B.1.5 Adjust the volume of water in the syringe to 25 % of the nominal graduated capacity.

B.1.6 Seal the needle tip.

B.1.7 With the syringe nozzle downwards withdraw the piston to the nominal graduated capacity. Hold for 15 s.

B.1.8 Examine the syringe for leakage as indicated by the continued formation of air bubbles from the union. Bubbles formed during the first 5 s shall be discounted.