INTERNATIONAL STANDARD

ISO 11040-6

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Prefilled syringes —

Part 6: Plastic barrels for injectables

Seringues préremplies —

Partie 6: Cylindres en plastique pour produits injectables

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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 11040-6 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

ISO 11040 consists of the following parts, under the general title *Prefilled syringes*:

— *Part 1: Glass cylinders for dental local anaesthetic cartridges*

— *Part 2: Plunger stoppers for dental local anaesthetic cartridges*

— *Part 3: Seals for dental local anaesthetic cartridges*

— *Part 4: Glass barrels for injectables*

— *Part 5: Plunger stoppers for injectables*

— *Part 6: Plastic barrels for injectables*

The following parts are under preparation:

— *Part 7: Packaging systems for prefillable ready-to-use syringes*

Introduction

Until now, ampoules and injection bottles have been mainly used as primary packaging material for the administration of injectables. However, for the injection of the liquid medicinal products stored in these containers, a hypodermic syringe combined with the appropriate injection cannula is also needed. This requires that the medicinal product be transferred into the hypodermic syringe before its final use. This procedure is not only time-consuming; it can also easily result in mix-ups and possible contamination.

In conjunction with the appropriate sealing components, pre-filled single use syringes conforming to this part of ISO 11040 form a safe system for the transport, storage and administration of medicine. Due to relatively simple handling procedures, they permit fast injection of the medicinal products contained within them.

This part of ISO 11040 can also be used by engineers as a basis for the development and marketing of standardized filling and processing equipment, e.g. so-called tub and nest filling presentations. Manufacturers of filling equipment and ancillary processing equipment can use this part of ISO 11040 to achieve a certain degree of unification with regard to the design of these standardized items of equipment.

NOTE Primary packaging materials are an integral part of medicinal products. Thus, the principles of the current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components (see ISO 15378).

Prefilled syringes —

Part 6:
Plastic barrels for injectables

1 Scope

This part of ISO 11040 specifies the materials, dimensions and requirements for plastic barrels (single-chamber design) for injection preparations, which are to be subsequently filled and assembled on standardized processing equipment.

It is applicable to pre-filled plastic syringes intended for single use only.

Pre-filled syringes can be produced on dedicated and specifically designed processing equipment. This part of ISO 11040 is not applicable to such dedicated pre-filled syringes.

Before the final approval for human use is granted, compatibility tests applying the intended pharmaceuticals are carried out. This part of ISO 11040 does not specify the procedures for such compatibility tests.

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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*[1)]

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[2)]

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11040-5, *Prefilled syringes — Part 5: Plunger stoppers for injectables*

ISO 15223-1:—[3)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15378:2011, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP)*

European Pharmacopoeia 7, available at http://www.edqm.eu

1) To be replaced by ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

2) To be replaced by ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

3) To be published.