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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).