First edition
2016-11-15

Prefilled syringes —

Part 8: Requirements and test methods for finished prefilled syringes

Seringues préremplies —

Partie 8: Exigences et méthodes d'essai pour seringues préremplies prêtes à l'emploi

Reference number
ISO 11040-8:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is 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 and sterilized subassembled syringes ready for filling*

— *Part 5: Plunger stoppers for injectables*

— *Part 6: Plastic barrels for injectables*

— *Part 7: Packaging systems for sterilized subassembled syringes ready for filling*

— *Part 8: Requirements and test methods for finished prefilled syringes*

Introduction

Historically, injectable (parenteral) liquid pharmaceutical products have been mainly provided in primary containers (i.e. ampoules and vials) which required the liquid to be transferred into a hypodermic syringe and combined with the appropriate injection needle before its final use. This procedure is not only time-consuming, but also presents a great number of possibilities for contamination and use errors.

Over the past several years, the presentation of liquid pharmaceutical products in prefilled syringes for single use, many with staked needles, is becoming more prevalent. The simplicity of use that is provided not only benefits their use in the clinical setting, but also enables these to be used by lay users in a home setting.

The standardization of the requirements for prefilled syringes has been addressed by ISO/TC 76 in two ways:

— the specification of the components of the prefilled syringe prior to filling is included in the previous parts of the ISO 11040 series;

— the requirements for the final prefilled syringe, presented to the user as a finished product, are addressed in this part of ISO 11040.

Finished prefilled syringes require marketing authorization as a drug, in some regions as a combination product or as a medical device, depending on the content and the intended use. The syringe plays a dual role in the prefilled syringe product — as a container closure system and as a delivery device. Safety, performance and usability need to be considered, as well in case of intended preassembly, copackaging or label reference for use with other devices and equipment. This part of ISO 11040 addresses the content and syringe as a system, with the intent to ensure the successful performance for its intended purpose.

There are other international and national standards and guidance publications and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals. Their requirements might supersede or complement this part of ISO 11040. Developers and manufacturers of finished prefilled syringes are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their products.