Third edition
2012-01-15

Prefilled syringes —

Part 5:
Plunger stoppers for injectables

Seringues préremplies —

Partie 5: Bouchons-pistons pour produits injectables

Reference number
ISO 11040-5:2012(E)

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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 11040-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 11040-5:2001), which has been technically revised by:

— adjusting the title of this part of ISO 11040;

— aligning this International Standard with the ISO 8871 series;

— revising the requirements on the height of the spacers and requirements on material and hardness;

— adding requirements on resistance to ageing.

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 ready-to-use prefillable syringes*

— *Part 5: Plunger stoppers for injectables*

— *Part 6: Plastics barrels for injectables*

The following parts are under preparation:

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

Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products. Therefore, the principles of current good manufacturing practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in e.g. ISO 15378 or in the GMP Guidelines published by the European Community and the United States of America.