Third edition
2017-11

Pen systems —

Part 2: Plunger stoppers for pen-injectors for medical use

Systèmes de stylos-injecteurs —

Partie 2: Bouchons-pistons pour stylos-injecteurs à usage médical

Reference number
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Foreword

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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).

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For an explanation on the voluntary nature of standards, 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.

This document 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 13926-2:2011), which has been technically revised. It also incorporates the Amendment ISO 13926-2:2011/Amd. 1:2015.

The main changes compared to the previous edition are as follows:

— the dimensions d_1, d_2 and d_3 in Table 1 have been changed from normative to informative; d_2 is required to align with ISO 13926-1;

— Formula (A.1) has been corrected.

A list of all parts in the ISO 13926 series can be found on the ISO website.

Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus, the principles of current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, for example, ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.