International Standard

ISO 13926-1

Cartridge systems —

Part 1: Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use

Systèmes à cartouche —

Partie 1: Flacons en verre pour systèmes d'injection à aiguille (NIS) de type cartouche à usage médical

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Foreword

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

This fifth edition cancels and replaces the fourth edition (ISO 13926-1:2018), which has been technically revised.

The main changes are as follows:

— changing the title extending glass cylinders application to needle-based injection system general application;

— changing the scope extending glass cylinders application to needle-based injection system general application;

— updating the terms and definitions;

— updating Table 1 for dimension and introduction of designation using nominal volume (ml)/inner diameter (mm);

— changing the dimensions d_1, d_2 and d_3 in Table 1 from informative to normative;

— updating designation according to Table 1;

— adding Figure 2 and Table 2 for cartridges with vial flange configuration.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Primary packaging components made of glass 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[6],[7].