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Irish Standard
I.S. EN ISO 8362-5:2016

Injection containers and accessories - Part 5: Freeze drying closures for injection vials (ISO 8362-5:2016)

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National Foreword

I.S. EN ISO 8362-5:2016 is the adopted Irish version of the European Document EN ISO 8362-5:2016, Injection containers and accessories - Part 5: Freeze drying closures for injection vials (ISO 8362-5:2016)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8362-5

March 2016

ICS 11.040.20

English Version

Injection containers and accessories - Part 5: Freeze drying closures for injection vials (ISO 8362-5:2016)

Récipients et accessoires pour produits injectables - Partie 5: Bouchons à lyophilisation pour flacons d'injection (ISO 8362-5:2016)

Injektionsbehältnisse und Zubehör - Teil 5: Gefriertrocknungsstopfen für Injektionsflaschen (ISO 8362-5:2016)

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European foreword

This document (EN ISO 8362-5:2016) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by September 2016.

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INTERNATIONAL STANDARD

ISO 8362-5

Third edition
2016-02-15

Injection containers and accessories —

Part 5: Freeze drying closures for injection vials

Récipients et accessoires pour produits injectables —

Partie 5: Bouchons à lyophilisation pour flacons d'injection

Reference number
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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.

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is 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 8362-5:2008), which has been technically revised to include a new 7.5.

ISO 8362 consists of the following parts, under the general title *Injection containers and accessories*:

— *Part 1: Injection vials made of glass tubing*

— *Part 2: Closures for injection vials*

— *Part 3: Aluminium caps for injection vials*

— *Part 4: Injection vials made of moulded glass*

— *Part 5: Freeze drying closures for injection vials*

— *Part 6: Caps made of aluminium-plastics combinations for injection vials*

— *Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*

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Introduction

Freeze drying closures are put on the top of a glass container after filling, leaving sufficient openings for the sublimation process and vacuum. At the end of the drying process, they are fully inserted into the glass container by hydraulic or mechanical means in the vacuum chamber.

Freeze drying closures can pick up water during shipping, storage, washing and steam sterilization cycles, which is difficult to remove in a subsequent drying cycle. As a consequence, the freeze drying closures are usually loaded with residual moisture. Depending upon the mass of the freeze-dried product and the degree of its sensitivity to water, the residual moisture in the rubber material can spoil the freeze-dried preparation during storage.

These specific process requirements have been addressed in this part of ISO 8362 by specifying relevant requirements for freeze drying closures, including a test method for determining residual moisture.

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, for instance, in ISO 15378 or in the GMP Guidelines as published by the European Community and the United States of America.

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Injection containers and accessories —

Part 5:
Freeze drying closures for injection vials

1 Scope

This part of ISO 8362 specifies the shape, dimensions, material, performance requirements and labelling for the type of closure for injection vials, as described in ISO 8362-1 and ISO 8362-4, which is used in connection with the freeze drying (or lyophilization) of drugs and biological materials.

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this part of ISO 8362 are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can be strongly affected by the nature and performance of the primary packaging.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 3302–1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 3302–2, *Rubber — Tolerances for products — Part 2: Geometrical tolerances*

ISO 7619–1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 8871–1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871–4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

ISO 8871–5:2005, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
freeze drying
lyophilization
drying process designed to remove solvents from both aqueous and non-aqueous systems by sublimation and desorption

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