

STN	Obaly na injekčné preparáty a príslušenstvo. Časť 2: Uzávery na injekcie (ISO 8362-2: 2015).	STN EN ISO 8362-2 70 3360
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Injection containers and accessories - Part 2: Closures for injection vials (ISO 8362-2:2015)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/16

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English Version

Injection containers and accessories - Part 2: Closures for injection vials (ISO 8362-2:2015)

Réipients et accessoires pour produits injectables -
Partie 2 : Bouchons pour flacons (ISO 8362-2:2015)

Injektionsbehältnisse und Zubehör - Teil 2: Stopfen für
Injektionsflaschen (ISO 8362-2:2015)

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Contents

Page

European foreword..... 3

European foreword

This document (EN ISO 8362-2:2015) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use".

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of an identical text or by endorsement, at the latest by April 2016, and conflicting national standards shall be withdrawn at the latest by April 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8362-2:2010.

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Endorsement notice

The text of ISO 8362-2:2015 has been approved by CEN as EN ISO 8362-2:2015 without any modification.

**Injection containers and
accessories —**

Part 2:
Closures for injection vials

*Réipients et accessoires pour produits injectables —
Partie 2: Bouchons pour flacons*





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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Classification	1
4 Shape and dimensions	2
5 Designation	3
6 Material	3
7 Performance requirements	4
7.1 General.....	4
7.2 Physical requirements.....	4
7.2.1 Hardness.....	4
7.2.2 Penetrability.....	4
7.2.3 Fragmentation.....	4
7.2.4 Self-sealing and aqueous solution tightness test.....	4
7.2.5 Dye solution tightness test.....	4
7.2.6 Resistance to ageing.....	4
7.3 Chemical requirements.....	4
7.4 Biological requirements.....	4
7.5 Particulate contamination requirements.....	5
8 Labelling	5
Bibliography	6

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 8362-2:2008), which has been technically revised in order to include a new 7.5 particulate contamination requirements.

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*

Introduction

The purpose of this part of ISO 8362 is to specify the shape and dimensions of, and the requirements for, elastomeric closures intended for pharmaceutical use. Closures made from elastomeric materials are suitable primary packaging materials for parenteral preparations. In order to provide seal integrity of the container closure systems, the dimensions of the elastomeric closures have to be compatible with the dimensions of the glass vials and the caps as specified in corresponding parts of ISO 8362.

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.

Injection containers and accessories —

Part 2: Closures for injection vials

1 Scope

This part of ISO 8362 specifies the shape, dimensions, material, performance requirements and labelling of closures for injection vials covered by ISO 8362-1 and ISO 8362-4.

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 strongly be 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 8362-1, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

ISO 8362-4, *Injection containers and accessories — Part 4: Injection vials made of moulded glass*

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN