

This is a preview of "ISO 8362-2:2015". [Click here to purchase the full version from the ANSI store.](#)

Third edition
2015-10-01

Injection containers and accessories —

Part 2: Closures for injection vials

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



Reference number
ISO 8362-2:2015(E)

© ISO 2015

This is a preview of "ISO 8362-2:2015". Click here to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

This is a preview of "ISO 8362-2:2015". Click here to purchase the full version from the ANSI store.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*

This is a preview of "ISO 8362-2:2015". [Click here to purchase the full version from the ANSI store.](#)

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.