

This is a preview of "ISO 8362-5:2008". [Click here to purchase the full version from the ANSI store.](#)

Second edition  
2008-10-15

---

---

## **Injection containers and accessories — Part 5: Freeze drying closures for injection vials**

*Réipients et accessoires pour produits injectables —*

*Partie 5: Bouchons à lyophilisation pour flacons d'injection*



Reference number  
ISO 8362-5:2008(E)

© ISO 2008

This is a preview of "ISO 8362-5:2008". [Click here to purchase the full version from the ANSI store.](#)

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2008

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 8362-5:2008". [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 Terms and definitions .....	2
4 Shape and dimensions .....	2
5 Designation .....	4
6 Material .....	4
7 Performance requirements.....	4
7.1 General .....	4
7.2 Physical requirements .....	4
7.3 Chemical requirements.....	5
7.4 Biological requirements.....	5
8 Labelling.....	5
Annex A (informative) Determination of moisture .....	6
Bibliography.....	9

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8362-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8362-5:1995) which has been technically revised in order to align this International Standard with ISO 8871-2, ISO 8871-4 and ISO 8871-5.

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*

This is a preview of "ISO 8362-5:2008". [Click here to purchase the full version from the ANSI store.](#)

## 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.