INTERNATIONAL STANDARD

ISO 8362-2

> Second edition 2008-10-15

Injection containers and accessories —

Part 2:

Closures for injection vials

Récipients et accessoires pour produits injectables — Partie 2: Bouchons pour flacons

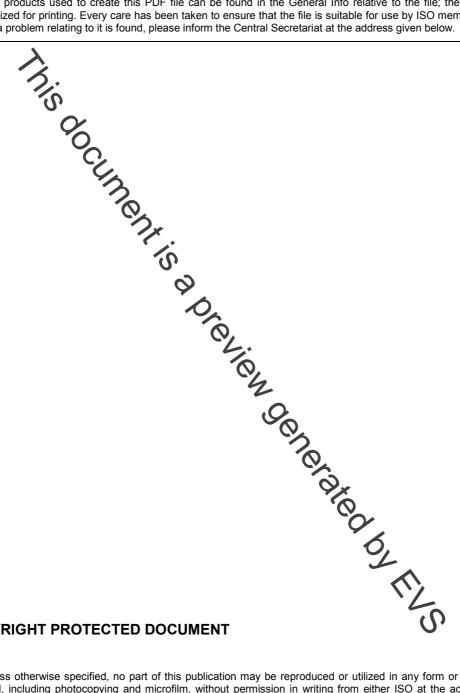


PDF disclaimer

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 Web www.iso.org

Published in Switzerland

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 8362-2 was prepared by Technica committee ISO/TC 76, Transfusion, infusion and injection equipment for medical and pharmaceutical use.

This second edition cancels and replaces the first edition (ISO 8362-2:1988) which has been technically revised in order to align this part with 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

© ISO 2008 – All rights reserved

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.

İ۷

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 \$2,8362 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 referenced documents are indispensable for the application of this document. 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: Geométrical 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 Classification

Closures for injection vials shall be classified as follows:

- Type A: closures for injection vials without no-pop/blow-back feature.
- Type B: closures for injection vials with no-pop/blow-back feature.

© ISO 2008 – All rights reserved