

This is a preview of "ISO 8871-5:2016". [Click here to purchase the full version from the ANSI store.](#)

Second edition
2016-10-15

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5: Functional requirements and testing

*Éléments en élastomère pour administration parentérale et dispositifs
à usage pharmaceutique —*

Partie 5: Exigences fonctionnelles et essais



Reference number
ISO 8871-5:2016(E)

© ISO 2016



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, 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 8871-5:2016". 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	1
4 Requirements	2
4.1 Penetrability	2
4.2 Fragmentation	2
4.3 Self-sealing and aqueous solution tightness	2
4.4 Aqueous solution tightness	2
5 Preparation of elastomeric closures for testing	2
5.1 Sampling	2
5.2 Cleaning	2
5.3 Sterilization	2
Annex A (normative) Test for penetrability	3
Annex B (normative) Test for fragmentation	4
Annex C (normative) Test for self-sealing and dye solution tightness	6
Annex D (normative) Test for dye solution tightness	8
Bibliography	10

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 second edition cancels and replaces the first edition (ISO 8871-5:2005), which has been technically revised.

ISO 8871 consists of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

- *Part 1: Extractables in aqueous autoclavates*
- *Part 2: Identification and characterization*
- *Part 3: Determination of released-particle count*
- *Part 4: Biological requirements and test methods*
- *Part 5: Functional requirements and testing*

This is a preview of "ISO 8871-5:2016". [Click here to purchase the full version from the ANSI store.](#)

Introduction

Elastomeric or rubber closures for pharmaceutical use are used in combination with vials and many times in conjunction with piercing devices. There are three functional parameters which are important to the piercing process. These are penetrability, fragmentation and self-sealing. The three functional tests described in this part of ISO 8871 can be used as a reference method for testing elastomeric closures that are pierced using injection needles made from metal. In addition, the aqueous solution tightness test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.