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Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles

Matériel de perfusion à usage médical —

Partie 6: Bouchons à lyophilisation pour flacons de perfusion



Reference number
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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 8536-6 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 8536-6:1995), which has been technically revised in order to align this part of ISO 8536 with ISO 8871-1, ISO 8871-4 and ISO 8871-5.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- *Part 1: Infusion glass bottles*
- *Part 2: Closures for infusion bottles*
- *Part 3: Aluminium caps for infusion bottles*
- *Part 4: Infusion sets for single use, gravity feed*
- *Part 5: Burette infusion sets for single use, gravity feed*
- *Part 6: Freeze drying closures for infusion bottles*
- *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*
- *Part 8: Infusion equipment for use with pressure infusion apparatus*
- *Part 9: Fluid lines for use with pressure infusion equipment*
- *Part 10: Accessories for fluid lines for use with pressure infusion equipment*
- *Part 11: Infusion filters for use with pressure infusion equipment*
- *Part 12: Check valves*

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Introduction

Freeze drying closures are put on the top of infusion bottles after filling, leaving sufficient openings for the sublimation process and vacuum. At the end of the drying process they can be 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 8536 by specifying relevant requirements for freeze drying closures including a test method on determination of 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 in, e.g., ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.