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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

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Foreword

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 8871-5:2016), which has been technically revised.

The main changes are as follows:

— "aqueous solution tightness" has been replaced with "dye solution tightness";

— definition for fragmentation has been clarified;

— definitions for "filling volume" and "nominal volume" have been added;

— information on the fragmentation test and new information on the fragment size have been added;

— "pore size of 0,5 µm" has been replaced with "pore size of maximum 5,0 µm" to be aligned with ISO 11608-3;

— clarification on the fragments counting measurements has been added;

— “dye solution tightness” from the self-sealing test has been removed;

— “solution of methylene blue” has been replaced by “appropriate dye solution” and new information on the dye solution;

— “methylene blue” has been replaced by “dye solution”;

— references to USP <788> and USP <1207> have been added.

A list of all parts in the ISO 8871 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The elastomeric parts specified in the ISO 8871 series are produced from rubber and thermoplastic elastomers (TPE). These pharmaceutical use closures 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 document can be used as a reference method for testing closures that are pierced using injection needles made from metal. In addition, the dye solution tightness test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.