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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

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

Partie 2: Identification et caractérisation

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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 second edition cancels and replaces the first edition (ISO 8871-2:2003), which has been technically revised. It also incorporates the Amendment ISO 8871-2:2003/Amd.1:2005. The main changes compared to the previous edition are as follows:

— expansion of the scope to include coated stoppers;

— addition of terms and definitions;

— addition of H.6 on the interpretation of results for ATR.

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. However, rubber is not a unique entity, since the composition of rubber materials can vary considerably. The base elastomer and the type of vulcanization have a major influence on the principle characteristics of an individual rubber material, as do additives such as fillers, softeners and pigments. These might have a significant effect on the overall properties. Polymer coatings or films are often applied to either entire or partial surface(s) of a rubber component to impart certain physical or chemical properties. The effectiveness, purity, stability and safe handling of a drug preparation can be affected adversely during manufacture, storage and administration if the rubber part used has not been properly selected and validated (approved).