FINAL DRAFT International Standard

ISO/FDIS 11040-7

Prefilled syringes —

Part 7: Packaging systems for sterilized subassembled syringes ready for filling

Seringues préremplies —

Partie 7: Systèmes d'emballage pour les seringues pré-assemblées stérilisées préremplissables

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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*.

This second edition cancels and replaces the first edition (ISO 11040-7:2015), which has been technically revised.

The main changes are as follows:

— Clause 3 was updated;

— former Annex B was removed because this specific method for determination of nest deflection was not commonly adopted by the industry;

— former Annex F was removed because the specific measurement method of determining the distance between the edge of the protective bag to rear end of the tub is not commonly adopted by the industry;

— a new Annex E was added to support automated processing;

— in Annex A, Annex B, the existing market ranges and tolerances have been revised and updated because fully automated and/or high-speed processes require smaller variations of certain tolerances;

— Table D.1 for bag sizes was revised. Bags and header bags are combined, and two main groups of bag sizes have been defined based on market experience and future expectations. They were entered into Table D.1 as column “recommended dimensions for 3” and 4” tub and “recommended dimensions for 4” tub”.

A list of all parts in the ISO 11040 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

At the start of prefilled syringe processing by the pharmaceutical industry, syringes made of tubing glass were delivered to the pharmaceutical companies in the form of a so called non-sterile “bulkware” only. The process steps such as washing, drying, inner lubrication, sealing the syringe with a closure system, sterilization, as well as filling, and closing were then performed by the pharmaceutical companies. Since their introduction to the market and with the emergence of specialized process equipment, sterilized subassembled syringes have more and more replaced the non-sterile “bulkware” to become the preferred approach for pre-filled syringe filling operations.

In the case of sterilized subassembled syringes ready for filling, responsibility for the aforementioned process steps relevant to the injectable product lies within the manufacturer of the subassembled syringes. Following the assembly of the needle shield on syringes with a staked needle or tip caps for the luer cone version, the subassembled syringes are placed into so called nests. The nests, in turn, are placed into a plastic tub. The syringes in the nest are protected by means of an insert liner and the tub itself is sealed by a sealing lid (which is currently, and so far, primarily achieved using a porous material). Thus, the tub properly sealed with the sealing lid represents the “sterile barrier system”. The sealed tub is then wrapped into a sealable bag and, thus, ready for sterilization, which is currently, and so far, primarily performed using ethylene oxide.

In this form, the sterilized subassembled syringes ready for filling are delivered to the pharmaceutical companies in a sterile condition where they are processed on suitable machines.

The packaging design and material maintain sterility and should be compatible with the process of the customer. The packaging characteristics, material, thickness, shape, and resistance to deformations among others are such that they maintain, up to the point of use, the integrity of the product and a validated barrier against particulate and bacterial contamination.

The objective is to support the development of standardized equipment with automatic debagging process steps for aseptic processing.