Titles and scopes for Draft Uganda Standards

a) DUS ISO 11040-4:2024, Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling

Scope

This document specifies materials, dimensions, quality, and performance requirements, as well as relevant test methods.

This document also specifies components that are part of the sterilized subassembled syringe ready for filling.

This document is applicable to

— tubing-glass barrels (single-chamber design) for injection preparations, and

— sterilized subassembled syringes ready for filling.

Glass barrels and sterilized subassembled syringes ready for filling in accordance with this document are intended for single use only.

Components to complete the subassembled syringe, such as plunger stopper and plunger rod, are outside the scope of this document.

b) DUS ISO 11040-5:2012, Prefilled syringes — Part 5: Plunger stoppers for injectables

Scope

This part of ISO 11040 specifies the shape, dimensions, material, performance requirements and labelling of plunger stoppers for glass barrels (single-chamber design) for injection preparations in accordance with ISO 11040-4.

Plunger stoppers specified in this part of ISO 11040 are intended for single use only.

This part of ISO 11040 is not applicable to barrier-coated plunger stoppers.

c) **DUS ISO 11040-6:2019, Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling**

Scope

This document specifies materials, dimensions, quality, and performance requirements, as well as test methods for polymer barrels and sterilized subassembled syringes ready for filling, intended for single use only.
This document also specifies those components that are part of the sterilized subassembled syringe ready for filling.
Polymer barrels and sterilized subassembled syringes ready for filling in accordance with this document are intended for single use only.
Components to complete the subassembled syringe, such as plunger and rod, are not specified in this document.
Prefilled syringes can be produced on dedicated and specifically designed processing equipment such as inline moulding and filling. This document does not apply but can be used also for such dedicated prefilled syringes.

d) **DUS ISO 11040-7:2024, Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling**

Scope

This document specifies a packaging system that is used to deliver sterilized subassembled syringes ready for filling in tubs and nests.
Downstream processes (processes after filling such as in house/outside transport, reprocessing) can result in specific requirements on the packaging system used to deliver sterilized subassembled syringes ready for filling. However, these requirements are not within the scope of this document.

e) **WDUS ISO 11040-8:2016, Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes**

Scope

This part of ISO 11040 is applicable to aseptically filled or terminally sterilized finished prefilled syringes (intended for single use only) based on ISO 11040-4 or ISO 11040-6, together with ISO 11040-5, for parenteral injection preparations with focus on quality, functional performance and safety requirements, as well as relevant test methods.

Finished prefilled syringes which have undergone an additional preparation step by the user before injection (e.g. diluent syringes that have been emptied for reconstitution and in which the reconstituted drug solution has been aspirated after reconstitution) are excluded from the scope of this part of ISO 11040.