

## SYNOPSIS

**Doc: MHD 12 (13021) IS/ISO 11040-4: 2015 - Prefilled syringes Part 4 Glass barrels for injectables and sterilized subassembled syringes ready for filling**

**a) Scope:**

This Indian Standard applies to:-

- tubing-glass barrels (single-chamber design) for injection preparations, and
- sterilized subassembled syringes ready for filling.

It specifies materials, dimensions, quality, and performance requirements, as well as relevant test methods. This Indian Standard also specifies those components that are part of the sterilized subassembled syringe ready for filling.

Glass barrels and sterilized subassembled syringes ready for filling are intended for single use only. Components to complete the subassembled syringe, such as plunger and rod, are not specified in this standard.

**b) Salient features of content:**

This Indian Standard applies tubing-glass barrels (single-chamber design) for injection preparations and sterilized subassembled syringes ready for filling.

To ensure safe use of an injectable product, prefilled syringes for single use are on the market for many years. Without a doubt, such prefilled syringes permit immediate injection of the product contained after relatively simple handling. These syringes can also be used in injectors with automated functions where further and particular requirements apply.

Based on the diameter of the prefilled syringes, appropriate components, such as rubber plungers, tip caps, needle shields, and other closure systems can also be standardized. In conjunction with the right sealing components, they offer a system for (parenteral) injectable use. The producers of filling machines can apply this standard to achieve a degree of standardization in the equipment of the machines.

**c) Type/grades/classes, if any covered in the standard: Nil.**

**d) Disclaimer (to be automatically provided by the program/software)**

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