Indian Standard IS 10258: PART 1: 2022 - A Standard for safe Injection

When single-use syringe to administer medications by injection your safety, durability, accuracy of dose, and proper size for compatibility with needle are key concerns. You want syringe which are safe for use, administer accurate dose, smooth for operation and compatible with needles. It's also crucial to select the correct single use syringe which can effect your **health and safety**.

This Indian standard which is identical to ISO standard ISO 70886-1 provides a sets requirements, design criteria for **single-use syringes**, primarily for use in medical and healthcare sectors to administer medications by injection. This standard ensures that these syringes meet quality, safety, and functionality requirements, helping healthcare providers deliver safe and accurate doses to patients.

Caution: Sterile single use syringes for manual operation specified in this standard are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.

Key features of the Standard

- 1. Single-Use Design: IS 10258 (Part-1) applies to syringes intended for one-time manual use only. After a single use, they should be discarded to prevent contamination and infection.
- 2. Material and Durability: The standard specifies the **materials and construction** of syringes to ensure they are safe, durable, and resistant to breakage or leakage during use.
- 3. Accuracy and Precision: Syringes are required to be **accurate and precise in delivering the intended dosage** by providing $\pm 1.5\%$ to $\pm 5\%$ tolerance on graduated capacity depending on expelled volume. This includes calibrating the syringe markings, which helps ensure patients receive correct dosages.
- 4. Sterility: Syringes must be **sterile** when packaged, and packaging must protect them from contamination until opened.
- 5. Compatibility with Needles: The design of the syringe must allow for compatibility with various needle types, ensuring ease of use across different medical needs.
- 6. Ease of Use: Syringes should be user-friendly, with clear graduations and easy-to-read markings for safe and efficient administration.
- 7. Design ensures that, it shall not be possible to easily withdraw the piston completely from the barrel and are free from leakage.
- 8. Testing and Quality Control: The standard outlines **testing procedures** that manufacturers must follow to ensure that syringes meet all requirements for Quantity of silicone, force required to operate the piston, leakage under compression, performance, safety, and reliability.

In summary, this standard ensures that healthcare providers and consumers can rely on single use syringes that are safe, accurate, effective, and suitable for use in a variety of medical situations.