

IS 10258 (2002): Sterile Hypodermic Syringes for Single Use outlines the specifications, requirements, and testing methods for sterile hypodermic syringes intended for single-use medical applications. This standard ensures syringes are safe, functional, and meet performance criteria to protect both patients and healthcare providers.

The standard applies to single-use syringes made of plastic or glass, used for administering medications or withdrawing fluids. Key requirements include:

1. **Design and Materials:** Syringes must be transparent to allow fluid visibility and made of non-toxic materials that are compatible with medicinal products.
2. **Sterility:** Each syringe must be sterile and individually packed to prevent contamination.
3. **Performance Requirements:** Syringes must be free from leakage under pressure, operate smoothly without jamming, and ensure accurate volume delivery. Piston movement should be consistent without unnecessary resistance.
4. **Graduation Marks:** Clear, indelible, and accurate graduations are essential for precise measurements.
5. **Needle Compatibility:** Syringes must allow secure fitting of hypodermic needles.
6. **Testing Methods:** The standard specifies various tests for sterility, volume accuracy, leakage, and material compatibility to ensure compliance.
7. **Labeling and Packaging:** Syringes must have clear labels indicating capacity, sterilization method, manufacturer details, and single-use status. Packaging must maintain sterility.

The document emphasizes that single-use syringes must not be reused to minimize infection risks. Compliance with IS 10258 helps maintain safety standards, accuracy, and quality in medical procedures.