



Draft Guidance on Quality Control of Sterile Single-Use Syringes

Document No: DRAP/GL/MD-002

Document History: First Version

Effective Date:00-00-0000

**Drug Regulatory Authority of Pakistan
Islamabad – Pakistan**

Table of Contents

1.	HISTORY	3
2.	APPLICATION - Guidelines for Regulators & Industry	3
3.	PURPOSE	3
4.	INTRODUCTION AND LEGAL PREAMBLE	3
5.	GLOSSARY & ACRONYMS.....	5
6.	KEY REGULATORY DIRECTIVES.....	8
7.	TESTING CATEGORIZATION FRAMEWORK.....	8
8.	TESTING CATEGORIZATION.....	9
9.	PRODUCT DEVELOPMENT & DESIGN VERIFICATION TESTING	9
10.	BATCH OR LOT RELEASE TESTING OR POST-MARKETING SURVEILLANCE.	11
11.	TYPE-SPECIFIC BATCH OR LOT RELEASE TESTING PARAMETERS	12

1. HISTORY

This is the first edition of these guidelines.

2. APPLICATION - Guidelines for Regulators & Industry

This guidance document applies to DRAP, Notified Laboratories for testing of syringes and the medical device stakeholders (enlistment or registration holders, local manufacturers and importers).

- i. **For Regulatory Authorities & Notified Laboratories:** DRAP, Medical Device Board (MDB), assessors/evaluators, inspectorates and notified quality control testing laboratories should adopt these harmonized testing standards as the official benchmark for inspections and post-marketing surveillance testing by Notified Laboratories.
- ii. **For Industry (Manufacturers, Importers & Enlistment/Registration Holders):** Industry stakeholders shall utilize this framework to align their Quality Management Systems, raw material procurement policies, internal Quality Control (QC) batch release protocols, and laboratory testing. Registration holders remain solely responsible for identifying and verifying all applicable standards for each registered product, ensuring material compliance with ISO 10993 biocompatibility requirements, submitting their formal list of applicable standards within sixty (60) days of issuance of these guidelines to all notified laboratories under intimation to MDB.

3. PURPOSE

This regulatory guidance document establishes internationally harmonized technical framework for the quality evaluation, design verification and quality control testing of sterile single-use syringes in Pakistan. Pursuant to decisions of the Medical Device Board (MDB) under Rule 68 of the Medical Devices Rules, 2017, the primary purpose of this guidance document is to standardize product development and lot or batch release testing performed by registration holders (local manufacturers and importers) and streamline post-market surveillance testing carried out by notified laboratories.

4. INTRODUCTION AND LEGAL PREAMBLE

The Drug Regulatory Authority of Pakistan (DRAP), in exercise of its statutory power and mandate provided under the DRAP Act, 2012, strives to safeguard public health by ensuring that

Therapeutic goods conform to international standards of quality, safety and performance. Due to reported surge of HIV cases associated with unsafe medical practices, particularly the alleged reuse of contaminated syringes and deficiencies in infection prevention and control mechanisms and in pursuance to the directives of the Prime Minister's Office, the Ministry of National Health Services, Regulations and Coordination constituted a Working Group to implement the directives. Accordingly, Medical Device Board in its 139th meeting held on 13th august, 2026 decided to implement decisions taken by the Working Group.

In line with DRAP's ongoing commitment to public health safety and regulatory harmonization, this document explicitly distinguishes between comprehensive Product Development (Design Verification and Qualification) testing and routine Batch Release (Lot Quality Control) testing. It further enforces mandatory policy directives, including complete restriction on manufacturing, import and sale of conventional syringes of 10 cc and below (except insulin syringe) and prohibition of use of non-medical grade raw materials. All local manufacturers, importers, and enlistment/registration holders are required to align their quality management systems (QMS), dossier submissions and testing protocols with these guidelines.

The primary objective of this guidance is to harmonize quality parameters, ensure compliance with internationally recognized standards including ISO, Pharmacopeial standards, etc and streamline both quality control (QC) lot release by registration holders and post-market surveillance testing performed by notified laboratories. This framework aims to eliminate healthcare-associated infections (HAIs) may be stemming from syringe re-use, protect healthcare workers from accidental needle-stick injuries (NSIs), and assurance that only biocompatible, medical-grade syringes of standard quality are distributed within the national healthcare system.

This regulatory guidance document operationalizes the decisions of the Medical Device Board (MDB) taken during its 139th meeting held on 13th August 2026, establishing a standardized technical framework for the quality evaluation, design verification and batch release testing of sterile single-use hypodermic syringes across Pakistan.

To ensure seamless conformity assessment during initial product development as well as during ongoing commercial manufacturing, this document delineates between:

- i. **Product Development & Design Verification Testing:** A comprehensive testing required

to establish design safety, material biocompatibility, shelf-life, and functional performance during product development or major design or material changes.

- ii. **Batch or Lot Release Testing and PMS Testing:** Batch or lot release testing performed on every production batch or lot by local manufacturers or in case of importer, by foreign principle or testing by public sector notified laboratories as part of post-marketing surveillance activities.

5. GLOSSARY & ACRONYMS

Acronyms

Acronym	Definition
AA	Accelerated Aging
AD	Auto-Disable
ASTM	American Society for Testing and Materials
BMR	Batch Manufacturing Record
BP	British Pharmacopoeia
BPR	Batch Processing Record
CoA	Certificate of Analysis
DHF	Design History File
DRAP	Drug Regulatory Authority of Pakistan
EO	Ethylene Oxide
FTIR	Fourier-Transform Infrared Spectroscopy
GLP	Good Laboratory Practice
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MDB	Medical Device Board
MSDS	Material Safety Data Sheet

NSI / NSIs	Needle-Stick Injury / Needle-Stick Injuries
Ph. Eur.	European Pharmacopoeia
PMS	Post-Marketing Surveillance
QC	Quality Control
QCL	Quality Control Laboratory
QMS	Quality Management System
USP	United States Pharmacopeia

GLOSSARY OF DEFINITIONS & REFERENCES

Terminology	Definitions	References
Auto-disable syringes for fixed-dose immunization (AD)	Sterile hypodermic syringes for single use that deliver fixed-doses, most have non-removable needles and all have a feature that blocks the syringe from being used a second time. This definition is limited to equipment for immunization services.	ISO 7886-3 WHO Guideline <i>WHO/HIS/SDS/2015.5</i>
Lot or Batch	One finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	21 CFR 801.3 (USFDA)
Biocompatibility	ability of a medical device or material to perform with an appropriate host response in a specific application	ISO 10993-1
Verification	confirmation by examination and provision of objective evidence that the specified	GHTF/SG3/N99-10 GHTF/SC/N4:2012 (Edition 2)

	requirements have been fulfilled.	
Quality Management System (QMS)	A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results.	ISO 9000:2015
Sterile Hypodermic syringes for single use with a reuse prevention feature (RUP)	Sterile Hypodermic syringes for single use that can measure flexible dosing amounts, have removable needles and a feature that blocks the syringe from being used a second time. The reuse prevention feature is activated following a single aspiration and injection in reuse prevention syringes Type A while in syringes Type B the mechanism allows multiple plunger aspirations if reconstitution of the medication or the vaccine is required , or if multiple drugs needs to be mixed in the same syringe before being injected to the patient. This definition is provided for syringes used in curative services where a broad range of injection procedures are performed.	ISO 7886-4 WHO Guideline <i>WHO/HIS/SDS/2015.5</i>
Sterile Hypodermic Syringes with a Sharps Injury Protection Feature (SIPs)	These are Sterile hypodermic syringes with a sharps injury protection feature (SIP). Some SIPs can also have a built-in reuse prevention feature. SIPs cover AD and RUP syringes that have an additional feature to prevent sharps injury, such as a means to contain the infected sharp after use.	ISO 23908 WHO Guideline <i>WHO/HIS/SDS/2015.5</i>

Sterile Barrier System	Minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use.	ISO 11607-1

6. KEY REGULATORY DIRECTIVES

- a) All enlistment and registration holders (local manufacturers and importers) of sterile single-use syringes shall ensure compliance with the relevant standards. Enlistment/registration holders remain solely responsible for identifying and complying with the complete set of specific technical standards applicable to each of their registered product.
- b) All enlistment and registration holders of syringes shall submit complete list of standards applicable to each of their enlisted/registered syringe to all notified laboratories under intimation to MDB within **sixty (60) days** of the issuance of this Notification.
- c) All enlistment/registration holders of syringes shall only use biocompatible and medical grade materials including packaging materials for imported as well as locally manufactured syringes for each component of the syringe i.e barrel, plunger, gasket/plunger seal, tip, needle, primary packaging materials, etc, strictly complying with all relevant standards i.e ISO 10993 series, ISO 11607, etc.
- d) Use of non-biocompatible or non-medical grade material or material not complying relevant standards for medical devices is strictly prohibited. All enlistment/registration holders shall keep complete record of documentation/certificates (mentioning compliance with all relevant biocompatibility standards i.e ISO 10993 series) of each lot of material procured by them.

7. TESTING CATEGORIZATION FRAMEWORK

Scope:

This document covers specifications for:

S. No.	Scope
1.	Sterile hypodermic syringes for single use —Syringes for manual use
2.	Sterile hypodermic syringes for single use —Syringes for use with power-driven syringe pumps
3.	Sterile hypodermic syringes for single use —Auto-disabled syringes for fixed-dose immunization
4.	Sterile hypodermic syringes for single use —Syringes with re-use prevention feature
5.	Sterile single-use syringes with Sharps injury protection feature
6.	Sterile single-use syringes, with or without needle, for insulin

8. TESTING CATEGORIZATION

The testing regime for sterile single-use hypodermic syringes is divided into two distinct operational tiers:

TESTING REGIME	
Tier 1: Product Development (Design Verification and Qualification)	Tier 2: Batch/ Lot Release or post-marketing surveillance testing.
Complete Biocompatibility Matrix	Physical & Visual Inspection
Full Characterization & FTIR Fingerprint	Material Verification (Identification)
Usability & Human Factors	Mechanical & Functional Performance
Sterilization Process Validation	Sterility & Endotoxin (LAL) Testing
Shelf-Life Stability (Accelerated Aging and/ or Real-Time)	Particulate Matter & Chemical Limits
Mechanical Override Force Limits	Sterile Barrier Packaging Integrity

9. PRODUCT DEVELOPMENT & DESIGN VERIFICATION TESTING

(For Design/Material/Process and Major Changes)

The applicable testing parameters be applied during device development to qualify the design, establish material safety profiles, validate manufacturing processes, and prove compliance with essential principles of safety and performance.

Parameters	Sub-parameters	Reference Standard	Documents
Material Characterization	material chemical profiling, polymer identification, additive quantification, and extractables/leachables assessment.	ISO 10993-17 ISO 10993-18 ISO 10993-19	Material Safety Data Sheet (MSDS), Raw Polymer Resin CoAs, FTIR reference spectrum.
Biocompatibility	Biological evaluation matrix: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Haemocompatibility, Pyrogenicity.	ISO 10993 Series (Parts 1, 4, 5, 10, 11)	Biocompatibility Test Report/certificates.
Sterilization Process Validation	Validation of EO gas concentration, temperature/humidity distribution, bioburden determination, half-cycle studies, or radiation dose mapping ($D_{\max}/D_{\min}$)	ISO 11135 (EO) ISO 11137 series (Radiation) ISO 13004 (Substantiation of selected sterilization dose) ISO 11737 series (microbiological methods) ISO 10993-7 (EO residuals)	Sterilization Validation Master Report
Shelf-Life & Stability Testing	Accelerated Aging (AA) and Real-time stability testing	ASTM F1980 ISO 11607-1 & 2	Stability study Reports (e.g., 3-year, 5-year, etc).
Usability & Human Factors	Evaluation of user interface, ergonomic activation of safety/auto-disable features, prevention of accidental	IEC 62366-1&2 ISO 23908	Human Factors Validation Study Report & Risk File (ISO 14971).

	needle-sticks, and clear user comprehension.		
Design Over-Force & Mechanical Limit Testing	Measuring maximum destructive mechanical limits: plunger override force, safety shield override force, Luer torque limits, and stress cracking.	ISO 7886-3 / ISO 7886-4 ISO 80369-7	Mechanical Destructive Evaluation & Stress Test Report.

10. BATCH OR LOT RELEASE TESTING OR POST-MARKETING SURVEILLANCE

(Quality Control testing of each batch or lot prior to Market Release or Post-Marketing Surveillance)

These tests be conducted on representative samples drawn from every finished product lot.

4.1 Common Testing Parameters (All Syringe Types)

Sr.	Testing Parameter	Test Description & Acceptance Criteria	Reference Standard
1	Physical & Visual Inspection	Visual inspection under 1.0 corrected vision: Free from cracks, flash, burrs, air bubbles, deformation, or foreign particulate matter.	ISO 7886-1
2	Material Identification	FTIR spectrum verification against the established reference spectrum of the declared polymer resin.	ISO 7886-1
3	Volumetric Accuracy & Graduation	Scale line clarity, indelible ink resistance to ethanol, and volumetric accuracy within $\pm 5\%$ of designated volume.	ISO 7886-1
4	Liquid Leakage Past Stopper	Conform to applicable requirement	ISO 7886-1
5	Air Ingress during Aspiration	Conform to applicable requirement	ISO 7886-1
6	Sterility	No microbial growth observed after incubation period.	USP <71> / Ph. Eur. 2.6.1
7	Bacterial Endotoxins	Endotoxin level as per limit.	USP <85> / Ph. Eur. 2.6.14
8	Particulate Matter	Sub-visible particulate limits: Meets USP limits for small-volume parenterals/medical	USP <788>

		devices.	
9	Physicochemical Tests	- pH (within ISO limits) - Extractable heavy metals (within ISO limits) - UV Absorbance, Residue on Evaporation, Reducing Substances (Within applicable pharmacopeial limits) - Silicone oil quantity (where applicable)	ISO 7886-1 ISO 7886-1 Applicable USP/BP/Ph. Monographs Eur. ISO 7886-1
10	EO Residuals (where applicable)	Within applicable ISO limits	ISO 10993-7
11	Sterile Barrier Integrity	Package seal strength (peel test), visual seal integrity, and dye penetration / bubble emission leak testing.	ASTM F88 ASTM F1886 ASTM F1929 ASTM F2096
12	Attached Needle Testing (if integrated)	Needle pull-off force, flow rate, sharpness/penetration force, and freedom from burrs.	ISO 7864 ISO 9626

11. TYPE-SPECIFIC BATCH OR LOT RELEASE TESTING PARAMETERS

In addition to common batch release parameters, specific functional mechanism tests be executed depending on device classification:

Type Specific Batch Release Matrix		
Syringe Category	Specific Test	Standard
Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	All tests mentioned in the standard	ISO 7886-1
Power-Driven Pump Syringes	All tests mentioned in the standard	ISO 7886-2
Auto-Disable (Fixed Dose)	All tests mentioned in the standard	ISO 7886-3

syringes		
Syringes with Re-use Prevention Feature	All tests mentioned in the standard	ISO 7886-4
Syringes with Sharps Injury Protection mechanism	All tests mentioned in the standard	ISO 23908
Insulin Syringes	All tests mentioned in the standard	ISO 8537

This guidance document has been prepared to assure the safety and performance of syringes manufactured and imported in Pakistan to safeguard public health by ensuring that syringes conform to international standards of quality, safety and performances. Effective quality management system, appropriate testing, validation, post-marketing surveillance and continuous compliance are important to maintaining product quality. This guidance is intended to promote a consistent approach for control of syringe quality to contribute in improving patient safety.

DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister's National Health Complex, Park Road, Islamabad, Pakistan
Email: babar.khan@dra.gov.pk Phone: 92-51-9255965
www.dra.gov.pk