



Test Methods for Prefilled Syringes

Horst Koller, CEO, HK Packaging Consulting GmbH

Roman Mathaes PhD, Senior Group Leader, Lonza Drug Product Services

• References



EUROPEAN PHARMACOPOEIA COMMISSION



International Organization for Standardization
 Organisation internationale de normalisation
 Международная организация по стандартизации [1]

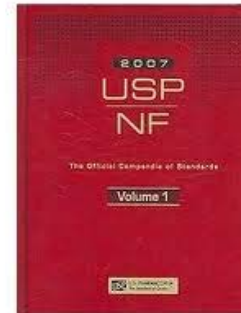


International Organization for Standardization
 English language logo of the ISO



List of members

Formation	23 February 1947
Type	NGO
Purpose/focus	International standardization
Headquarters	Geneva, Switzerland
Membership	162 members [2]
Official languages	English, French and Russian
Website	www.iso.org [3]



• References

Type	No.	Name	PFS Relevant Content
ISO	7886-1	Sterile hypodermic syringes for single use – part 1: syringes for manual use	Residual volume; side load, graduations, axial compression, piston vacuum
ISO	7886-2	Sterile hypodermic syringes for single use – part 1: syringes for use with power driven syringe pumps	Dose accuracy, dose consistency
ISO	11040-4	Prefilled syringes – part 4: glass barrels for injectables and sterilized subassembled syringes ready for filling	Cone and flange breakage, particulate matter, endotoxin, closure tightness, closure removal, siliconization performance, dimensions
ISO	11040-6	Prefilled syringes – part 6: plastic barrels for injectables (and sterilized subassembled syringes ready for filling)	Cone and flange breakage, particulate matter, endotoxin, closure tightness, closure removal, siliconization performance, dimensions
ISO	11040-7	Prefilled syringes – part 7: Packaging systems for sterilized subassembled syringes ready for filling	Tubs, nests materials , dimensiosn, bag configurations, glass and polymer syringes
ISO	11040-8	Prefilled syringes – part 8: Requirements and test methods for finished prefilled syringes	System, physical and pharmaceutical characterization

• References

Type	No.	Name	PFS Relevant Content
ISO	11040-5	Prefilled syringes – part 5: plunger stopper for injectables	Shapes and dimensions, requirements (non coated)
ISO	11608-1	Needle based injection system for medical use – requirement and test methods part 1: needle based injection system	Requirements for pens, autoinjectors, on-body delivery systems
ISO	11608-2	Needle based injection system for medical use – requirement and test methods part 2: needles	Pen needles, others
ISO	11608-3	Needle based injection system for medical use – requirement and test methods part 3: finished containers	Tests for combined system
ISO	11608-5	Needle based injection system for medical use – requirement and test methods part 5: automated functions	Tests for combined system

• References

Type	No.	Name	PFS Relevant Content
ISO	7864	Sterile hypodermic needles for single use	Length, inner and outer diameter
ISO	80369-7	Small-bore connectors for liquids and gases in healthcare applications – part 7 connectors with 6% (Luer) taper for intravascular or hypodermic applications	Substitute for ISO 594 (Dimensions)
ISO	80369-20	Small-bore connectors for liquids and gases in healthcare applications – part 20 common test methods	Substitute for ISO 594 (Testing)

• References

Type	No.	Name	Information
USP	660	Containers Glass	Physical, chemical testing
USP	661.1*	Plastic materials of Construction	Physical, chemical testing,
USP	661.2*	Plastic Packaging Systems for Pharmaceutical Use	Physical, chemical testing, functional
USP	671	Containers Performance Testing	General testing
EP	3.1.8	Silicone oil used as lubricant	Usually used for glass and Polymer PFS and needle siliconization
EP (planned)	3.1.16	“COP and additives for container for parenteral and ophthalmic preparations”	Chemical testing, Identification
EP (planned)	3.1.17	“COC and additives for container for parenteral and ophthalmic preparations”	Chemical testing, Identification

* Implementation date May 2020 [under discussion]

• References

Type	No.	Name	Information
EP	3.2.8	Sterile Single Use Plastic Syringe	Chemical testing, Identification (Silicon oil limit)
EP (planned)	3.2.10	“Prefilled Syringes” COP / COC / PP	Chemical testing, Identification
JP	7.01	Glass containers for injections	General testing
JP	7.02	Plastic container for injections	General testing

Thank You !
QUESTIONS ?