

Guidance for Industry and FDA Staff

Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4

DRAFT GUIDANCE

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Food and Drug Administration
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Office of Combination Products in the Office of the Commissioner**

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Guidance for Industry and FDA Staff¹

Glass Syringes for Delivering Drug and Biological Products: Technical Recommendations to Supplement International Organization for Standardization (ISO) Standard 11040-4 (Draft)

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I. INTRODUCTION

FDA has recognized International Organization for Standardization (ISO) Standard 11040-4 for glass syringes that are intended to deliver drugs or biological products.² FDA has become aware of adverse events and product quality events related to connectivity problems when certain glass syringes are used with connecting devices, including connecting devices that conform to the FDA-recognized ISO 594-2 standard. "Connecting devices" include needles, needless luer connectors, adapters, and transfer units. Accordingly, FDA has determined that, for glass syringes, demonstrating conformity with the ISO 11040-4 standard alone does not ensure that the glass syringe can be properly connected to connecting devices. Therefore, this guidance identifies additional, technical information that should be submitted by sponsors who seek to rely on conformity to ISO 11040-4 for a glass syringe product.

The recommendations provided in this guidance document are applicable to the sponsor of an IDE, HDE, 510(k), or PMA for the following glass syringe products, and to the sponsor of an IND, BLA, NDA, or ANDA³ for a drug or biological product that is delivered with such a glass syringe product:

¹ This guidance was prepared by the Office of Combination Products in the Office of the Commissioner in conjunction with the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

² The FDA database of currently recognized versions of these ISO documents is accessible at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. This website identifies the currently recognized version and any addition guidance information.

³ These submission abbreviations refer to the following: IDE is an investigational device exemption; HDE is a humanitarian device exemption; 510(k) is a premarket notification; PMA is a premarket application; IND is an investigational new drug application; BLA is a biologics license application; NDA is a new drug application; and ANDA is an abbreviated new drug application.

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1. Needleless glass syringes prefilled with a drug or a biological product;
2. Empty glass syringes co-packaged with a drug or a biological product and/or connecting device, and
3. Empty glass syringes intended for use with marketed drugs or biological products.

This document focuses mainly on connectivity issues between the glass syringe and connecting device(s). It should be used in conjunction with the following FDA guidance documents: “*Draft Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet and Related Injectors Intended for use with Drugs and Biological Products*” (when finalized);⁴ “*Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics*,”⁵ and “*Guidance on the Content of 510(k) Submissions for Piston Syringes*,”⁶ as appropriate.

FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, these guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

III. BACKGROUND

Glass syringes intended to deliver drugs or biologics to a patient are a critical aspect of patient care. Typically, glass syringes are intended to connect to other devices such as needles for injection, intravenous (IV) line luer connections, needleless luer locks, adapters, and transfer units.

In November 2010 and May 2011, FDA issued Stakeholder or Safety Alerts advising of adverse events and product quality events related to connectivity problems when certain prefilled needleless glass syringes are used with some needleless IV access systems.^{7,8} These events could cause a delay in the administration of medication in emergency situations, and potentially result in serious harm to patients. The reported events

⁴ *Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet and Related Injectors Intended for Use with Drugs and Biological Products* (June 2013), available at:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM147095.pdf>

⁵ *Guidance for Industry, Container Closure systems for Packaging Human Drugs and Biologics* (May 1999), available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070551.pdf>.

⁶ *Guidance on the Content of 510(k) submissions for Piston Syringes* (April 1993), available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081324.htm>

⁷ *Needleless Pre-filled Glass Syringes: Stakeholder Advisory - Compatibility Problems with Needleless Intravenous Access Systems*; <https://www.fda.gov/drugs/drug-safety-and-availability/letter-stakeholders-update-certain-needleless-pre-filled-glass-syringes>

⁸ FDA Drug Safety Communication: *Connection problems involving certain needleless pre-filled glass syringes containing adenosine and amiodarone*; <http://www.fda.gov/Drugs/DrugSafety/ucm254215.htm>

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occurred upon attempted connections between the needleless glass syringe and certain needles or needleless pin activated luer connectors. These events included syringe tips breaking upon injection, needles detaching during injection, and syringes breaking or jamming the IV lines or other patient use lines.

Because of these glass syringe connection events and associated adverse events, FDA has recognized that demonstrating conformity to the ISO 11040-4 standard alone does not ensure that the glass syringes can be properly connected to connecting devices. Therefore, sponsors who seek to rely on conformity to the ISO 11040-4 standard in submissions for glass syringe products should also submit information from supplemental tests to demonstrate that the glass syringe can be properly connected to connecting devices. The purpose of this guidance document is to identify the supplemental tests that should be performed, and to recommend possible design modifications, to ensure that glass syringes are properly connected to connecting devices.

IV. DISCUSSION

A. What are the key ISO standards related to glass syringes and connecting devices and why is conformity to these standards not sufficient?

There are two key ISO standards related to glass syringes and connecting devices, ISO 11040-4 (Prefilled Syringes - Part 4: Glass barrels for injectables and ready-to-use prefillable syringes) and ISO 594-2 (Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings). Both standards are currently recognized by FDA.⁹ FDA expects all glass syringes intended to deliver drug or biological products that meet the ISO 11040-4 standard have, as applicable, design features to connect to connecting devices.

Prior to the occurrence of the adverse events described above, the general assumption was that glass syringes that conform to the ISO 11040-4 standard would ensure connectivity (interoperability) with any connecting devices that conform to the ISO 594-2 standard. However, the glass syringe standard, ISO 11040-4, has certain undefined key dimensions. For example, the standard lacks dimensions for the glass syringe nozzle internal diameter, thickness of nozzle wall, and barrel neck curvature. In contrast, the standard for the connecting devices, ISO 594-2, has specified dimensions in these areas.¹⁰ Therefore, it is possible that a glass syringe that meets the ISO 11040-4 standard may not properly connect to a device that conforms to the ISO 594-2 standard.¹¹ More

⁹ See footnote 2.

¹⁰ Plastic syringe ISO standard 7886 has internal dimensions that are compatible with the ISO 594-2 standard.

¹¹ For example, assume a given pin-piercing needleless connector complies with ISO 594-2. FDA has received reports that when such a pin-piercing needleless connector is mated with a glass syringe, the pin could jam and break the glass syringe when threaded together.

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specifically, conformance to ISO 11040-4 alone cannot ensure connectivity to connecting devices without breakage or other product performance failure as described above.

B. What other glass syringe dimensions are critical in addition to those specified in ISO 11040-4?

Generally, the dimensions for glass syringes that are not specified in ISO 11040-4 but that are important for the connection to connecting devices include the following:

1. Syringe inner and outer diameter,
2. Height of the nozzle for a glass barrel syringe intended to connect to a luer lock fitting,
3. Thickness of nozzle wall,
4. Barrel neck curvature, and
5. Dimensions to accommodate luer locks with a center pin piercing element.

V. WHAT IS FDA RECOMMENDING?

FDA recommends that sponsors submit data to demonstrate that their glass syringe has connectivity (interoperability) to connecting devices to ensure proper delivery of the drug or biological product. To achieve this, the glass syringe design and validation data should include information beyond the information needed to conform to ISO 11040-4. Recommended design or re-design options are listed in subsection A. The general types of data and information the Agency recommends in the premarket or investigational submission for glass syringes are listed in subsection B.

A. What are the recommended design or re-design options?

1. Use bonded or staked needle with appropriate sharps protection feature for subcutaneous or intramuscular injections.
2. Design the glass syringe with internal dimensions that ensure connectivity to connecting devices. (Although several designs may be possible, one example might be to enlarge the internal diameter of the glass syringe nozzle to accommodate pin-piercing design of needleless connectors.)
3. Develop designs for dedicated dual connections between the glass syringe and connecting devices. For example, the designs may consist of a connecting device with dual connections: one end for the glass-syringe and one end for the connecting device with which it may be used. These dedicated connections may be appropriate for co-packaging with a prefilled syringe.

B. What data and information does the Agency recommend be included in premarket submissions?

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1. Data and information demonstrating dimensional conformance to relevant FDA-recognized ISO standards to ensure compatibility with connecting devices:
 - a. ISO 11040-4: applies to glass barrels of glass syringes
 - b. ISO 594-2: applies to luer lock

When a glass syringe is used with an injector or other device, additional ISO standards may apply. These are listed in the Section V.C of this document.

2. For dimensional elements that are not addressed in the relevant ISO standards, but are otherwise critical for connectivity, the submission should include data and information demonstrating how design features address these elements. (See Section IV.A, above.) These data should include design verification and validation testing to ensure that the product can be used as intended. For example,
 - a. If the glass syringe design is modified to add new internal diameter dimensions specifications to ensure connectivity, then design validation and functional performance data should be included in the submission.
 - b. If changes are made to a part of a delivery system, then any submission regarding those changes should contain or reference all necessary data for the entire system. For example, a newly designed syringe tip adapter should have design validation and functional performance data to show proper interoperability with connecting devices. If the glass barrel is modified to hold the adapter, similar data should be submitted.
3. Functional Performance of Syringe: The ISO standards include recommendations for the performance of glass syringes as stand-alone products, but do not include recommendations for the performance of these syringes when connected to connecting devices. Data to show syringe performance and proper connectivity in this context include, but are not limited to, the following:
 - a. Seal Integrity Testing to assess liquid leakage, air ingress, and dye ingress once the syringe is filled with the drug or biological product as intended and when connected to a connecting device. The sensitivity of the selected test method should be specified and validated. System integrity should be demonstrated throughout the product shelf-life.
 - b. Glide Force
 - c. Break Force
 - d. Separation Force

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- e. Unscrewing Torque
 - f. Ease of Assembly
 - g. Resistance to Overriding
 - h. Stress Cracking
 - i. Validation of Graduation Markings
 - j. Dead Space
 - k. Coring Needle Test
 - l. Performance testing of an anti-needlestick mechanism with a glass syringe to demonstrate safety and effectiveness as recommended in FDA's guidance document, "*Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features.*"¹²
 - m. Connectivity to other devices necessary for use (e.g., needles, adapters, transfer systems, extension tubing, luer connectors, and sharps prevention features).
 - n. Injection force necessary to depress the plunger and eject the drug contents
 - o. Tip cap removal force
 - p. Piston seal blowback (ability of syringe with tip cap to hold a certain pressure on the piston)
4. Biocompatibility: Data and information demonstrating conformance to ISO 10993 with a combination of physicochemical, analytical, and biological testing as appropriate.
 5. Sterilization: Data and information demonstrating consistency, as appropriate, with FDA's guidance document, "*Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products,*"¹³ and with FDA-recognized ISO 11135 (Ethylene oxide Sterilization) and ISO 11137 (Radiation).¹⁴ For prefilled glass syringes, additional methods may be used to demonstrate sterility assurance of the combination product, as appropriate. In cases when terminal sterilization of the combination product may not be feasible, sterility assurance should include a demonstration of syringe component sterilization and the aseptic filling with the drug/biologic and/or diluent.

¹² *Guidance for Industry and FDA Staff - Medical Devices with Sharps Injury Prevention Features* (August 2005), available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071663.htm> ¹³

Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (November 1994), available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072171.pdf>

¹⁴ See footnote 2. For further recommendations on device sterility, you may consult FDA's guidance document, *Guidance for Industry and FDA Staff: Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (January 2016), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>

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6. Human Factors - Data and information from human factors testing. Human factors testing and risk analysis of use errors help ensure proper design of the user interface. Sponsors must meet design control requirements in 21 CFR Part 820, including establishing and maintaining procedures to ensure that the design requirements relating to the device address the intended use of the device, including the needs of the user and patient.¹⁵ Analysis of use error is particularly important when products are re-designed to mitigate connectivity and compatibility issues such as those described in this document. A hazard analysis should be submitted that, among other things, identifies any use-related risks of the product, including medication errors. For additional information, see FDA's guidance on human factors.¹⁶

7. Performance testing for prefilled glass syringes or co-packages: Prefilled glass syringes and co-packages of drug/biological products with empty glass syringes are combination products (as described below is Section V.A). The sponsor should submit data and information from performance testing on the final assembled product filled with the drug or biologic product. Performance testing should take into consideration the viscosity of the drug or biological product, resistance created by the fluid contact path, and the back pressure/shear force generated during the injection as to whether it could alter the characteristics, functionality, safety, and/or effectiveness of the drug/biologic. In addition, testing should evaluate whether the back pressure generated during the injection could detach the needle from the syringe.

8. Other testing for prefilled glass syringes and co-packages: There may be elements that impact the safety and effectiveness of prefilled glass syringes and glass syringes that are co-packaged with a drug or a biological product that are unique to the specific drug/biological product. Whether a sponsor should submit data and information to address these product-specific elements will be assessed on a case by case basis. As an example, dual-chamber prefilled glass syringes are combination products containing lyophilized drug/biologic and diluent in separate chambers of the device. For this type of syringe, the following specifics should be addressed:
 - a. The prefilled syringe assembly which includes lyophilization of drug/biologic and subsequent aseptic filling with the diluent;
 - b. Assurance of system integrity to exclude drug/biologic-diluent contact during storage and shipment;

¹⁵ 21 CFR 820.30(c).

¹⁶ *Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (February 2016), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>. See also FDA's "Human Factors and Medical Devices" webpage, available at: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices>.

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- c. Drug/biologic reconstitution process before the syringe is connected to an administration device; and
 - d. Comprehensive drug/biologic-device compatibility assessment.
9. The submission to FDA describing each test performed should include a summary that explains the objective, acceptance criteria, sample size (statistically significant number with justification), method, results, discussion, and discussion of deviations.

FDA notes that the above items focus specifically on the glass syringe connectivity aspects of development. For additional recommendations for product development, you should refer (as appropriate) to the following FDA guidance documents: *Draft Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet and Related Injectors Intended for use with Drugs and Biological Products*;¹⁷ *Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics*;¹⁸ and *Guidance on the Content of 510(k) Submissions for Piston Syringes*.¹⁹

IV. ADDITIONAL INFORMATION

A. What is the regulatory pathway for submitting a marketing application for a prefilled glass syringe or a co-package of glass syringe with a drug or a biological product?

Glass syringes prefilled with drug or biological products are combination products under 21 CFR Part 3. Specifically, they meet the combination product definition under 21 CFR 3.2(e)(1). A co-package of a drug or biological product and an empty glass syringe (“co-packaged glass syringe”) also meets the definition of a combination product under 21 CFR 3.2(e)(2).

Combination products are assigned to a lead center based on the primary mode of action as defined in 21 CFR 3.2(m). For a prefilled or co-packaged glass syringe with a drug or biological primary mode of action (PMOA), CDER (Center for Drug Evaluation and Research) or CBER (Center for Biologics and Research) is the lead center. Applications requesting approval to conduct clinical trials or to market these products are generally submitted under an IND, BLA, NDA, or ANDA. The device information may be included in these submissions or it may be provided in a device master file.²⁰ There are

¹⁷ See footnote 4.

¹⁸ See footnote 5.

¹⁹ See footnote 6.

²⁰ See FDA’s “Introduction to Master Files for Devices (MAFs),” available at: <https://www.fda.gov/medical-devices/premarket-approval-pma/master-files>

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also general use empty (unfilled) syringes for injection of unidentified drug/biological products. These are marketed under a device premarket notification, 510(k).²¹

Regardless of submission type, when a master file is used, the master file submitter should provide a letter to the application holder to authorize master file cross-reference. FDA does not approve the master file; FDA regulatory action is on the investigational or marketing application. FDA will, however, notify the master file holder of any deficiencies related to the master file only. As with other medical products, the overall application holder is responsible for resolution of any product specific deficiencies. To that end, for applicants with prefilled or co-packaged glass syringes, FDA recommends that the applicant work closely with their manufacturers and suppliers to address the issues described in this document.

B. Does FDA recommend early interactions with the Agency?

We recommend that you have early discussions with FDA if you are developing a glass syringe or injector that uses the type of glass syringe described in this document. If you are uncertain about the type of technical and scientific information that may be appropriate or necessary for your submission, FDA encourages you to request a joint meeting with the involved FDA centers (CBER/CDER and CDRH) and appropriate product representatives (the applicant, the device manufacturer if not the applicant, etc.). In these meetings we recommend that you outline your proposed steps to ensure the connectivity of the glass syringe when connected to connecting devices. For a glass syringe prefilled or otherwise intended for use with a specific drug or biological product, drug/biologic-specific information is available from the CDER or CBER review division. Additional general device information is available from the CDRH, General Hospital Devices Branch at 301-796-2585. For combination product policy, procedures, and regulatory questions you may contact the Office of Combination Products by email to combination@fda.gov. General guidance information and links to the different center documents are accessible at <https://www.fda.gov/combination-products>.

C. What are the related guidance and FDA recognized standards?

Many of the concepts described in this document are detailed further in other agency documents. The following FDA guidance and informational documents may be useful when developing a glass syringe.

- *Guidance for Industry and FDA Staff - Technical Considerations for Pen, Jet and Related Injectors Intended for Use with Drugs and Biological Products*, (June 2013), available at:
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM147095.pdf>

²¹ Empty glass syringes marketed in isolation for general use are under regulated under 21 CFR 880.5860. See also *Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes* (April 1993), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081324.htm>.

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- *Guidance for Industry and FDA Staff - Medical Devices with Sharps Injury Prevention Features (August 2005)*, available at:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-sharps-injury-prevention-features-guidance-industry-and-fda-staff>
 - *Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design (February 2016)*, available at:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>
 - *Guidance for Industry - Container Closure Systems for Packaging Human Drugs and Biologics (May 1999)*, available at:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-packaging-human-drugs-and-biologics>, and the associated *Guidance for Industry - Container Closure Systems for Packaging Human Drugs and Biologics, Questions and Answers (May 2002)*, available at:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-packaging-human-drugs-and-biologics-questions-and-answers>
 - Related ISO standards are listed at the FDA webpage on recognition and use of consensus standards;
<https://www.fda.gov/regulatory-information/standards>. This website includes information describing how to access to the following standards.
 - a. ISO 594-1: Conical Fittings with 6% (Lure) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Specifications
 - b. ISO 594-2: Conical Fittings with 6% (Lure) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: Lock Fittings
 - c. ISO 720: 1985: Glass - Hydrolytic Resistance of Glass Grains a 121° C - Method of Test and Classification
 - d. ISO 7864: Sterile Hypodermic Needles for Single Use
 - e. ISO 7886-1: Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use
 - f. ISO 7886-2: First Edition 1996-05-15: Sterile Hypodermic syringes for Syringes for Single Use - Part 2: Syringes for use with power driven syringe pumps
 - g. ISO 7886-3: First Edition 1996-05-15: Sterile Hypodermic syringes for Syringes for Single Use - Part 3: Auto-disposable syringes for fixed-dose immunization
 - h. ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
 - i. ISO 11040-4: Prefilled Syringes Part 4: Glass Barrel for Injectables
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- j. ISO 11135-1: 2007: Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- k. ISO 11137-1: 2006(R) 2010: Sterilization of Health Care Products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- l. ISO 11137-2: 2006 Sterilization of Health Care Products - Radiation - Part 2: Establishing the sterilization dose
- m. ISO 11137-3: 2006(R) 2010 Sterilization of Health Care Products - Radiation - Part 3: Guidance of dosimetric aspects
- n. ISO 11608-1: Pen-Injectors for Medical Use - Part 1: Pen-injectors - Requirements and test methods
- o. ISO 11608-2: Pen-Injectors for Medical Use - Part 2: Needles - Requirements and test methods
- p. ISO 11608-3: Pen-Injectors for Medical Use - Part 3: Finished Cartridge - Requirements and test methods
- q. ISO 11608-4: Pen-Injectors for Medical Use - Part 4: Requirements and test methods for electronic and electromechanical pen-injector.