ALK LIFE SCIENCE SOLUTIONS™

Our Vials Adhere to 11 USP Guidelines

The United States Pharmacopeia (USP) is an independent, scientific nonprofit organization that develops quality standards, used globally, for the production of medicines, dietary supplements and foods. ALK Life Science Solutions™ manufactures clear and amber sterile empty vials (SEVs) that adhere to a total of **11 applicable USP Chapters** and to the Food and Drug Administration's Current Good Manufacturing Practices.

USP <71>

Sterility Testing[1]: Tests for sterilization validation and lot release for medical devices, pharmaceutical products and radiopharmaceuticals. Procedures include membrane filtration (pharmaceutical products), direct transfer (medical devices) and product flush (products with hollow tube construction).

ALK Life Science Solutions SEVs are verified for sterility in accordance with parenteral administration by the use of membrane filtration methods described in USP <71>.

USP <85>

Bacterial Endotoxins Test[2]: Detects endotoxin levels in medical devices and ensures that medical devices are free of dangerous endotoxins that could be harmful to patients. This test applies to any product that contacts intravascular, intrathecal, intraocular or intralymphatic patient systems.

Gray stoppers used to plug ALK Life Science Solutions SEVs are verified for endotoxin levels and validated against USP <85>. The finished product is also tested for bacterial endotoxins.

USP <87>

Biological Reactivity *In Vitro*[3]: Determines the biological reactivity of mammalian cells following contact with elastomeric plastics and other polymeric materials.

ALK Life Science Solutions stoppers are qualified to verify there is no biological reactivity of the elastomeric (rubber-like) material.

USP <381>

Elastomeric Closures for Injections[4]: Defines how pharmaceutical packaging/delivery system should be proven suitable for its intended use. The purpose of this chapter is to provide baseline chemical and biological reactivity requirements for the selection of elastomeric injectable packaging/delivery system components.

Our stoppers are tested and qualified in accordance with <381> and <87/88> requirements. Stoppers are composed of chlorobutyl elastomer, can be punctured up to 10 times and do not contain any natural rubber.

USP <660>

Containers – Glass for Pharmaceutical Use[5]: Outlines specific qualification tests based on the type of glass used for containers that come into direct contact with the pharmaceutical formulation.

ALK Life Science Solutions SEVs are composed of USP **Type 1 borosilicate glass** in a variety of sizes. Other benefits of this type of glass include resistance to thermal shocks and the ability to be sterilized before or after filling.

USP <797>

Pharmaceutical Compounding – Sterile Preparations[6]: Governs the sterile preparation of compounded pharmaceuticals, including both hazardous and nonhazardous drugs, to ensure patient safety and reduce risks associated with compounding pharmaceuticals, including contamination, infection and incorrect dosage. Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging or otherwise altering a drug product or bulk drug substance to create a sterile medication.

ALK Life Science Solutions provides endotoxin-free components and issues certificates of analysis, ensuring vials are manufactured in an FDA regulated facility.

USP <825>

Radiopharmaceuticals[7]: Provides uniform minimum standards for the preparation, compounding, dispensing and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals. This guideline describes facilities and engineering controls, personnel training and qualifications and procedural standards for processing radiopharmaceuticals in nuclear pharmacies, nuclear medicine areas in hospitals and clinics and other healthcare settings that utilize radiopharmaceuticals.

ALK Life Science Solutions has a comprehensive report about how USP <825> is applied in our manufacturing process. For more information, please visit sterilevialsolutions.com/our-process.

USP <1207>

Container Closure Integrity Testing (CCIT)[8]: Evaluates container closure systems to maintain a sterile barrier against potential contaminants. This USP is applicable to primary package components, or those that come into direct contact with the product (i.e., glass vial or syringe), and secondary package components, or those that are critical to ensuring correct package assembly (i.e., aluminum cap over a rubber stopper).

ALK Life Science Solutions' finished sterile empty vial configurations meet the requirements of USP <1207>.

USP <1231>

Water for Pharmaceutical and Analytical Purposes[9]: Process to control the quality of various grades of water used for pharmaceutical purposes.

ALK Life Science Solutions manufactures WFI (water for injection) bulk waters, which are produced on-site at our facility, for processing of vials.

USP <1663>/ <1664>

Assessment of Extractables/Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems[10,11]: Describes the risks of extractables and leachables in pharmaceutical packaging and delivery systems, including definitions, why testing should be carried out, where extractables or leachables can occur and information on testing procedures.

We perform testing for USP <1663> qualification of the chlorobutyl stoppers used with ALK Life Science Solutions' sterile empty vials.

References

[1] Commentary: USP–NF 2023 Issue 3. United States Pharmacopoeia (USP). Updated June 1, 2023. Accessed April 3, 2024. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/uspnf-2023-issue-3-commentary-20230601.pdf

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[3] USP General Chapter <87> Biological Reactivity Tests, *In Vitro*. Updated November 1, 2015. Accessed June 16, 2023. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/iras/gc-87-biolgoical-reactivity.pdf.

[4] USP General Chapter <381> Elastomeric Closure for Injections. United States Pharmacopeia (USP); 2018. Updated January 1, 2018. Accessed June 16, 2023. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/381_elastomeric_closure_for_injections_rb_notice.pdf.

[5] USP General Chapter Containers—Glass. United States Pharmacopeia (USP); 2020. Updated April 23, 2017. Accessed June 16, 2023. https://www.usp.org/sites/default/files/usp/document/workshops/660_glass_containers_used_in_pharmaceutical_packaging_delivery_systems_pf_43_3.pdf.

[6] USP General Chapter Pharmaceutical Compounding – Sterile Preparations. United States Pharmacopeia (USP); 2020. Updated November 8, 2022. Accessed June 16, 2023. https://www.usp.org/compounding/general-chapter-797.

[7] USP General Chapter Radiopharmaceuticals–Preparation, Compounding, Dispensing, and Repackaging. United States Pharmacopeia (USP); 2020. Updated March 12, 2020. Accessed June 16, 2023. https://www.usp.org/chemical-medicines/generalchapter-825.

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[9] FAQs: Water for Pharmaceutical and Analytical Purposes. Updated April 18, 2023. Accessed June 16, 2023. https://www.usp.org/frequently-asked-questions/water-pharmaceutical-and-analytical-purposes.

[10] United States Pharmacopeia (2023). *General Chapter, <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems.* USP-NF. Rockville, MD: United States Pharmacopeia. DOI: https://doi.org/10.31003/USPNF_M7126_03_01.

[11] United States Pharmacopeia (2023). *General Chapter, <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems.* USP-NF. Rockville, MD: United States Pharmacopeia. DOI: https://doi.org/10.31003/USPNF_M7127_02_01.

ALK Life Science Solutions™ provides a Certificate of Analysis to summarize quality release testing results for its SEV products.
For more information, visit **SterileVialSolutions.com.**