USP Standards for Quality Vaccines–Standards That Relate to Packaging and Distribution of Medicines

The United States Pharmacopeia–National Formulary (USP-NF) contains general chapters that provide requirements and best practices for manufacturers, regulators and laboratories that are developing, manufacturing, testing and releasing drug substances and products.

Learn more about some of the key standards that apply to quality vaccine development below.

Accessing *USP–NF Online*

To access details about the standards below and other relevant information, you must be signed in to USP–NF Online. *If you are a scientist, developer or manufacturer working on COVID-19 vaccines or treatments, and would like to request free access, complete this online request.*

Standards That Relate to Packaging and Distribution of Medicines

Standard name	Brief description
<2027> Package Integrity Evaluation—Sterile Products	This chapter provides guidance on the integrity assurance of nonporous packages intended for sterile pharmaceutical products. Background instruction is provided on the topics of leaks, leakage rate and package sealing/closure mechanisms. Explanation is given as to how packages that conform to specified leakage limits help to ensure the contained product meets and maintains sterility and relevant physicochemical specifications. **Not intended to convey requirements enforceable by regulatory agencies.**
<1031> The Biocompatibility of Materials Used in Drug Containers, Medical Devices, and Implants	This chapter provides guidance on the identification and performance of procedures for evaluating the biocompatibility of drug containers, elastomeric closures, medical devices and implants. Biocompatibility refers to the tendency of these products to remain biologically inert throughout the duration of their contact with the drug product or the body. The biocompatibility testing procedures referenced in this chapter are designed to detect the nonspecific, biologically reactive, physical or chemical characteristics of medical products or the materials used in their construction. **Not intended to convey requirements enforceable by regulatory agencies.**
<1079> Good Storage and Distribution Practices for Drug Products	This general information chapter describes good storage and distribution practices to ensure that drug products (medicines) reach the end user (practitioners and patient/consumers) with quality intact. **Not intended to convey requirements enforceable by regulatory agencies.**
<1178> Good Packaging Practices	This chapter is intended to provide guidance to those engaged in repackaging of oral solid drug products. The chapter also provides information relevant to any person who removes drugs from their original container-closure system (new primary package) and repackages them into a different container-closure system for sale and/or for distribution. **Not intended to convey requirements enforceable by regulatory agencies.**
<1663> Assessment of Extractables Associated With Pharmaceutical Packaging/Delivery Systems	This general information chapter presents a framework for the design, justification and execution of an extractables assessment for pharmaceutical packaging and delivery systems. The chapter establishes critical dimensions of an extractables assessment and discusses practical and technical aspects of each dimension. The principles and best demonstrated practices outlined in this general chapter represent a consensus interpretation of sound science and can therefore be applied to any situation in which an extractables assessment is required for pharmaceutical application. **Not intended to convey requirements enforceable by regulatory agencies.**

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<1664> Assessment of Drug Product Leachables Associated With Pharmaceutical Packaging/ Delivery Systems	This general chapter presents a framework for the design, justification and implementation of assessments for drug product leachables derived from pharmaceutical packaging and delivery systems. A scientifically sound leachables assessment is important to manufacturers and their various suppliers primarily as a means of establishing the suitability for use of pharmaceutical packaging/delivery systems, as leachables can potentially affect drug product efficacy, safety and quality. **Not intended to convey requirements enforceable by regulatory agencies.**
<1787> Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections	Parenteral products are designed and manufactured to minimize particulate matter, which is differentiated into two broad categories: visible and subvisible. The absolute limit of visibility, or detectability, depends on the test conditions and the nature of the particulate matter. This general information chapter covers subvisible particles in the range of 2-100 µm. This chapter will focus on enumeration, characterization and, when possible, identification of inherent particles, distinguishing them from extrinsic and intrinsic particles. The chapter does not cover formulations that are suspensions or emulsions, or those that contain adjuvants or similar intended particle components. **Not intended to convey requirements enforceable by regulatory agencies.**
<1790> Visual Inspection of Injections	This chapter provides guidance on the inspection of injections for visible particles. The terms “particle,” “particulates” and “particulate matter” are equivalent and do not have different meanings when used in this chapter. “Particulate matter” is defined in 788 Particulate Matter in Injections as “mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions.” The methods discussed in this chapter are also applicable to the detection of other visible defects not the subject of 790 Visible Particulates in Injections but critical to a qualified, comprehensive inspection process. The primary focus of this chapter is a manual reference inspection method; however, semi-automated and automated methods are also discussed and permitted by the pharmacopeia. **Not intended to convey requirements enforceable by regulatory agencies.**