

Particle Count Set

Quality Solutions



It is expected that all injectable drug products be free of chemical and physical contaminants to achieve quality product. As a regulatory requirement, particulate matter must be controlled in all injectable drug products which can be achieved via particulate matter testing. However, due to current manufacturing capabilities, it remains a challenge to manufacture injectable products that are totally free of particulate matter contamination.

By utilizing USP's Particle Count Set Reference Standard and related General Chapters, manufacturers can meet these testing requirements for controlling extrinsic, intrinsic, and inherent particles, as well as reduce overall risk and help avoid remediation costs.

Learn how USP's Particle Count Set Reference Standards, along with USP General Chapters and USP Education webinars, can be used to calibrate particle count analyzers and other particle analysis instrumentation.

Official Documentary Standards and Materials

Reference Standard	
Particle Count Set (2 Blanks and 2 Suspensions)	1500502

Relevant General Chapters	
Light Obscuration Method for the Determination of Subvisible Particulate Matter	<1788.1>
Membrane Microscope Method for the Determination of Subvisible Particulate Matter	<1788.2>
Flow Imaging Method for the Determination of Subvisible Particulate Matter	<1788.3>
Methods for the Determination of Subvisible Particulate Matter	<1788>
Subvisible Particulate Matter in Therapeutic Protein Injections	<787>
Particulate Matter in Injections	<788>
Particulate Matter in Ophthalmic Solutions	<789>
Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections	<1787>
Visible Particulates in Injections	<790>
Visual Inspections of Injections	<1790>
Injections and Implanted Drug Products	<1>



All the Particulars on Particles:

USP On-Demand Webinars on Particulate Matter

- ▶ **Introduction to Compendial Particulate Standards**
- ▶ **Visible Particles:**
USP General Chapters 1, 790, and 1790
- ▶ **Subvisible Particles:**
USP General Chapters 787, 788, 1787, and 1788