

Determining Particulate Matter in Liquids: Parenteral & Ophthalmic Products (Classroom)

Art. ID	USP-CM-788-01
Unit	Each
Deliverydetails	No Dangerous Good

Description

Particle determination for sterile injectable products has been required for more than 30 years, however, recent improvements in standard methods for sensitive protein products have brought changes and additional background information to the Compendial guidance. This course will discuss the current, USP <788> Particulate Matter in Infections and <1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions, requirements for sub-visible particle determination. In addition, a discussion on the new USP General Chapter <787> Subvisible Particulate Matter in Therapeutic Protein Injections for particle determination in protein formulations and the informational USP Chapter <1787> Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections which provides background and rationale for sub-10µm characterization. A portion of the course will focus on visible particle determination and the two new Compendial chapters on the topic, USP <790> Visible Particulates in Injections and <1790> Visual Inspection of Injections