

美国药典微粒测试和药典标准

Particulate Matter Testing and Compendial Standards

2024年8月26日 上海

课程纲要 Course Outline:

- **微粒概览 Overview of Particulate Matter**
 - 定义、来源、分类、USP 相关标准和指南
Historical Definition, Sources, Classification, Compendial Standards and Guidance
- **可见微粒 Visible Particles**
 - USP 通则<1> “注射剂和植入药物（注射用）- 产品质量测试” 及要点
USP <1> *Injections and Implanted Drug Products (Parenteral) – Product Quality Tests*, and Key Points
 - USP 通则<790> “注射剂中可见微粒检查” 及要点
USP <790> *Visible Particulates in Injections*, and Key Points
 - USP 通则<1790>注射剂的目视检查 USP <1790> *Visual Inspection of Injections*
 - 关键主题和要点 Key Topics and Key Points
 - 典型检查流程 Typical Inspection Process Flow
 - 检查过程的确认和验证 Qualification and Validation
 - 培训和资格认证 Training and Qualification
 - 难以检验产品的补充试验 Supplemental Testing for Difficult to Inspect Products
 - 其他相关指南 Other Relevant Guidance
 - FDA/EMA/EP/PDA 可见微粒指南 FDA/EMA/EP/PDA
- **亚可见微粒 Subvisible Particles**
 - 亚可见微粒通则和药典方法的演变 Subvisible Chapters and Evolution of Compendial Methods
 - 药典方法的要求 Compendial Method Requirements
 - 主要方法介绍：光阻法、膜显微镜法、流动成像法
Primary Methods: Light Obscuration, Membrane Microscopy, Flow Imaging
 - 其他方法：Other Methods
 - USP 通则<1787>治疗性蛋白注射液中亚可见微粒的测定
USP <1787> *Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections*
 - 批次取样 Lot Sampling
- **眼用产品 - USP 通则<771>和<789> Ophthalmic Products - USP General Chapters <771> and <789>**
 - USP 相关通则修订历史、<771>重大修订 Revision History and <771> Major Revision
 - 眼用制剂的可见微粒和异物 - 目视检查及其替代方案
Visible Particulate and Foreign Matter in Ophthalmic - Visual Inspection & Alternatives
 - 眼用制剂中的亚可见微粒和异物 Subvisible Particulate and Foreign Matter in Ophthalmic
 - 亚可见微粒检测方法：通则<788>、<789> Subvisible Methods: <788>, <789>
- **微粒控制 Particle Control**
- **微粒调查 Particle Investigation**

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课程日程 Agenda:

时间 Time	主题 Topic	
9:00 am - 12:00 pm	微粒概览	Overview of Particulate Matter
	可见微粒	Visible Particles
	亚可见微粒	Subvisible Particles
12:00 pm - 13:00 pm	午餐	Lunch
13:00 pm -17:00 pm	亚可见微粒 (续)	Subvisible Particles (cont.)
	眼用产品 - USP 通则<771>和<789>	Ophthalmic Products - USP General Chapters <771> and <789>
	微粒控制	Particle Control
	微粒调查	Particle Investigation

This agenda is subject to change. 此表仅供参考，具体日程以现场课程为准