美 国 药 典 在 线 点 播 课 程
USP On-Demand Webinar

剂量均匀度：美国药典通则<905>
Uniformity of Dosage Units: *USP–NF* General Chapter <905>

课程时长 Course Duration:

1小时45分钟　**1 hour 45 mins**

课程介绍 Course Description and Objectives:

美国药典通则<905>“剂量均匀度”经过国际间的药典协调于 *UP34-NF29*（2011 年）生效。“基于值的测试”方法应运于这个经协调的通则用来评定剂量均匀度。本课程将通过各种案例分析介绍“可接受值”这一关键步骤的计算方法和 USP 通则<905>方法在不同剂型中的具体应用。课程最后部分还将与您分享部分讲师与学员的问答内容。

通过学习，您将能够：

- 解释现行经协调的药典方法剂量均匀度的基本原理
- 计算接受值来确定一致性
- 如何应用接受值、L1 和 L2、目标值、标准值和接受常数
- 将 UP-NF 通则<905>运用于各种剂型
- 如何决定何时使用“重量差异测试”与“剂量均匀度测试”
- 了解如何将 USP 通则 <905>扩展到大样本量
- 确定批量释放策略，确保符合 USP 通则 <905>的规定

USP General Chapter <905> Uniformity of Dosage Units is internationally harmonized and has been official since *USP 34–NF 29* (2011). A “Test by Values” approach is used in this harmonized chapter to assess the uniformity of dosage units. This webinar will explain, through various case studies, the calculation of the Acceptance Value, which is a critical step of the “Test by Values” approach—this webinar will also discuss the application of USP General Chapter <905> to various dosage forms.

Upon completion of this course, you will:

- Explain the rationale of the current harmonized compendial approach to the problem of uniformity of dosage units; Calculate the Acceptance Value in determining conformance with the acceptance criteria;
- Describe and use the concepts of the Acceptance Value, L1 and L2, Target Value, Reference Value, and Acceptability Constant;
- Apply USP–NF General Chapter <905> to various types of formulations;
- Determine when to use the “Weight Variation Test” and when to use the “Content Uniformity Test”.
- Understand how to extend USP <905> to large sample sizes.
- Determine a batch release strategy to ensure compliance with USP <905>

参课对象 Who Should Attend:

化学分析人员、QC/QA 经理、法规符合经理、实验室经理、生产经理、法规事务专员、R&D 人员。

Analytical chemists, QC managers, QA managers, Compliance managers, Lab managers, Production managers, Regulatory affairs specialists, R&D scientists.

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剂量均匀度：美国药典通则<905>

Uniformity of Dosage Units: *USP–NF* General Chapter <905>

讲师 Instructor:

Steven Walfish，前美国药典委员会科学部门通则高级首席科学家
Steven Walfish, Former Sr. Principal Scientist, Science-General Chapters, USP

Walfish 先生曾是美国药典委员会(USP)科学部门通则高级首席科学家，负责统计学专家委员会。在加入 USP 之前，他是美国新泽西州 BD 公司的高级统计员，负责支持全球业务的持续改进和流程开发。他还曾在通用电气医疗保健、人类基因组科学和 Chiron 等公司任职。此外，Walfish 先生曾任统计外包服务公司(Statistical Outsourcing Services)总裁，该公司为 FDA 监管行业提供统计分析和培训。Walfish 先生在开发和应用统计方法解决复杂的商业问题方面拥有 30 多年的专业知识，包含统计方法应用于分析方法验证、验证和稳定性分析的经验。Walfish 先生拥有布法罗大学(University of Buffalo)统计学学士学位、罗格斯大学(Rutgers University)统计学硕士学位和波士顿大学(Boston University) EMBA 学位。

Mr. Steven Walfish was the former Principal Science & Standards Liaison at United States Pharmacopeia (USP) responsible for the Statistics Expert Committee. Mr. Walfish has held roles at Becton Dickinson GE Healthcare, Human Genome Sciences and Chiron. Steven was President of Statistical Outsourcing Services, a consulting company that provides statistical analysis and training to the FDA regulated industries. Steven brings over 30 years of industrial expertise in the development and application of statistical methods for solving complex business issues. Steven has experience applying statistical methods to analytical method verification and validation and stability analysis. Steven holds a Bachelors of Arts in Statistics from the University of Buffalo, Masters of Science in Statistics from Rutgers University and an Executive MBA from Boston University.

授课语言 Language:

英语（含中文字幕） English (with Chinese subtitles)

课程有效期 Access Deadline:

课程在线观看有效期：自在线报名并缴费成功日起，14 天内有效，逾期课程访问通道将自动关闭。
（报名成功后您会收到课程登录信息通知邮件）

This course will only be available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript– whichever occurs first.

培训费用 Fee: 350 元人民币/人 RMB 350/attendee

报名方式 Register Procedures:

1. **请点击这里（课程报名）进行在线报名**

   USP-China 收款账户： USP-China account
   收款人 Beneficiary： 美药典标准研发技术服务（上海）有限公司
   账号 Account No.： 6841 12464 120
   银行 Bank： 美国银行有限公司上海分行

2. 发票领取：快递/邮寄方式提供 Invoice is available after registration

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