

美国药典在线点播课程 USP On-Demand Webinar

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

课程时长 Course Duration:

1.5小时 1.5 hour

课程介绍与目的 Course Description and Objectives:

美国药典“通则<905>含量均匀度”经过国际间的药典协调于 *USP34-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含量均匀度。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，您将了解：

- 现行经协调的药典方法含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 USP–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“含量均匀度测试”

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 on-demand 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. By taking this course you will understand the rationale of the current harmonized compendial approach to the problem of uniformity of dosage units; learn to calculate the Acceptance Value in determining conformance with the acceptance criteria; understand and learn how to use the concepts of the Acceptance Value, L1 and L2, Target Value, Reference Value, and Acceptability Constant, learn to apply USP–NF General Chapter <905> to various types of formulations, gain the knowledge to determine when to use the “Weight Variation Test” and when to use the “Content Uniformity Test”.

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.

讲师 Instructor:

William E. Brown, 美国药典委员会科学部门通则标准资深科学事务联络人

William E. Brown, Senior Scientific Liaison, Science-General Chapters, USP

报名请登录 USP 会议与培训中文平台，[点击这里](#)（[课程报名](#)）进行在线报名。

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含量均匀度：美国药典通则<905>

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

授课语言 Language:

英语（配中文字幕） 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用户名、密码邮件）

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:** 600 元人民币/人 RMB 600/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.