

美国药典在线点播课程 *USP On-Demand Webinar*

溶出原理：溶出装置的确认指南

Fundamentals of Dissolution: Guidance for the Verification and Qualification of a Dissolution Apparatus

课程时长 Course Duration: 5小时45分钟 5 hours and 45 minutes

课程介绍与目的 **Course Description and Objectives:**

课程介绍了固体口服剂型溶出度测试的基础知识，并阐述与 USP 溶出装置 1 和装置 2 的确认相关的细节。课程将特别介绍溶出度理论和美国药典通则<711>、溶出数据的处理、以及装置确认以证明其适用性。

通过学习，您将了解美国药典通则<711>中介绍的溶出度测试理论用于实际应用；溶出度测试的关键定义；设置、验证和鉴定溶出装置（特别是装置 2）；使用结果判定表；说明可能会影响溶出度结果的溶出装置的操作参数。

This one-day course will emphasize the fundamentals of dissolution testing of solid oral dosage forms and address specifics related to the qualification of USP dissolution apparatus 1 and apparatus 2. Specifically, this course is dedicated to dissolution theory and the guidance presented in USP–NF General Chapter <711>, the handling of dissolution data and the qualification of an apparatus to prove its suitability for use.

Upon completion of this course, you will be able to:

- Understand the theory of dissolution testing presented in USP–NF General Chapter <711> to apply in practical application
- Explain key definitions of dissolution testing
- Set up, verify and qualify a dissolution apparatus (focus on apparatus 2)
- Use acceptance tables
- Explain the operational parameters of a dissolution apparatus that could affect dissolution results

参课对象 **Who Should Attend:**

溶出度分析员、化学分析员、实验室技术人员、法规专员等。

Dissolution chemists, Analytical chemists, Laboratory Technicians, Regulatory professionals

授课语言 **Language:**

中文 Chinese

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讲师介绍 Instructor:

曹文军，美国药典委员会中华区战略客户发展高级经理

Wenjun Cao, Senior Manager, SCD, USP-China

曹文军先生是美国药典委员会中华区战略客户发展高级经理，USP 认证讲师，负责为中国大陆、香港、台湾、澳门等大中华地区的医药领域用户提供美国药典标准和标准物质的技术支持及解决方案。他有超过 17 年制药行业的工作经验。在加入 USP 之前，曾任职于 BMS 上海、普霖贝利生物医药等公司从事实验室分析、质量控制、ANDA 项目管理等方面的工作。曹文军先生毕业于华东理工大学制药工程专业。

Wenjun Cao is a SCD Senior Manager, USP China, who is responsible for communicating with USP stakeholders in the Great China region to providing technical supports and solutions. He is a USP qualified instructor of USP Education. He has more than 17 years of technical, project management and business development experience in pharmaceutical industries. Prior to USP, he worked at BMS Shanghai, Prinbury Biopharm, etc. focused on work of lab analysis, quality control, ANDA project management, etc. Wenjun holds a bachelor's degree in Pharmacy from East China University of Science and Technology.

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 be only 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: 1,200 元人民币/人 RMB 1,200/attendee

报名方式 Register Procedures:

1. 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 by express after successful registration.