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

溶出度方法的开发和验证
Development and Validation of Dissolution Procedures

课程时长 Course Duration: 11小时 12分钟

课程介绍与目的 Course Description and Objectives:

生物利用度在国内外仿制药申报和审批流程中是不可缺少的评价项目。作为其重要指征，溶出度对药品的效力、质量、纯度和生物利用度起着重要作用。溶出测试被通用于大多数制剂（如片剂、胶囊、混悬剂、透皮贴剂、栓剂等）的体外性能测试。课程为相关部门进行批放行和稳定性测试提供溶出度方法开发和验证基础，并讲授与之相关的现行规范及综合考量因素。课程以 USP 通则<1092>为基础，介绍美国药典的溶出测试要求。

通过学习，您将能够：

- 描述基于药用原料理化属性的溶出与药物释放测试的开发
- 确定测试时的生理学考量
- 列出溶出测试条件，如仪器和介质等
- 描述溶出测试的自动化和方法验证，解释溶出测试结果
- 描述性能确认测试

Dissolution tests are in vitro performance tests for most dosage forms, such as tablets, capsules, suspensions, transdermal patches, suppositories, etc. They are important components of the specifications that establish the strength, quality, purity, and bioavailability of a drug product. This course has been entirely revised in order to reflect the content of the complete overhaul of USP General Chapter <1092> published in USP 38–NF 33 First Supplement with the official date of August 1, 2015. Building on your basic understanding of USP's approach to dissolution, this course provides a foundation for developing and validating dissolution methods used for batch release and stability testing.

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

- Describe development of dissolution and drug release testing methods based on physicochemical characterization of drug substances
- Identify physiological considerations when setting up tests
- List dissolution testing conditions, such as instruments and media, etc.
- Describe automation, validation and interpretation of dissolution test results
- Describe performance verification tests

参课对象 Who Should Attend:

从事溶出度测试的科研人员、化学分析员、实验室经理、质控人员、产品/剂型开发人员、法规专员等

Scientists, Chemists who perform dissolution testing, Lab managers, Quality control staff, Product/formulation development, Regulatory professionals.

授课语言 Language:

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

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室（200137）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org

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

溶出度方法的开发和验证

Development and Validation of Dissolution Procedures

讲师介绍 Instructor:

Erika S. Stippler 博士，USP药典培训讲师，前USP制剂性能实验室总监

Erika S. Stippler, Ph.D., USP Qualified Education Faculty，Ex-Director, Dosage Form Performance Laboratory, USP

Stippler 博士拥有超过 25 年制药工业界的丰富工作经验，曾任 USP 制剂性能实验室总监。在加入 USP 之前她曾任职于德国和瑞士多家研究机构。Stippler 博士研究领域专注于基于溶出度方法开发研究不同制剂体内外相关性，溶出系统的评定和标准化，以及针对药品性能评价的溶出度测定方法研究。Stippler 博士于 2007 年加入 USP 并支持 USP 制剂性能实验室工作。Stippler 博士也是美国药学科学家协会和国际制药技术协会成员。

Dr. Stippler has more than 25 years of experience in the pharmaceutical industry, including ex-director of USP Dosage Form Performance Laboratory and serving at various contract research organizations in Germany and Switzerland. Her scientific interest is focused on IVIVC-based dissolution method development for various dosage forms and on the characterization and standardization of dissolution apparatus and dissolution methods for performance evaluation of pharmaceutical products. Dr. Stippler's career at USP began in 2007, and she supported the Dosage Forms Performance Laboratory. Dr. Stippler is also a member for American Association of Pharmaceutical Scientists and Association for International Pharmaceutical 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 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: 2000 元人民币/人　RMB 2000/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.

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室（200137）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org