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

USP 通则<467>残留溶剂检测

Residual Solvents in *USP-NF*

课程时长 Course Duration: 2小时 2 hours

课程介绍与目的 Course Description and Objectives:

2019 年 3 月 1 日，美国药典通则“<467>残留溶剂”的重大修订及其配套的通则“<1467> 残留溶剂-药典方法的确认和替代方法的验证”正式生效。2020 年 12 月 1 日，通则<467>额外修订的部分正式生效，以与 ICH Q3C(R6) 保持一致，将甲基异丁酮从第 3 类残留溶剂重新分类为第 2 类残留溶剂，并添加了三乙胺作为新的第 3 类残留溶剂。课程还将讨论其他相关主题，包括 USP 通则<1467>中概述的残留溶剂测试的验证和确认。

通过学习，您将能够：

- 了解 USP 通则<467>的历史方法和标准
- 应用基于风险的策略概念，以符合通则<467>的药物要求中的残留溶剂量
- 举例说明选项 1 和 2，以及 USP<467>中方法 A、B 和 C
- 区分验证和确认，并了解何时使用替代方法
- 了解 USP 通则<1467> 中所述的验证和确认要求

Significant revisions to standards for residual solvents found in *USP-NF* General Chapter <467> Residual Solvents became official on March 1, 2019. At the same time the companion USP chapter <1467> Residual Solvents-Verification of Compendial Procedures and Validation of Alternative Procedures became official. Additional revisions were made to USP <467> and became official on December 1, 2020 to align with ICH Q3C(R6) which reclassified methylisobutylketone from a Class 3 to a Class 2 residual solvent and added triethylamine as a new Class 3 residual solvent. Other related topics will be discussed including validation and verification of residual solvent testing as outlined in USP <1467>.

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

- Understand the historical approaches and standards contained in USP General Chapter <467>.
- Apply a risk-based strategy concept for complying with residual solvents content in pharmaceutical requirements of USP <467>.
- Illustrate Options 1 and 2, as well as Procedures A, B, and C as described in USP <467>.
- Differentiate between validation and verification and understand when to use alternative procedures.
- Understand validation and verification requirements as described in USP General Chapter >1467>.

参课对象 Who Should Attend:

QC/QA，合规性人员，实验室分析员，制药和相关行业管理者，法规专员等。

QC/QA, Compliance staff, Laboratory scientists, Managers in the pharmaceutical and allied industries, Regulatory professionals.

授课语言 Language:

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

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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Residual Solvents in *USP-NF*

讲师介绍 Instructor:

Edmond Biba 博士，美国药典委员会通则科学部门首席科学家

Edmond Biba, Ph.D., Principal Scientist, Science-General Chapters, USP

Edmond Biba 博士是 USP 通则-化学分析专家委员会和 USP 通则-物理分析专家委员会的首席科学家。自 2001 年加入 USP 以来，Biba 博士一直担任研发实验室和标准物质评估部的科学家。在加入 USP 之前，Biba 博士是美国国家研究委员会-沃尔特里德陆军研究所实验治疗部药物化学系的博士后研究员，从事生物检定导向药物发现、基于作用的设计机制、以及新抗疟药物的合成研究。Biba 博士拥有美国大学化学-合成有机化学博士学位，阿尔巴尼亚地拉那地拉那大学化学工程/化学专业学士学位。Biba 博士是 Sigma Xi-The Scientific Research Honor Society、美国化学学会、美国药物科学家协会、ICH Q3C(R8)工作组成员，以及药物质量研究所(PQRI)药物质量技术委员会成员。

Dr. Edmond Biba is a Principal Scientist to the USP General Chapters-Chemical Analysis Expert Committee and USP General Chapters-Physical Analysis Expert Committee. Since Joining USP in 2001, Dr. Biba served as a scientist in the Research and Development Laboratory and in the Reference Standards Evaluation Department.
Prior to joining USP, Dr. Biba was a National Research Council-Walter Reed Army Institute of Research Postdoctoral Fellow in the Medicinal Chemistry Department of Experimental Therapeutic Division conducting research on bioassay directed drug discovery and mechanism of action-based design and the synthesis of new antimalarial drug candidates.
Dr. Biba received his Ph.D. in Chemistry-Synthetic Organic Chemistry from the American University, Washington DC, and a B.Sc. in Chemical Engineering /Chemistry from University of Tirana, Tirana, Albania.
Dr. Biba is member of Sigma Xi- The Scientific Research Honor Society, American Chemical Society, American Association of Pharmaceutical Scientists, ICH Q3C(R8) Working Group, and a member of Pharmaceutical Quality Technical Committee of the Pharmaceutical Quality Research Institute (PQRI).

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: 700 元人民币/人　RMB 700/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 after registration.

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