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

总有机碳测定法：USP 通则 <643>

Total Organic Carbon: USP General Chapter <643>

课程时长 Course Duration: 1小时 1 hour

课程介绍与目的 Course Description and Objectives:

美国药典通则<643>“总有机碳测定法”(TOC)作为法定标准被其他药典采纳为纯化水和注射用水中有机杂质测定的主要方法。通则<643>是制药用水系统的两种主要的化学限度测试之一，用于确定水净化系统中化学物质的控制/减少是否充分（另一项为 USP 通则<645>“水电导率测定法”，用于检测离子杂质）。本课程将解析 TOC 测试的目的、仪器要求、校准要求、在线和离线测量的重要性、以及各种制药用水的测试限值要求。

通过学习，您将能够：

- 了解 TOC 方法的基本原理
- 识别 TOC 杂质的来源及其控制方法
- 列出通则<643>的仪器要求
- 熟悉在线测量与离线测量之间的差异及其要求
- 了解美国药典与其他药典对于各种散装水和无菌水的检测限值

USP General Chapter <643> Total Organic Carbon (TOC) is official and it has been adopted by other pharmacopoeias as the primary method for the determination of organic impurities in Purified Water and Water for Injection. USP <643> Total Organic Carbon is one of the two primary chemical limit tests (USP <645> Water Conductivity is the other for ionic impurities) to determine that there is sufficient control/reduction of chemicals in the water purification system. This webinar will explain the purpose of this test, the instrumentation requirements, calibration requirements, the value of on-line and off-line measurements, and the test limit requirements for various pharmaceutical waters.

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

- Identify the basic principles of the TOC method.
- Identify where TOC impurities come from and how they are controlled.
- List the instrumentation requirements of <643>.
- Identify the differences between on-line and off-line measurements and requirements.
- Describe the test limits for various bulk and sterile waters for USP and their comparison with other pharmacopoeias

参课对象 Who Should Attend:

化学分析员、QA/QC 经理、合规经理、水系统工程师及业主、实验室经理、生产经理、法规事务人员等。

Analytical chemists, QA/QC managers, Compliance managers, Water system engineers and owners, Lab managers, Production managers, Regulatory affairs specialists

授课语言 Language:

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

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讲师介绍 Instructor:

Antonio Hernandez-Cardoso, 美国药典委员会科学部门通则资深科学家
Antonio Hernandez-Cardoso, Senior Principal Scientist General Chapters, USP

自 2005 年 7 月起，Hernandez-Cardoso 博士一直在 USP 全球科学标准部门 (GSSD) 负责科学支持工作，尤其是科学通则部门。他支持物化分析/剂型/测量/数据质量专家委员会的专家顾问组和分委会，协调专家志愿者对通则进行开发和修订工作，并回答来自内部和外部的美国药典相关问题。他的专业领域包括原料药和制剂中的杂质、制药用水和分析用水。Hernandez-Cardoso 博士是美国药学科学家协会（AAPS）的成员，也是国际制药工程协会(ISPE)的 USP 联络员。在加入 USP 之前，他在药典领域有 14 年的工作经验，曾为墨西哥药典工作，参与制定了对抗疗法、顺势疗法、草药药典、以及医疗器械和药房出版物工作。此外，他还在墨西哥国立自治大学教授药典主题和一般制药主题课程超过 12 年。

Since July 2005, Antonio has worked at USP providing general scientific support within the Global Science and Standards Division (GSSD), specifically in the General Chapters Department, coordinating the volunteer experts works for the development and revision of general chapters by supporting Expert Panels and Subcommittees of the Physical Analysis, Chemical Analysis, Dosage Forms, and Measurement and Data Quality Expert Committees, assisting in the development and revision of general chapters and responding to internal and external queries related to USP–NF. Specific areas of expertise include impurities in drug substances and drug products and water for pharmaceutical and analytical purposes. He is member of the AAPS and the USP liaison to the ISPE. Antonio brought fourteen years' experience in pharmacopeial issues working for the Mexican Pharmacopeia developing the Allopathic, Homeopathic, and Herbal Pharmacopeias, and special publications for medical devices and drugstores. Also, Antonio has taught compendial topics to the pharmaceutical industry and general pharmaceutical topics at the National Autonomous University of Mexico for over twelve years.

课程有效期 Access Duration:

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）

Access to this course expires 14 days from the date of registration or until you mark it 'Complete' in your transcript–whichever occurs first.

培训费用 Fee: 250 元人民币/人　RMB 250/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：电子发票通过电子邮件发送　e-Invoice is available by email after successful registration.

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