国内外
《药物分析》教材
比较

杭太俊
中国药科大学 药物分析教研室
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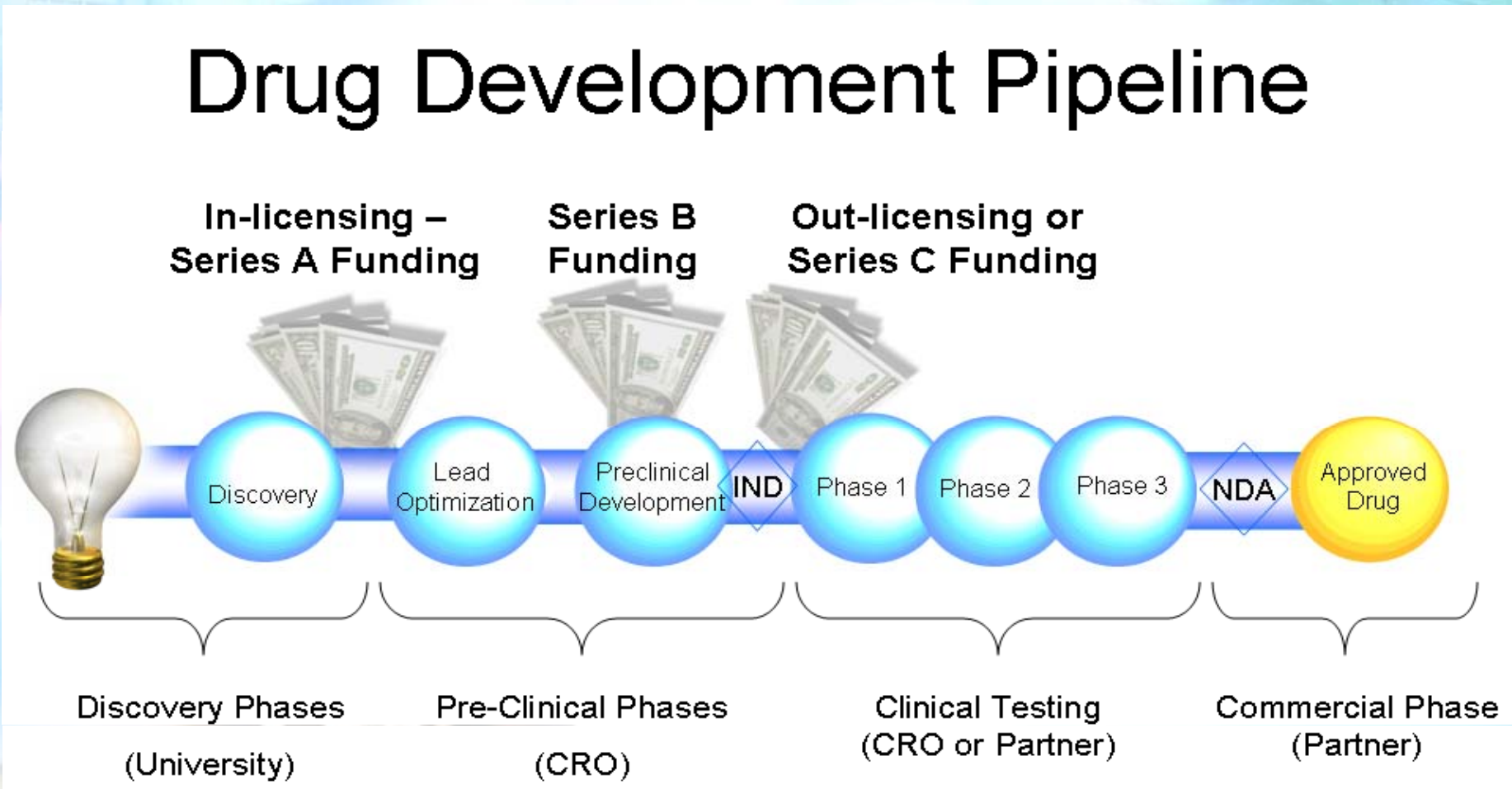
13851622961

1. 概要
2. 国外的药物分析教材
3. 国内的药物分析教材
4. 国内外药物分析教材比较
5. 国外教材的借鉴作用
6. 建议引进的国外药物分析教材

创新药物研究开发是多学科的系统工程



药物分析学是研究开发药物分析方法、研究药物质量、并对药物进行质量分析、控制和评价的科学。

药物分析研究对象：

传统工作－药物分析检验；

研究广泛覆盖－药物研究开发、生产和使用各环节的质量分析研究和监测问题。

药物分析重要性的体现：

各国药物的质量和安全状态，直接体现医药水平。

药物分析研究与应用：

在药物质量分析控制和保障、药物微量有关物质研究、复杂体系内的药物形态及作用机制分析研究等方面都发挥着越来越重要的作用。

药物分析教学：

是国内外药学和医学教育的重要课程。

地址(D) http://www.pharmacy.ac.uk/modules.html

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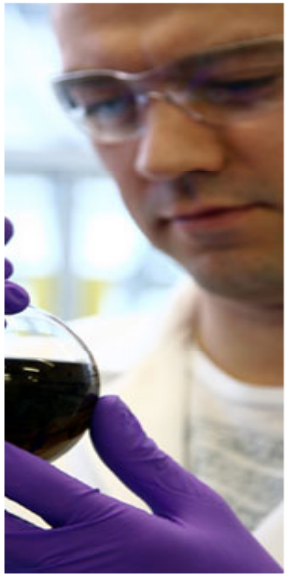
Course modules and sections

- Introduction to Drug Targets and the Molecular Basis of Disease
- History of Drug Discovery and Lead Identification
- Molecular Modelling and Structure-Based Drug Design
- Advanced Synthetic Chemistry for Drug Discovery
- Physiochemical Properties of Drugs
- Preclinical and Clinical Development
- Regulatory Affairs, Commercial Affairs and Intellectual Property
- Modern Aspects of Drug Discovery
- Pharmaceutical Analysis
- First Semester Practical Classes
- Anticancer Drug Development
- New Drug Targets in the CNS
- Pharmacogenomics and the Identification of Biomarkers
- Natural Products and Medicinal Plants in Drug Discovery
- Structure Based Drug Design



Introduction to Drug Targets and the Molecular Basis of Disease
Dr Mike Munday

This section provides a revision of basic macromolecular structure and the types of cellular components that constitute drug targets. The molecular basis of disease is considered with examples of genetic and multifactorial clinical conditions and the mechanism of action of certain drugs in their therapy.

2. 国内外的教学

地址 (D) http://www.ipph.purdue.edu/graduateprogram/courses.php

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For more information, visit This Website. To apply, visit *This* Website.

Also see: Purdue Course Catalog

Course Number	Title	Semesters	Credits
IPPH 52100	Drug Development	All	3
	A review of drug discovery and drug development, with emphasis on the regulatory aspects of these activities. Animal preclinical research and human clinical research are discussed in detail. In addition, the process for the assembly of an IND and NDA is discussed along with the Phases (I,II,III) of human clinical trials. The CMC (chemistry manufacturing and control) aspects of drug development are presented along with ICH documents and manufacturing process analytical technologies. The course concludes with a brief review of international regulatory issues and patents. **Website:** https://courses.pnhs.purdue.edu/ipph521		
IPPH 52200	Good Regulatory Practice	All	3
	A review of the FDA and ICH regulations on good manufacturing, good laboratory, and good clinical practices. The meaning of these regulations, the globalization of practices, and the roles and responsibilities of various professionals implementing these regulations are addressed. Special emphasis is on detailed coverage of the process for the assembly and submission of an IND or NDA and the function of the regulatory affairs department in a pharmaceutical company. **Website:** https://courses.pnhs.purdue.edu/ipph522		
IPPH 52300	Quality Management, Audits And Inspections	Fall	3
	Advanced topics in quality management and business improvement methods that apply to the pharmaceutical industry. Emphasis is placed on specific issues of industry audits and inspections, as well as successful selection and presentation of business and quality improvement projects. **Website:** https://courses.pnhs.purdue.edu/ipph523		
IPPH 56200	Introduction To Pharmaceutical Manufacturing Processes	Fall	3
	A course intended to provide the student with basic understanding of both the theoretical and practical aspects of pharmaceutical manufacturing by combining a thorough classroom treatment of the underlying principles of each pharmaceutical unit operation with hands-on execution of these activities in the laboratory. **Website:** https://courses.pnhs.purdue.edu/ipph562/		
IPPH 58000	Physical Chemical Principles	Fall	3
	Applications of physical chemical principles to pharmaceutical systems.		

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Dane O. Kildsig Center for Pharmaceutical Processing Research

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University of Strathclyde Science

Strathclyde Institute of Pharmacy and Biomedical Sciences

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Postgraduate Courses in Pharmaceutical Analysis

MSc/PgDip in Pharmaceutical Analysis

The taught MSc course in Pharmaceutical Analysis trains students in the range of analytical techniques used for the quality control of medicines. The course consists of a formal taught element running between October and April followed by examinations. The students then undertake a three month project and submit a dissertation at the end of August. The course is currently supported by an EPSRC Master's Training Package that provides five studentships for UK students. In addition there are two studentships supported by AstraZeneca which are open to EU students.

There are currently 55 students attending the course with about two thirds being from overseas. About one third of project placements are in industry and the remainder of the projects are supervised by staff within the Institute.

Further information on the distance learning and taught courses is available on the course website

MSc/PgDip/PgCert in Analysis of Medicines

The on-line version of the course has been developed for part-time distance learning and started in November 2006.

Undergraduate

Postgraduate

Graduate School

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Apply online

Apply for Sep 2011 entry to full time MSc Pharmaceutical Analysis

Apply for Sep 2011 entry to full time PG Diploma Pharmaceutical Analysis

地址(D) https://www.kcl.ac.uk/kis/schools/life_sciences/health/pharmacy/courseinfo/paqcinfo.html

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University of London

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MSc Pharmaceutical Analysis & Quality Control Course Information

You are in Pharmacy Course information PAQC

Introduction

The degree programme is directed towards science graduates contemplating a career in Pharmaceutical Analysis and/or Quality Assurance, or currently employed in the pharmaceutical industry, a research institute, the health service, or a regulatory authority. A broad knowledge of the pharmaceutical sciences is presented with an emphasis placed on both the academic and professional aspects of the subject. The course also prepares graduates for entry into research degree programmes in the pharmaceutical sciences.

Main aims

The MSc (PAQC) degree programme is an advanced course concerned with the science and application of modern and traditional techniques for the analysis of Pharmaceutical products to support the discovery and development of better medicines and to provide regulatory data ensuring product integrity.

2. 国内外的教学

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Pharmaceutical Analysis (M.Sc./P.Grad.Dip)

Institution:	Trinity College Dublin		
Dept/School/Faculty:	School of Pharmacy and Pharmaceutical Sciences		
Duration:	One year full-time; two years part-time		
Entry Requirements:	2.1		
Start Month(s):	September	Course Type:	Standard
Contact Name:	Dr J F Gilmer	Study Type:	

email telephone website

TRINITY COLLEGE DUBLIN COLÁISTE NA TRÍONÓIDE, BAILE ÁTHA CLIATH THE UNIVERSITY OF DUBLIN

The course involves a comprehensive treatment of the science and technology of pharmaceutical analysis with particular emphasis on the regulatory environment in which the pharmaceutical industry operates. It is intended for suitably qualified graduates currently working in or aspiring to work in the pharmaceutical industry - in particular non-pharmacy graduates employed in quality control or quality assurance roles requiring specialised training, retraining or upgrading of skills. The course may also be attractive to technical managers in regulatory affairs, product development and other related areas. The objective is to equip graduates with the appropriate analysis skills required by the pharmaceutical and veterinary manufacturing industries.

The course is available for full-time study over one calendar year or part-time over two years and consists of lectures, workshop and laboratory work. Part-time teaching is normally scheduled for Fridays during academic terms. The course comprises lectures, workshops, seminars, laboratory work, written assignments and factory visits. In addition each student must write a major essay on a designated topic in the area of pharmaceutical analysis. Students proceeding to a M.Sc. degree will be required to undertake a research project and present a detailed scientific report at the end of the course.

The course consists of eight basic modules: regulatory aspects of pharmaceutical analysis, statistics, GLP chromatographic analysis, spectroscopic and physical methods of analysis, pharmacopoeial methods of drug analysis, analysis of low level drug analysis, specialized pharmaceutical methods of analysis, biological and pharmacological methods and pharmaceutical formulation.

The taught modules are supported by lectures and workshops on presentation and research skills and visits to industrial laboratories. The course is taught mainly by College staff, although there is a contribution from specialist visiting lecturers. The research project may be conducted either in the School of Pharmacy or at the student' s place of employment but in either case supervision is exercised by a member of the School of Pharmacy academic staff.

Overall assessment of candidates is based on tutor marked assignments (TMAs) during the course work and written examinations in May/June each year. Credits are available for all assignments including laboratory reports. The M.Sc. project report should be of 20,000 words and is examined in September. Candidates must successfully complete the taught component of the course at the Trinity term examinations, before proceeding

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School of Health Sciences

Comparative European Politics (M.Sc./P.Grad.Dip)
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School of Social Sciences & Philosophy

2. 国内外的教学


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2. 国内外的教学


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例题习题(28)
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Pharmaceutical Analysis
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学校链接
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我要纠错
学科/专业：医学/药学类
所属课程专区：
课程简介
1、本专业生源情况与课程培养目标 药物分析是药学领域中的一门“方法学科”，是浙江大学网络教育本科“药学”专业学生的专业必修课。从历年来的招生情况看，本专业的生源质量良好，在网络药学教育领域中处于中上层次，多数学生来自与医药相关的企事业单位，希望通过网络教育进行“充电”，学习新的知识、技能来更新、完善自己的知识结构和应用能力。
通过本课程的教学，使学生树立比较完整的药品质量观念，掌握药物分析的常用鉴别、检查和含量测定的基本原理与方法，能够
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2. 国内外的教学


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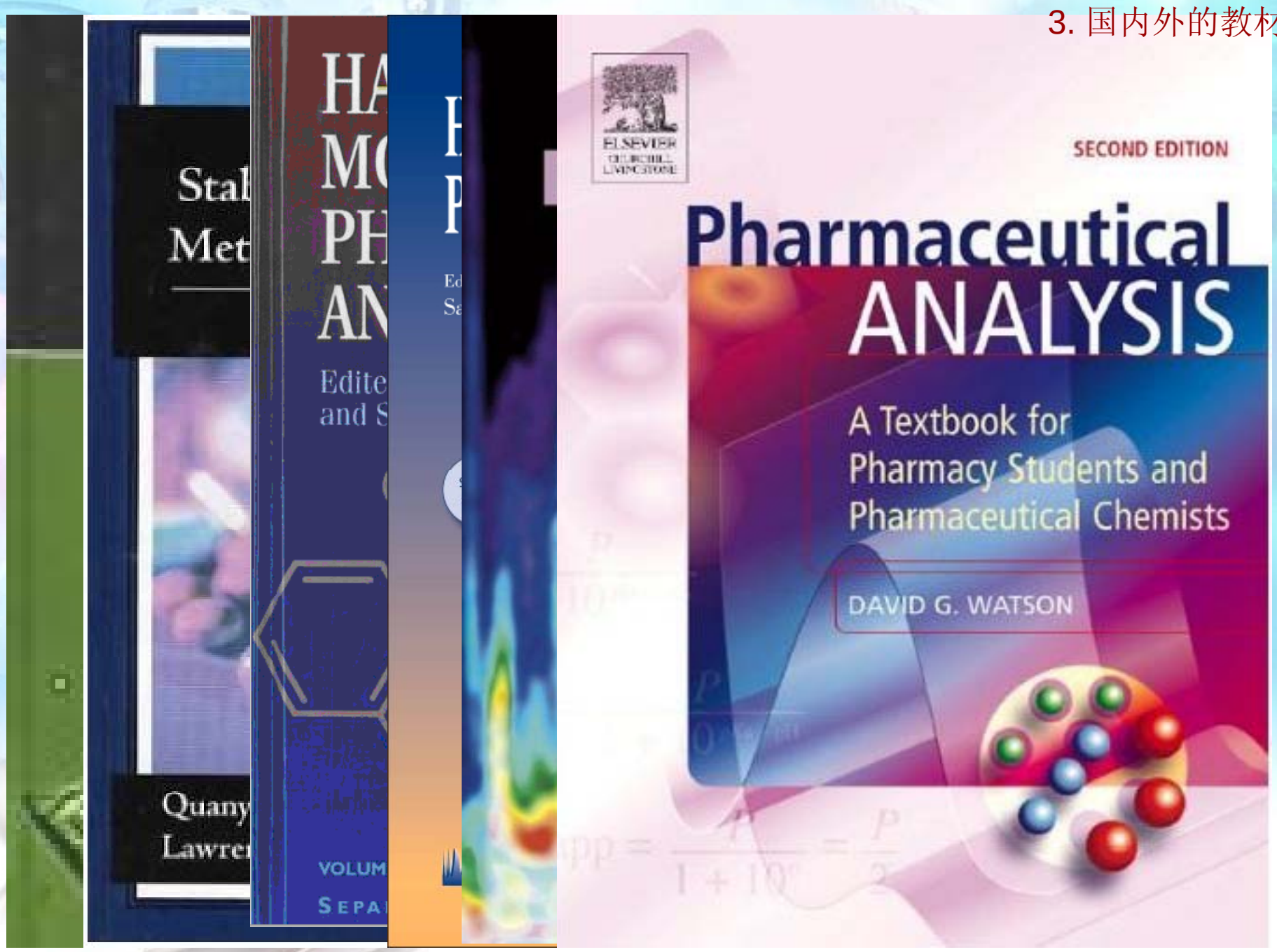
主编规划教材
主办全国药物分析教学研讨会
药物分析人才培养规模最大
相关链接
XIANGGUANLIANJIE
在线学习
特色与创新
本课程的主要特色及创新点
1）药物分析课程体系与教材建设为国内领先 主编国家级规划教材和系列配套教材；主办全国性教学研讨会；长期进行进修教师培训。在国内发挥了示范和辐射作用。
2）理论和实践相结合、动手能力与创新能力并重培养 改变传统教学方式，通过多种互动式理论教学、设计性和开放性实践教学，培养的学生具有较高的专业综合素质和创新能力。
3）药物分析研究国内先进，科研反哺教学 培养的药物分析人才受到普遍欢迎。
本课程与国内同类课程相比居领先地位。
1）药物分析教材建设全国先进 中国药科大学在国内最早独立设置“药物分析课程”，并主编《药物分析》教材，《药物分析》教材一直被列为全国普通高等教育国家级规划教材，在全国普遍使用。同时编著出版了《药物分析》大型参考书、《现代药物分析选论》等参考教材，以及《药物分析实验与指导》双语实验教材。教材建设与时俱进，常编常新。
2）开创并主持“全国药物分析教学研讨会” 从1980年开始至今已在全国主办召开了九次，以交流药物分析学教学经验、提高教学质量，促进学科发展，加强药物分析人才培养为目标。会议同时围绕教材编写与教学研究进行探讨。本课程组对提高我国药物分析学教学质量起到了积极的推动作用，在国内发挥了示范作用和辐射作用。
3）教学研究水平高，教学条件先进，教学梯队合理 担任课程教学的教师都曾作为国外访问学者，或在国外获得学位，中青年骨干教师发挥了主力作用，也有利于加强本课程与国外同类课程的联系和交流。
4）毕业生广受社会的欢迎 理论联系实践的教学方法，开放式实践训练，验证性、综合性、设计性实践教学合理安排，使培养的学生具有良好的动手能力和创新素质。多年来药学类专业学生的生源一直充足，历年来，我校药学专业药物分析方向学生的招生规模一直全国最大(约150人/年)，学生就业率一直名列教育部直属高校前列，培养的毕业生获社会的广泛好评。
5）药物分析师资培训发挥辐射作用 我校药物分析课程长期为国内其他医药院校培训药物分析进修教师。使他们在药物分析课程体系、药物分析教学安排、以及药物分析教学条件的建设等方面均得到了全面的提高。多位接受我校药物分析课程培训的教师已经成为各派送单位药物分析学科的骨干或带头人。如：山东大学药学院王唯红教授、浙江大学药学院姚彤炜教授、第二军医大学范国荣教授、广西中医学院甄汉深教授等等。
本课程现已成为中国药科大学校级一类精品课程，2006年被评为江苏省省级一类精品课程。

3. 国内外的教材


SECOND EDITION
Pharmaceutical
ANALYSIS
A Textbook for
Pharmacy Students and
Pharmaceutical Chemists
DAVID G. WATSON

3. 国内外的教材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药学实验
实验
高等学校
工业
Pharmaceutic
贺浪冲 主编

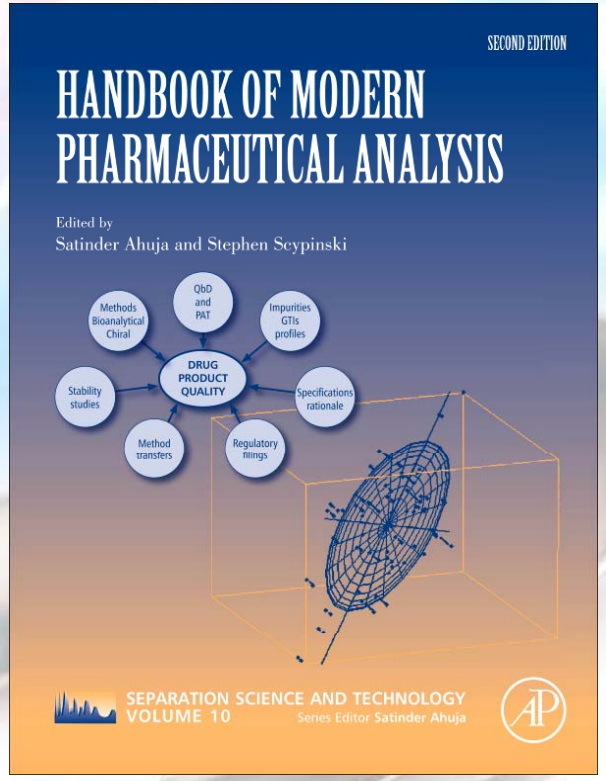
3. 国内外的教材

- 教材内容基本相同。
- 大多针对药物研发、生产和临床使用各环节的药物分析研究任务、常用的方法与技术手段、重要的分析应用等进行全面介绍。
- 都强调了药物分析研究必须根据指导原则和法规的要求进行；
- 药物分析研究的科学性和完整性是医药研究质量和水平的重要保障。

Ahuja编著
Handbook of modern pharmaceutical analysis
(现代药物分析指南)

该书对药物分析在药学研究的各个方面的应用进行了论述，对新药研究开发中的分析任务完成具有针对性的指导作用。

本书共**16**章：



1. 现代药物分析概要、
2. 新药发现中的组合化学和高通量筛选、
3. 药物固体分析、
4. 研发新药中的分降解杂质研究、
5. 制剂处方前研究、
6. 固体制剂研究、
7. 注射剂研究、
8. 新给药系统研究

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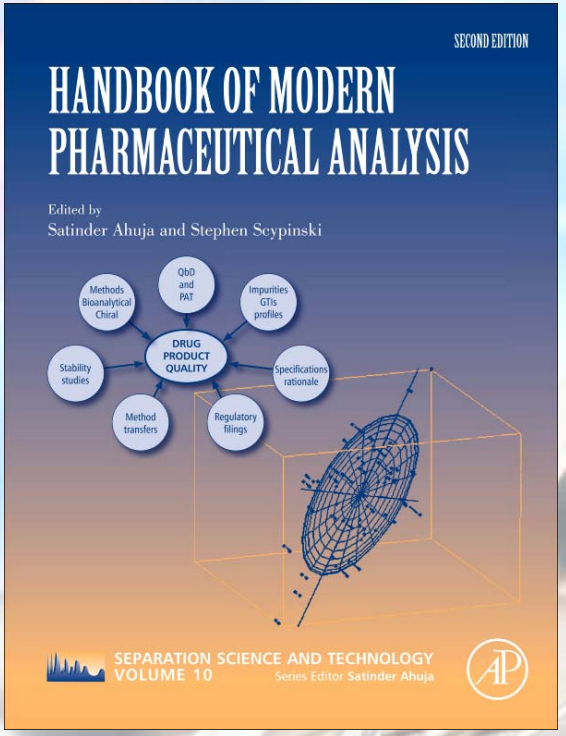
(现代药物分析指南)



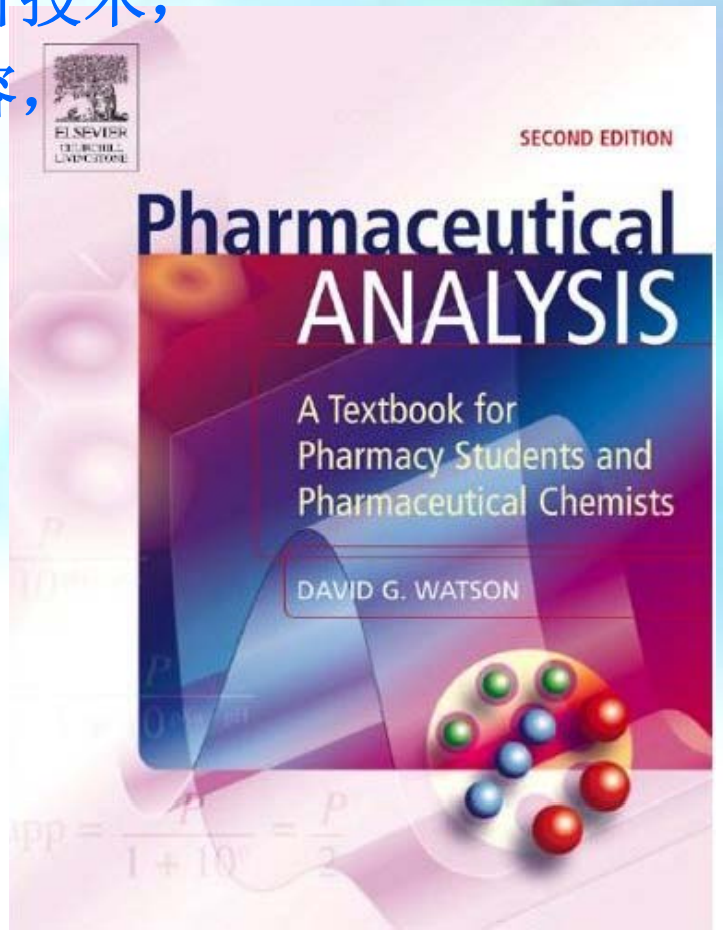
9. 药典标准与药物检验分析、
10. 分析方法开发、
11. 药品标准制订、
12. 药物分析方法验证、
13. 药物稳定性研究、
14. 药物分析方法替换、
15. 药物分析资料的整理与提交、
16. 药物分析新系统-微流控芯片电泳技术。

Watson编著
Pharmaceutical Analysis 2005(2Ed)
(药物分析)

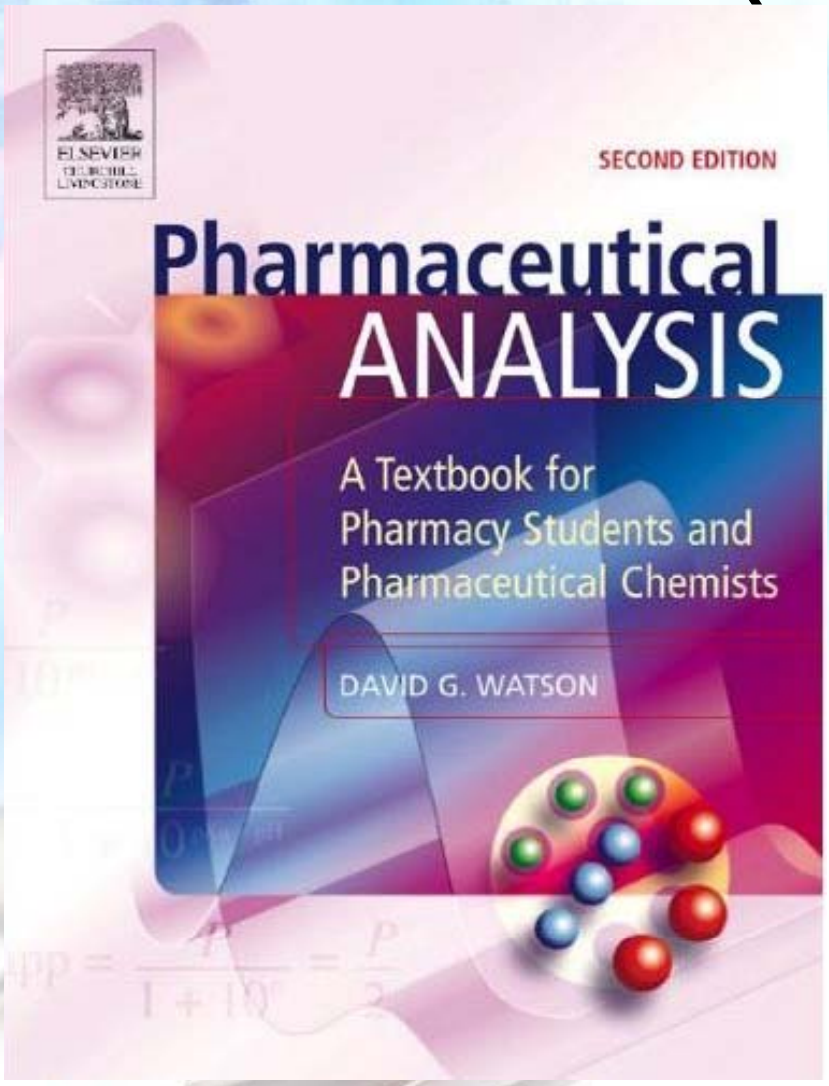
利用一本教材的有限篇幅，
既介绍了药物分析中的所有重要的分析技术，
又合理地控制了它们的难度与细节内容，
避免了深奥的理论，注重实际应用。

共**15**章

1. 分析方法保障与验证、
2. 药物的理化性质、
3. 容量滴定分析法、
4. 紫外-可见分光光度法、
5. 红外分光光度法、
6. 原子吸收分光光度法



Watson编著
Pharmaceutical Analysis 2005(2Ed)
(药物分析)

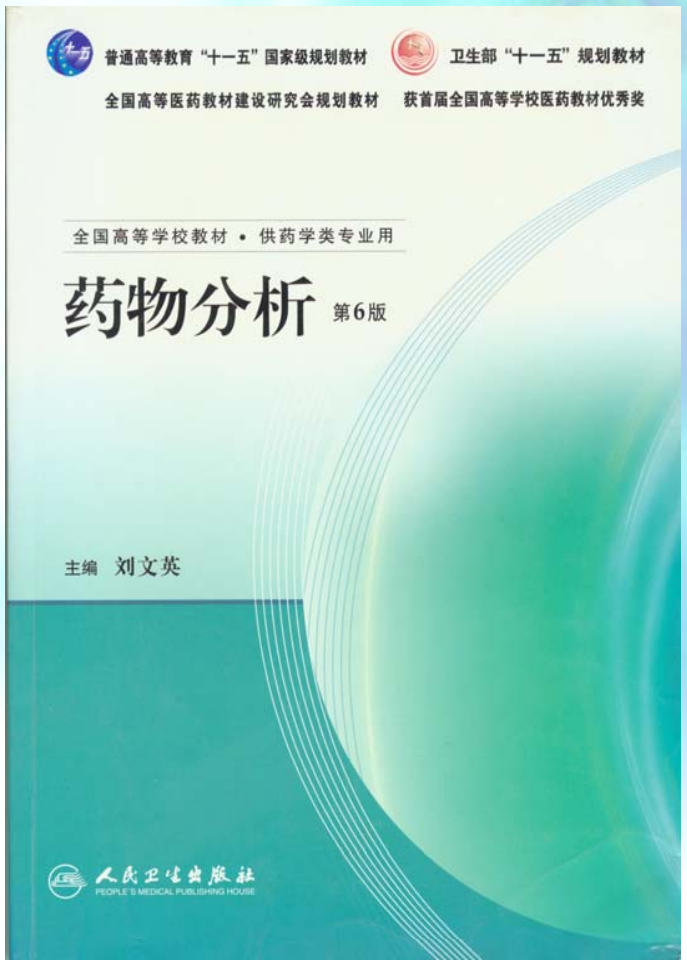


7. 发射光谱分析法、
8. 核磁共振谱法、
9. 质谱法、
10. 色谱理论、
11. 气相色谱法、
12. 高效液相色谱法、
13. 薄层色谱法、
14. 高效毛细管电泳法、
15. 药物分析中的提取分离方法。

刘文英主编《药物分析》

培养目标

- 学生强烈的药品质量观念，
- 具备药物分析知识技能，
- 能够胜任药品研究、生产、供应、使用和监督管理过程中的药物分析工作，
- 注重研究和解决药品质量问题的思路和能力培养，
- 使学生满足国内外医药产业迅速发展的需求。



刘文英主编
《药物分析》目录

绪论（+21章）

第一章 药品质量研究内容与药典概况

第二章 药物的鉴别

第三章 药物的杂质检查

第四章 药物的含量测定方法与验证

第五章 体内药物分析

做什么？
如何做？

药物分析的内容与方法

第六章 芳酸类非甾体抗炎药物的分析

第七章 苯乙胺类拟肾上腺素药物的分析

第八章 对氨基苯甲酸酯和酰苯胺类局麻药物的分析

第九章 二氢吡啶类钙通道阻滞药物的分析

第十章 巴比妥和苯二氮杂 类镇静催眠药物的分析

第十一章 吩噻嗪类抗精神病药物的分析

第十二章 喹啉与青蒿素类抗疟药物的分析

第十三章 莨菪烷类抗胆碱药物的分析

第十四章 维生素类药物的分析

第十五章 甾体激素类药物的分析

第十六章 抗生素类药物的分析

第十七章 合成抗菌药物的分析

如何做好？

第十八章 药物制剂分析概论

第十九章 中药及其制剂分析概论

第二十章 生化药物和生物制品分析概论

第二十一章 药品质量研究中现代分析技术进展

药物分析的相关应用与技术

国外教材的借鉴作用

- 国外专项教材丰富：

  针对药物分析的各类任务都有相对具体的系统全面的专业教学参考材料。

  如新药研究申报中的药物分析、药物有关物质研究分析、药物稳定性研究方法、药物分析方法验证等专著。

- 国外围绕新药研究申报中的药物分析任务编制的教材，值得我国药物分析教学参考

- 借鉴目的：以便学生理论联系实际地掌握好药物分析专业知识和技能，胜任新药创新研究工作需要。

需要进一步引进的6部药物分析教材：

- 1、Satinder Ahuja, Stephen Scypinski. Handbook of modern pharmaceutical analysis, 2010(2Ed), Academic Press, San Diego, USA 现代药物分析指南
- 2、Lena Ohannesian, Antony J. Streeter. Handbook of Pharmaceutical Analysis, **2002,** Marcel Dekker, Inc. New York, USA 药物分析指南
- 3、David C. Lee, Michael Webb. Pharmaceutical Analysis, 2008, Wiley India Pvt. Ltd. 药物分析
- 4、Joachim Ermer, John H. McB. Miller. Method validation in pharmaceutical analysis: a guide to best practice, 2005, Wiley-VCH 药物分析方法验证
- 5、Richard J. Smith, Michael L. Webb. Analysis of drug impurities, 2007, Wiley-Blackwell Publishing Ltd, Oxford, UK 药物杂质分析

这些教材从不同的角度对药物分析方法和技术进行了介绍，对于药物分析的系统学习与掌握、从事新药开发研究均具有良好的参考价值。


谢谢！