全国中医药行业高等教育“十三五”创新教材
National “Thirteenth Five-Year-Plan” Innovative Textbooks for Higher Education in Chinese Medicine Industry
国家级实验教学示范中心·药学及中药学实验系列教材
Experimental Teaching Material Series on Pharmacy and Chinese Materia Medica of National Experimental Teaching Demonstration Center

药学综合实验

Pharmaceutical Integrated Experiments

（汉英对照版）
(Chinese and English Edition)

（供药学、中药学、中药制剂专业用）
(Suitable for Majors of Pharmacy, Chinese Materia Medica and Chinese Pharmaceutics)

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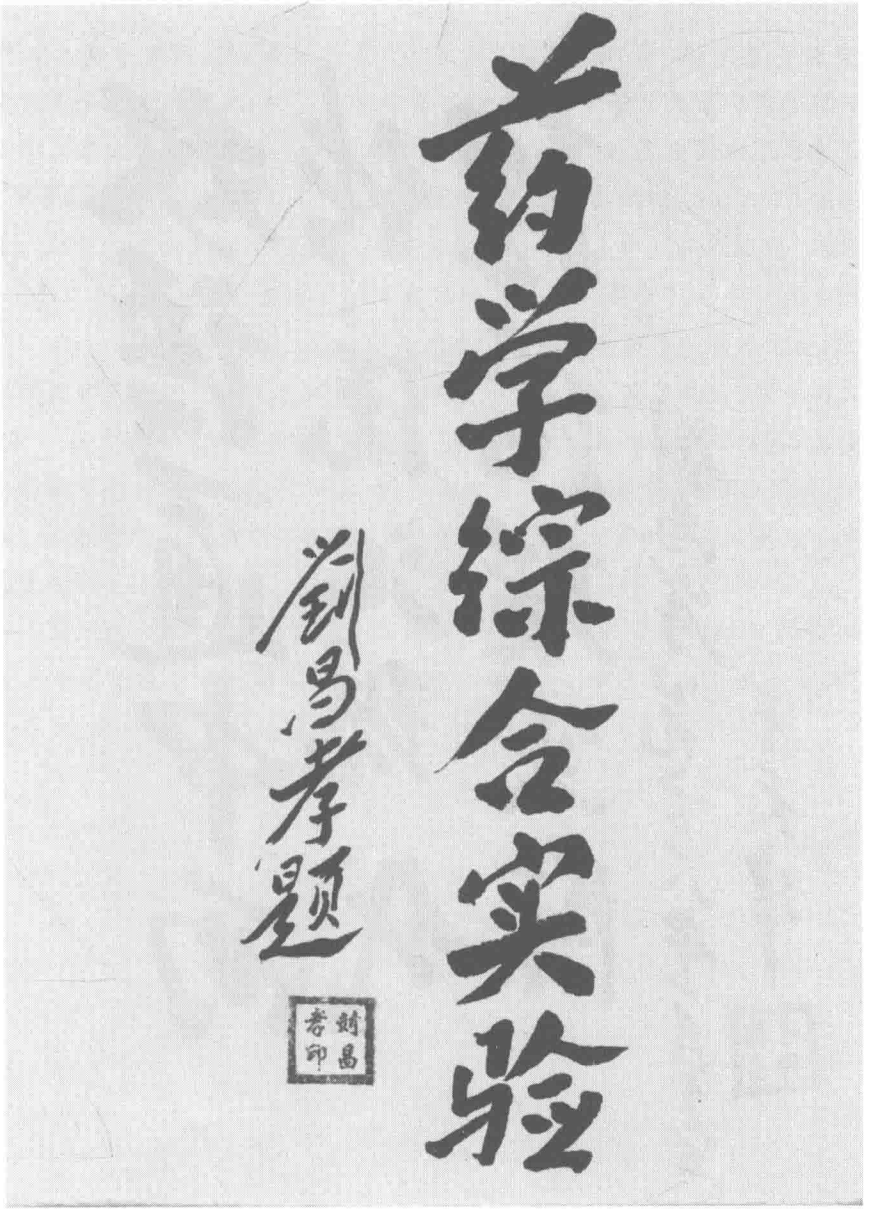
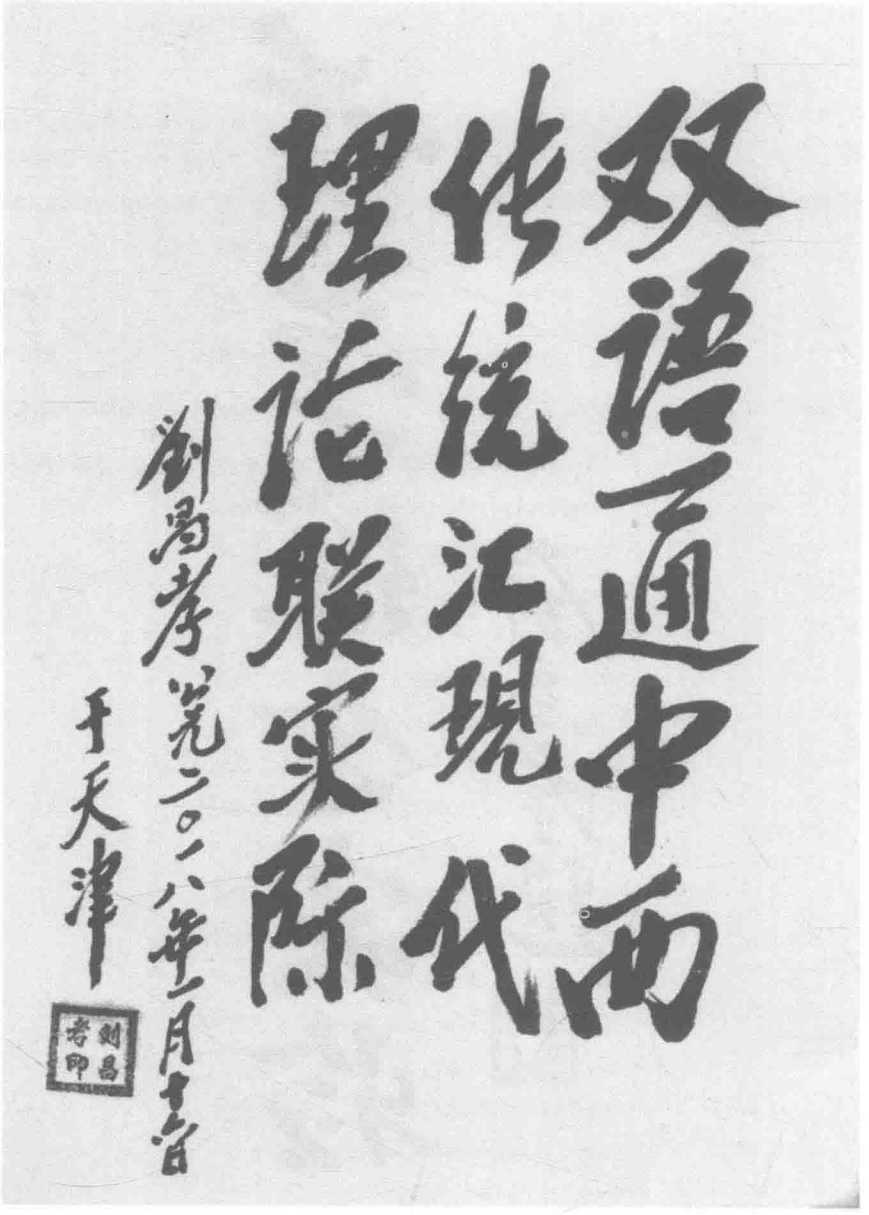


刘昌孝题词（一）



刘昌孝题词（二）

编写说明

本教材是全国中医药行业高等教育“十三五”创新教材和“国家级实验教学示范中心·药学及中药学实验系列教材”。药学综合实验为上海中医药大学中药学院与上海中医药大学中药学国家级实验教学示范中心共同开设的特色课程，主要面向上海中医药大学药学专业（中英合作办学）本科生开设。本课程包括绪论、导学、综合实验、拓展实验和相关知识链接内容。本课程依据现行中药新药研发相关的指导性文件和政策法规，以新药研发为主线，整合了与之相关的包括《生药学》《天然药物化学》《药剂学》《分析化学》和《药理学》等多学科的实验方法、技术和技能，从而提高学生分析问题和解决问题的综合能力，为将来从事天然药物及中药的研发奠定基础。本教材分上下篇。上篇实验篇，为中英文双语对照教材，考虑到中英文语言表达习惯不同，不做逐字翻译；下篇为知识链接篇，主要介绍与天然药物和中药新药研发相关的基本知识、药学文献的查阅和论文的撰写，下篇为中文版，不做双语对照。本教材除供药学专业（中英合作）学生使用外，同时可供中药学和中药制剂专业的本科生及研究生选用。

在教材编写过程中，中国科学院上海药物研究所果德安教授帮助翻译了部分章节，同时果德安教授与英国伦敦城市大学人类科学学院Don Green博士在全书英文审阅、润色方面做了大量工作，在此表示诚挚的谢意。

Writing Explanation

This book is one of the National "Thirteenth Five-Year-Plan" Innovative Textbooks for Higher Education in Chinese Medicine Industry and part of "the Experimental Teaching Material Series on Pharmacy and Chinese Materia Medica of the National Experimental Teaching Demonstration Center". The course of Pharmaceutical Integrated Experiments, as a unique curriculum for the undergraduates of pharmacy (Sino-UK cooperation), is jointly given by the College of Chinese Pharmacology and National Experimental Teaching Demonstration Center, Shanghai University of Traditional Chinese Medicine. This course includes an introduction, learning guidance, integrated experiments, expanded experiment and related knowledge links. Based on the current guidelines and regulations of new drug research and development of Chinese Materia Medica, the course focuses on the new drug research and development and has integrated related experimental methods, techniques and skills from multiple disciplines such as *Pharmacognosy, Natural Medicinal Chemistry, Pharmaceutics, Analytical Chemistry* and *Pharmacology*, etc. so as to improve students' problem analyzing and solving ability and lay the foundation for the engagement in the new drug research and development of Chinese Materia Medica and natural medicines in the future. This textbook is divided into two parts. Part one, written in both Chinese and English, focuses on pharmaceutical experiments. Part two, written in Chinese, mainly introduces basic knowledge related to new drug research and development of Chinese Materia Medica and natural medicines, retrieval of pharmaceutical literatures and scientific paper writing. Considering the different expression nuances of Chinese and English, one should be aware that it is not a literal translation. Besides pharmacy students (Sino-UK cooperation), this teaching material is also available for undergraduates and postgraduates majoring in Chinese Materia Medica and Chinese Pharmaceutics.

We are grateful to Prof. De-an Guo, from Shanghai Institute of Materia Medica, Chinese Academy of Sciences, for his effort in translating several chapters into English; meanwhile, we would like to express our gratitude to him and Dr. Don Green, School of Human Sciences, London Metropolitan University, for their great efforts made for English language and polishing of this book.

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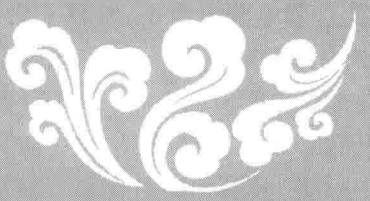
上篇　实验篇

Part One　Experiments



第一章 绪 论

药学综合实验以新药研发为主线，依据现行版《药品注册管理办法》，结合实例，根据中药新药研制的相关研究方法和实验手段，综合运用生药学、天然药物化学、分析化学、药剂学、药理学等学科的相关知识、实验技能和方法，学习研发新药的关键技术问题。课程主要涉及中药新药的药学和部分药理学研究，包括药材的真实性研究、有效成分提取分离和纯化工艺研究、药物剂型选择、质量标准制定和药理学研究等内容。

本课程教学采用中-英文双语和Team-Based Learning（TBL）相结合的教学方法，以组为单位进行。教学内容分为上下两篇，上篇包括导学（文献查阅与综述）、综合实验、论文写作、实验拓展和课程总结汇报五部分，下篇为药学综合实验涉及的相关知识。导学部分要求学生在教师指导下、根据综合实验所选药材查阅国内外近10年相关文献，了解该药材的本草考证、市场问题、药材鉴定方法、含有的化学成分及提取分离方法、有效成分或指标性成分的含量测定方法、主要的药理作用和研究方法、药剂研究现状等，并写成综述，为后续综合实验和拓展试验奠定基础。综合性实验部分，围绕中药或天然药物，以新药研究为背景，介绍相关中药及天然药物新药研究方法和实验技能，使学生将所学相关学科知识融会贯通。实验论文写作部分按科研实验论文要求撰写，对实验出现的问题进行充分讨论，寻求解决办法。拓展实验部分是要求学生在综合实验的基础上、结合查阅文献获得的资料，对感兴趣的待开发部分自行选题、自行设计实验方案；或选择其他天然药物集中命题、学生自主设计完整的实验。课程总结汇报以组为单位，采取中英文双语、PPT形式汇报和答辩。课程汇报答辩包括综合实验和拓展实验两部分。下篇为新药研发知识链接部分，主要介绍中药及天然药物新药研究主要内容、相关法规、新药申报与审批程序、中药及天然药物新药申报资料、中药及天然药物新药研究关键技术和方法，以及药学文献的查阅和论文的撰写。

本课程综合实验和拓展试验旨在增强学生的实验操作技能、独立工作能力、分析问题和解决问题的能力；双语教学旨在提高学生的专业英语水平；TBL教学方法旨在提高学生协调性和团队合作的精神，为药学专业学生今后运用现代实验手段从事天然药物的新药研究开发工作奠定基础。

Chapter 1 Introduction

Pharmaceutical Integrated Experiments is designed to focus on the new drug research and development and based mainly on the latest version of "*Drug Registration Regulation*" (implemented in October of 2007 in China), which aimed at teaching students the key techniques in the new drug research and development process by integrating the knowledge, experimental skills and methods in such disciplines as *Pharmacognosy, Natural Medicinal Chemistry, Analytical Chemistry, Pharmaceutics, and Pharmacology, etc*. The related research approaches and experimental methods in new drug development of Chinese Materia Medica were exemplified with certain showcases. This course is mainly involved in the pharmaceutical section of new drug development chain, including authentication of crude drugs, extraction and purification procedures of effective components, methodological and pharmacological research on setting quality standards, selection of pharmaceutical dosage forms and dissolution, *etc*.

This course will adopt the methods of bilingual teaching (Chinese-English) and Team-Based Learning (TBL). Students will be divided into teams. The teaching content is classified into two parts, in which part One includes learning guidance (literature searching and review writing), integrated experiments, scientific paper writing, expanding experiments, and course summary and report, while part Two is the related knowledge of pharmaceutical integrated experiments. The guidance learning part requires students, under the instruction of teachers, to retrieve literatures related to the selected experimental natural medicine of the last ten years, to learn its textual research, marketing status, natural medicine identification methods, chemical constituents contained and their extraction and purification methods, assay of effective or marker compounds, major pharmacological actions and research method, current situation of pharmaceutical research, and so on, and to write a literature review for the later integrated experiment and expanding experiments. The part of integrated experiments, focusing on new drug research and development of Chinese Materia Medica compound formulas, introduces related new drug research methods and experimental skills of Chinese Materia Medica and natural medicines, and tends to acquaint students with multi-disciplinary knowledge they have learnt. The experimental thesis should be written in accordance with the requirements for writing lab-based research papers and also the existing problems in the experiment should be thoroughly discussed in order to seek a solution. The expanding experiment part requires students to select their interested drug research project and design their own experimental program, based on the integrated experiment and the acquired literature data; or select other assigned natural medicine project to design a complete experiment.

The course summary report will be in groups to report and defend in both Chinese and English with the aid of PPT. The course report and defense should include both parts of integrated experiments and expanding experiments. Part Two is about knowledge of new drug development, including new drug development of Chinese Materia Medica and natural medicines, related policies and regulations, new drug application and review procedures await approval, new drug application dossiers of Chinese Materia Medica and natural medicines, key technologies in new drug research of Chinese Materia Medica and natural medicines, retrival of pharmaceutical literatures and scientific paper writing.

The design of integrated experiment and expanding experiment in this course aims at improving students' experiment operation skill, independent working ability, problem-analyzing and solving ability. Bilingual teaching may improve the professional English level of students. The TBL teaching method could enhance the coordination ability and spirit of teamwork and lay a solid foundation for pharmaceutical students to engage in the new drug research and development of natural medicines with the application of modern experimental means.

第二章　导　　学
Chapter 2　Learning Guidance

第一节　药学综合实验简介
1　Brief Introduction to the Pharmaceutical Integrated Experiments

传统实验教学大多是单一型实验，是针对某一课程的单一知识点、用单一方法或技能所设置的实验，旨在加强学生对某一知识点采用单一方法进行的验证性的技能训练，即使是课程内的综合型实验，综合的也仅仅是同一课程的不同知识点、不同方法或技能。

现代综合性实验大多是指实验内容涉及一门课程的综合知识或与本课程相关课程知识的实验，其内容应涉及一门课程或者多门课程的多个知识点，是对多项实验内容的综合。本教材设计的药学综合实验是上海中医药大学教学改革的创新实验。本教材以天然药物(或中药)新药研发的基础研究为主线，在整合了生药学、天然药物化学、药剂学、药物分析、药理学的教学资源的基础上开展的集探索性、设计性、TBL和双语实验教学为一体的多样式药学综合实验教学。实验目的是提高药学或中药学专业的教学质量、培养学生实际动手能力、专业知识综合运用能力、自主学习和创新精神，提高学生的专业英语水平，以达到提高学生的综合素质，培养复合型和创新型药学人才的目的。

The conventional experimental teaching is often designed with a single type of experiment, introduces a single method or skill, and focuses on a single knowledge point of a certain course, which aims at deepening students' understanding on a certain knowledge point through the confirmatory skill training with a single method. Even in the case of an intra-curriculum integrated experiment, it only integrates different knowledge points, methods or skills within the same course.

Modern integrated experiments mostly refer to experiments involving comprehensive knowledge of a course or related knowledge from other courses. The design of pharmaceutical integrated experiment designed in this book is an innovation of the educational reform of

Shanghai University of Traditional Chinese Medicine. With the fundamental investigation on the new drug research and development of natural medicines (or Chinese Materia Medica) as the principle line, this book is a diversified pharmaceutical comprehensive experimental teaching material which integrates exploration, designability, TBL, and bilingual experimental teaching by integrating instructional resources of *Pharmacognosy, Natural Medicinal Chemistry, Pharmaceutics, Pharmaceutical Analysis, and Pharmacology*. The reform purpose of these experiments is to enhance the teaching quality for the major of Pharmacy or Chinese Materia Medica, to train students' practical operational ability, comprehensive application competence of the professional knowledge, self-learning ability and innovative spirit, to improve their professional English levels, and finally advance their comprehensive quality and cultivate interdisciplinary and innovative pharmaceutical talents.

第二节 药学专业知识在综合实验中的综合应用

2 Comprehensive Application of Pharmaceutical Knowledge in Pharmaceutical Integrated Experiments

药学综合实验要求学生必须完成生药学(或中药鉴定学)、天然药物化学(或中药化学)、药剂学(或中药药剂学)、药物分析(或中药分析)、药理学(或中药药理学)、药学文献检索(包括中药文献检索)和科研论文写作等课程学习后方可选课。以下是各学科知识的综合运用和主要知识点。

国内常用的生药绝大多数是在历代本草中已有记载的中药。由于历代本草记载、地区用语、地区用药习惯的不同,部分中药外形相似以及人为造假等原因,使中药材品种混乱现象严重,常有同名异物、同物异名现象发生,如中药女贞子,别名冬青子,为木犀科植物女贞 *Ligustrum lucidum* Ait.的果实,在某些地区同科植物冬青 *Ilex chinensis* Sims的果实亦作为女贞子药用。该药既存在同名异物现象,又有同物异名问题。另外中药一药多基原情况较为普遍,如大青叶在历史上不同地区用药习惯不同,分别有不同科的植物叶入药,分别为十字花科植物菘蓝 *Isatis indigotica* Fort.、蓼科植物蓼蓝 *Polygonum tinctorium* Ait、爵床科植物马蓝 *Strobilanthes cusia* (Nees) O. Ktze和马鞭草科植物大青 *Clerodendrum cyrtophyllum* Turcz.。利用生药学或中药鉴定学知识进行真实性鉴定即基原鉴定是保证中药使用的安全、有效及质量可控的基础,是一切中药研究的前期保障,基原一错,满盘皆否。中药的真实性鉴定依据《中华人民共和国药典》及各级药品标准进行,即根据该中药的性状、显微、理化等特征,鉴定其原植(动)物学名。在鉴定生药(或中药)的真伪优劣实验方面,本实验设计提供多基原药材及易出现混乱品种的未知生药,要求学生利用生药学和分析化学知识相结合鉴定原材料的真伪优劣,从中选出优质、正品药材,为后续主要化学成分的提取分离等实验提供保障。

在正确选择了实验用药材的基础上,利用天然药物化学知识设计科学可行的提取分离