普通高等教育“十一五”国家级规划教材

全国高等医药院校药学类实验双语教材

QUANGUO GAODENG YIYAO YUANXIAO YAOXUELEI SHIYAN SHUANGYU JIAOCAI

药物分析实验与指导

（第二版）

〔主编 狄 斌〕

PHARMACEUTICAL ANALYSIS —— EXPERIMENTS AND INSTRUCTIONS

〔SECOND EDITION〕

中国医药科技出版社

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Pharmaceutical Analysis——Experiments and Instructions

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内 容 提 要

《药物分析实验与指导》是根据高等医药院校药学类各专业药物分析实验课程的基础要求，结合长期实验教学实践编写而成。全书共分为7章，包括一般性实验指导，药物的性状、鉴别和检查，药物的含量测定，药物质量的全检验，体液样品中药物的分析，设计性试验，分析方法验证。27个实验全部采用中英文对照，便于双语实验教学。

本书可供药学类院校的本科及专科学生使用。

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全国高等医药院校药学类规划教材常务编委会

出 版 说 明

全国高等医药院校药学类规划教材是目前国内体系最完整、专业覆盖最全面、作者队伍最权威的药学类教材。随着我国药学教育事业的快速发展，药学及相关专业办学规模和水平的不断扩大和提高，课程设置的不断更新，对药学类教材的质量提出了更高的要求。

全国高等医药院校药学类规划教材编写委员会在调查和总结上轮药学类规划教材质量和使用情况的基础上，经过审议和规划，组织中国药科大学、沈阳药科大学、广东药学院、北京大学药学院、复旦大学药学院、四川大学华西药学院、北京中医药大学、西安交通大学医学院、华中科技大学同济药学院、山东大学药学院、山西医科大学药学院、第二军医大学药学院、山东中医药大学、上海中医药大学和江西中医学院等数十所院校的教师共同进行药学类第三轮规划教材的编写修订工作。

药学类第三轮规划教材的编写修订，坚持紧扣药学类专业本科教育培养目标，参考执业药师资格准入标准，强调药学特色鲜明，体现现代医药科技水平，进一步提高教材水平和质量。同时，针对学生自学、复习、考试等需要，紧扣主干教材内容，新编了相应的学习指导与习题集等配套教材。

本套教材由中国医药科技出版社出版，供全国高等医药院校药学类及相关专业使用。其中包括理论课教材82种，实验课教材38种，配套教材10种，其中有45种入选普通高等教育“十一五”国家级规划教材。

全国高等医药院校药学类规划教材

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2009年8月1日

序

实验教学是高等药学院校最基本的教学形式之一，对培养学生科学的思维与方法、创新意识与能力，全面推进素质教育有着重要的作用。飞速发展的科学技术，已成为主导社会进步的重要因素。高等药学院校必须不断更新教学内容，以学科发展的前沿知识充实实验课程内容。

近年来，中国药科大学坚持以研究促教改，通过承担教育部“世行贷款——21世纪初高等教育教学改革项目”及立项校内教改课题等多种方式，调动了广大教师投身教学改革的积极性，将转变教师的教育思想观念与教学内容、教学方法的改革紧密结合起来，取得了实效。此次推出的国家“十一五”规划教材——药学专业双语实验教学系列，是广大教师长期钻研实验课程教学体系，改革教学内容，实现教育创新的重要成果。他们站在21世纪教育、科技和社会发展趋势的高度，对药学专业实验课程的教学内容进行了“精选”、“整合”和“创新”，强调对学生的动手能力、创新思维、科学素养等综合素质的全面培养。这套教材具有以下的特点：

1．教材将各学科的实验内容进行了广泛的“精选”，既体现了高等药学教育“面向世界、面向未来、面向现代化”，也考虑到我国药学教育的现状与实际；既体现了各门实验课程自身的独立性、系统性和科学性，又充分考虑到各门实验课程之间的联系与衔接，有助于学生在教学大纲规定的实验教学学时内掌握基本操作技术，提高动手能力，养成严谨、求实、创新的科学态度。

2．教材中新增的综合性、设计性实验有利于学生全面了解和综合掌握本门实验课程的教学内容。这一举措既满足了学生个性发展的需要，更注重培养学生分析问题、解决问题的能力和创新意识。

3．教材中适当安排一些反映药学学科发展前沿的实验，有利于学生在掌握实验基本技术的同时，对药学学科的新进展、新技术有所了解，激发他们学习药学知识与相关学科的兴趣。

4．教材以实践教学为突破口，采用双语体系编写，为实验课程改革构建数字化、信息化和外语教学的平台，有利于提高学生的科技英语水平。通过我校多年的药学系列实验课程双语教学实践，证明学生完全能够接受此套教材的教学。

国家十一五规划教材——药学专业双语实验教学系列教材的陆续出版，必将对推动我国高等药学教育的健康发展，产生积极而深远的影响。由于采用双语体系编写药学教学实验丛书尚属首次，缺乏经验，在内容选择及编写方法上的不妥之处，在所难免。欢迎从事药学教育的同行们批评赐教。

（中国药科大学校长、博士、教授、博士生导师）

Preface

Experimental teaching is one of the most fundamental teaching means in pharmaceutical colleges, playing an important role in training scientific thoughts and methods, creative consciousness and ability of the students as well as in promoting quality-oriented education in all-round way. Fast-advancing science and technology has come to be an important factor in dominating social progress. Teaching materials must be updated continually in pharmaceutical colleges, especially enriching the materials of experimental courses with the most advanced knowledge in the subject.

In recent years, China Pharmaceutical University have been stressing the promotion of teaching reform on the basis of research, succeeding in stimulating teachers' enthusiasm for teaching reform by various means such as undertaking the project of teaching reform in higher education at the beginning of 21st century sponsored financially by World Bank and entrusted by the Ministry of Education as well as approving and ratifying internal programs on teaching reform. Meanwhile, it yields fruits to integrate the transforming of teachers' educational ideology into the reform of teaching materials and methods. This series of textbook of national "the Eleventh Five-Year Plan" bilingual pharmaceutical experimental teaching series, is an important achievement made through studying ueaching system of experimental courses for long, reforming teaching materials and carrying out educational innovation of all the teachers concerned.

Meeting the new demands for education, science and technology and social growth, they select, integrate and innovate the teaching materials of pharmaceutical experimental courses, stressing the overall cultivation of comprehensive qualities, including experimental ability, creative thought and scientific attainments. This set of textbook possesses the following features:

1. These textbooks make an extensive "selection" of the experimental materials of each subject, reflecting the goal of facing the world, facing the future and facing the modernization in higher pharmaceutical education, and taking into account the status quota and reality of our pharmaceutical education; meanwhile embodying the individuality, systematicness and scientificalness of each experimental courses, which helps the students to grasp basic techniques of operation within the class hours of experimental teaching pre-

scribed by teaching syllabus and to improve their experimental ability and finally to cultivate a scientific approach of precision, practicality and creation.

2. The comprehensive designing experiments newly supplemented in the textbooks help the students to learn totally and grasp comprehensively the teaching materials of the experimental courses, which not only meets the students' needs for individual development but also trains their ability to analyze and solve problems and cultivates their creative consciousness.

3. Some experiments representing the latest development in pharmacy are properly included in the textbooks, which helps the students to learn about new advance and technology in pharmacy and to further arouse their interests in studying pharmacy and relevant subjects while grasping some basic techniques of experiment.

4. The textbooks take experimental teaching as starting point and are compiled in a system of bilingualism and aim to set up a platform of digitalization, information and foreign language teaching for the purpose of reforming experimental courses, which serves to enhance the students' level of technological English. It has been proved that the students have no difficulty being adapted to the teaching of this set of textbook through many years of bilingual teaching practice carried out in a series of pharmaceutical experimental courses of our university.

The successive publishing of the series of textbooks used for bilingual pharmaceutical experimental teaching-the national "the Eleventh Five-Year Plan" textbooks, will surely produce good and far-reaching influence in promoting the sound development of higher pharmaceutical education of our country. Since it is the first time that we have compiled this series of textbook of pharmaceutical teaching experiment in a bilingual system, we lack experience and thus some defects in choice of materials and way of compilation are inevitable. Experts engaged in pharmaceutical education are welcome to give any criticisms and advice.

Wu Xiaoming

Ph. D, prof., and supervisor of doctoral candidates
President of China Pharmaceutical University

第二版前言

药物分析学是运用经典和现代分析测定方法研究药品性质、制订药品质量标准、控制药品质量的一门综合性应用学科。

《药物分析实验与指导》是药物分析课程的配套教材之一，本书采用中英文双语编写。由七个部分组成，包括一般性实验指导、药物的性状鉴别和检查、药物的含量测定、药物质量的全检验、体液样品中药物的分析、设计性实验和分析方法验证等。其中药物分析的操作规范及通用方法贯穿于各实验指导中。通过典型的药物分析实验实践，学生能掌握药物分析的基本程序、内容和操作规范。

本书实验部分选择了具有代表性的一些药品以及分析对象，包括化学药物、中药及其制剂、体内样品。涉及的分析方法主要有化学分析、容量分析以及仪器分析。而仪器分析在本版教材中所占比重有所增加。实验中的分析方法主要依据2010年版《中国药典》进行了有代表性的选择，但新版药典分析方法较多地采用了仪器分析方法，尤其是含量测定方法较普遍使用了HPLC方法，这并不利于学生学习掌握多种分析方法和手段。因此本书在新版药典基础上进行了内容的更新，同时也保留了前一版教材中一些较为经典的方法，例如复方磺胺甲 唑片的质量分析，虽然新版药典已采用了HPLC方法进行含量测定，但考虑到双波长分光光度法的特点，在本书中仍进行了保留。

通过本实验课程的学习，既增强了学生对药物分析理论知识的理解，又规范了其基本操作。在设计性实验环节培养了学生进行药物分析研究的基本思路和独立从事药物分析研究的基本实验技能。

本书在中国药科大学药物分析教研室及其兄弟院校的药物分析教学积累基础上，参照2010年版《中国药典》的标准和相关文献，对杭太俊教授主编的2003年版《药物分析实验与指导》进行了修订。本书对前一版教材中未翻译

的操作规程和方法重新进行了双语的编写，并将其贯穿于各实验项目的实验指导项下，不再另列“药物检验操作规程”。由于篇幅的限制，对前一版教材中部分实验项目进行了增减，并仅将实验中涉及到的部分经典或有特点的方法列入本书，实验中多次使用的方法不再重复赘述，但可通过本书附录查阅。本书第二章、第三章、第四章、第五章分别由中国药科大学宋沁馨、宋敏和柳文媛，河北医科大学王巧，第二军医大学洪战英，桂林医学院徐勤，沈阳药科大学赵云丽以及上海市食品药品检验所乐健编写，其余部分由狄斌编写。感谢史志祥教授、刘文英教授和杭太俊教授及中国药科大学教务处对本实验教材的编写给予的悉心指导。

本书可供药学类本科学生药物分析实验教学使用，同时可供从事药品研究、生产和检验的相关专业人员参考。

因时间有限，书中疏漏之处，敬请读者批评指正。

编　者

2010 年 6 月

Preface to the Sencond Edition

Pharmaceutical Analysis is a comprehensive applied discipline applying classical and modern analytical techniques for the study of drug properties, setting of standards for drug quality and its control.

The book "Pharmaceutical Analysis——Experiments and Instructions" is the supporting workbook for the theorectical course of pharmaceutical analysis. This bilingual workbook consists of seven chapters, including general instructions, description, identification tests, assays, drug analysis, determination of drugs in body fluids, designing experiments and the validation of analytical methods. The operation procedures and general methods for pharmaceutical analysis are included in various experiments. Through the practice of a typical experiment of pharmaceutical analysis, students can master the basic procedures, contents and operation procedures for pharmaceutical analysis.

In the chapter of experiments, some representative drugs and substances were chosen for analysis, including chemical drugs, traditional Chinese medicines and their preparations as well as samples *in vivo*. Chemical, volumetric (titrimetric) and instrumental analyses were mostly used. The proportion of instrumental analysis has been added in this edition. Based primarily on the 2010 edition of "Chinese Pharmacopoeia", typical analytical methods were selected into this book. However, this book did not include as many instrument analytical methods, especially HPLC methods, as they are included in the 2010 Pharmacopoeia, because that does not help students learn a variety of analytical methods. Thus while updating this book, some classical methods from the previous edition have retained. For example, considering its specialty, dual-wavelength spectrophotometry was used to analyze the compound sulfamethoxazole tablets, although HPLC method was adopted in the 2010 Pharmacopoeia.

This experimental course helps enhance the students' understanding of the theories and standardize their basic operations. Through the experiments designed, students can learn the basic principles and the fundamental skills for independent research of pharmaceutical analysis.

On the basis of the teaching experience of the Department of Pharmaceutical Analysis of China Pharmaceutical University (CPU) and other universities, the 2010

edition of Chinese Pharmacopoeia and related literature, this book is a revised edition of Prof. Tai-Jun Hang's 2003 edition of "Experiment and Guide for Pharmaceutical Analysis". The untranslated operation procedures and methods in the previous edition have been translated into English in the current edition and have been included in the guidance part of each experiment, instead of being put in a separate part of the Operation Procedure. Due to space restrictions, only the typical methods were included in this book while those used many times were deleted, yet with reference in the appendix. Chapters Ⅲ, Ⅳ and Ⅴ were edited by Qin-Xin Song, Min Song, and Wen-Yuan Liu of China Pharmaceutical University, Qiao Wang of Hebei Medical University, Zhan-Ying Hong of Second Military Medical University, Qin Xu of Guilin Medical University, Yun-Li Zhao of Shenyang Pharmaceutical University and Jian Le of Shanghai Institute for Food and Drug Control, and the rest were prepared by Bin Di as the chief compiler. We are acknowledged to Professor Zhi-Xiang Shi, Professor Wen-Ying Liu and Professor Tai-Jun Hang for their help and instructions. Thanks also go to the Teaching Affairs Office of China Pharmaceutical University for their supervision.

As a laboratory workbook of pharmaceutical analysis for students in pharmacy, this book is also a good reference for those engaged in the research, manufacturing and quality control of drugs.

Due to lack of time, there may be some mistakes in this book. Your suggestions for further improvement are greatly appreciated.

Author

June, 2010

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