



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

06

(第3版)

药物分析 实验与指导

Experiment and
Guide for
Pharmaceutical Analysis

◎主编 宋 敏

中国医药科技出版社



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药物分析

Experiment and Guide for Pharmaceutical Analysis

实验与指导 (第3版)

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内 容 提 要

本书是“全国高等医药院校药学类实验双语教材”系列之一。药物分析是一门实践性很强的学科，而实验课是培养学生掌握药物分析基本实验技能必不可少的。本书采用中英文双语编写，全书分为七章，由一般性实验指导、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，生物样本中药物的分析，设计性实验和药物分析方法验证等组成。本书可供药学类本科师生使用，同时可供从事药品研究、生产和检验的相关专业人员参考。

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前 言

药物分析是运用经典的化学、物理学及生物学等方法和现代仪器分析方法研究药物性质、制订药物质量标准、控制药物质量的一门综合性应用学科，广义上包括了药物的化学检验、质量控制以及体内药物分析等内容。药物分析是一门实践性很强的学科，药物分析实验课培养学生掌握药物分析研究中的基本实验技能，使其具备基本的科学实验的思路和方法。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和内容，熟悉并掌握药物检验的操作规范与要求。

《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，生物样本中药物的分析，设计性实验和药物分析方法验证等七个部分组成。在药品质量评价方面，选取具有代表性的化学原料药及其制剂、中药及其制剂，分别采用化学分析、容量分析和仪器分析方法，从鉴别、检查和含量测定三个方面设计实验内容。在临床药物分析方面，针对常见药物及毒物的常用生物样本前处理和测定方法进行编写。本书药品类别多、方法手段齐全，可使实验者的药物分析实践能力得到多方面锻炼，难度包括验证性和设计性实验两个层次可供不同能力的实验者选用，以便于培养实验者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。实践教学可以根据学时和实验条件选择分项检测、测定或全检验进行。

本实验分析方法是在保留前两版教材中一些经典方法的基础上，依据《中国药典》2015年版进行补充，并将药物分析的操作规范及通用方法贯穿于各实验指导中，以便于实验者掌握多种分析方法和手段，既增强实验者对药物分析理论知识的理解，又锻炼和规范了实验操作。

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《中国药典》2015年版的标准和相关文献，对狄斌教授主编的2010年版《药物分析实验与指导》进行了修订。本书第二章、第三章、第四章、第五章、第六章分别由中国药科大学宋沁馨、郑枫、吴春勇、苏梦翔，河北医科大学许慧君、桂林医学院徐勤、沈阳药科大学赵云丽编写，其余部分由宋敏编写。感谢张桂军教授、狄斌教授和杭太俊教授对本实验教材编写给予的悉心指导。中国药科大学教务处

和参编院校对本教材编写给予的关心和支持，在此一并表示诚挚的谢意。

本书可供药学类专业本科师生使用，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，书中难免有疏漏错误之处，敬请读者批评指正。

编 者

2015年6月

Preface

Pharmaceutical analytics is a comprehensive applied discipline that uses classical chemical, physical and biological measures and modern analytical techniques to study drug properties, to establish the drug standards and to control the drug quality. It generally includes the physical and chemical inspection of drugs, quality control and biomedical analysis. Pharmaceutical analytics is a practical subject, and the experimental course helps student to master the fundamental experimental skill and basic methods in pharmaceutical analysis and to have the common sense of scientific experiment. Through the practice of typical experiments of pharmaceutical analysis, students can grasp the basic procedures and contents, and will be familiar with the standard operation procedures and requirements of drug quality control.

The book “Experiment and Guide for Pharmaceutical Analysis” is a supporting material of the pharmaceutical analysis course. This bilingual book consists of seven chapters, including general instructions, description, identification tests, assays, drug analysis, determination of drug in bio-sample, designing experiments and the validation of analytical methods. For drug quality control, the typical chemical medicines, Chinese medicines and their preparations are chosen as analytical objects, and the mostly used methods including chemical, volumetric and instrumental analyses were covered, identification, tests and assay were arranged in experimental content. In the terms of biomedical analysis, this book contains the common pretreatment and analysis methods for usual medicines and toxics. In experiment contents, the representative drugs and substances were carefully selected, and the methods employed are comprehensive, which can train the students in all the aspects. There were two difficulty levels, i. e. validation and design experiments that will help students enhance the basic principles and fundamental skills for independent research of pharmaceutical analysis. The practice teaching can be arranged according to the number of the course hours and the facility conditions.

Primarily based on the 2015 edition of “Chinese Pharmacopoeia”, representative

analytical methods were selected into this book, while some classical methods from the previous two editions were retained. The operation procedures and general methods for pharmaceutical analysis are included in various experiments, which will help students master a variety of analytical methods, and enhance the understanding of theories and standardize the operations. On the basis of teaching experience of Department of Pharmaceutical Analysis of China Pharmaceutical University and other universities, and the 2015 edition of “Chinese Pharmacopoeia” and related literatures, this book is a revised edition of Prof. Bin Di’s 2010 edition of “Experiment and Guide for Pharmaceutical Analysis”. Chapter 2, 3, 4, 5 and 6 were edited by Qinxin Song, Feng Zheng, Chunyong Wu, Mengxiang Su of China Pharmaceutical University, Huijun Xu of Hebei Medical University, Qin Xu of Guilin Medical College, Yunli Zhao of Shenyang Pharmaceutical University, and the rest were prepared by Min Song as the chief compiler. We are acknowledged to Prof. Guijun Zhang, Prof. Bin Di and Prof. Taijun Hang for their help and instructions. Thanks also go to the Teaching Affairs Office of China Pharmaceutical University and other universities in this book for their supervision.

As an experiment instruction of pharmaceutical analysis for students of pharmacy, and it is also a good reference book for those engaged in research, manufacturing, and quality control of drugs.

Please correct for the mistakes in this book. Your suggestions for further improvement are greatly appreciated!

Editors
June, 2015

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第一章 一般性实验指导

Chapter 1 General Instructions

第一节 实验室安全守则

- (1) 时刻注意眼睛防护（佩戴防护目镜）。
- (2) 实验室中禁止饮食。
- (3) 实验室中严禁吸烟。
- (4) 接触具有腐蚀性的、有毒的、易燃的及其他危险的化学品必须戴手套并穿着实验服。
- (5) 尽量避免单独工作。
- (6) 避免吸取试剂时用嘴吸移液管。
- (7) 及时提醒他人终止危险的实验操作。
- (8) 务必清楚各种安全设备（洗眼喷淋、淋浴水龙头、灭火器等）的位置。
- (9) 使用新试剂前仔细阅读化学品安全说明书（MSDS）。
- (10) 掌握常见化学试剂污染的清理方法，熟悉防泄漏推车的位置、容量，以及使用方法。
- (11) 接触化学试剂后及进食前请洗手。
- (12) 实验室禁止穿着短裙、短裤、凉鞋。
- (13) 实验服不应在实验室以外场所穿着。
- (14) 实验操作过程中禁止听音乐，尤其是佩戴耳机。

Section 1 Laboratory Safety

- (1) Eye protection glasses must be worn at all times.
- (2) Food/drink is not allowed in laboratories where chemicals are used/stored.
- (3) Smoking is prohibited in the laboratory.
- (4) Lab coats must be worn while handling corrosive, toxic, or flammable materials. Gloves must be worn when necessary, especially when handling corrosives, toxic and danger-

ously reactive materials.

(5) Do not work alone.

(6) Do not mouth pipet.

(7) If you see a colleague doing something dangerous, point it out to him or her.

(8) Be sure to know where safe facilities(eyewash, shower hydrant and fire extinguisher) is located.

(9) Always read material safety data sheet(MSDS) before handling new chemicals.

(10) Know how to clean up spills of common chemicals you see. Be familiar with the locations and contents of spill carts and the way to use them.

(11) Always wash your hands after handling chemicals and before eating.

(12) Mini-skirts, shorts, and open shoes must not be worn.

(13) Lab coats must not be worn outside laboratories or in public areas.

(14) Avoid wearing a walkman or other portable music devices while working in the lab.

第二节 天平使用规程

一、天平的种类

实验时,常需进行各种不同的称量操作。认识这些称量要求的准确度对于实验操作者来说是很重要的。不同的准确度要求应该使用合适的天平来称量。通常可供使用的天平分为两大类。

1. 托盘天平

托盘天平的准确度可以达到 $\pm 1\text{mg}$,适用于只要求保留两到三个有效数字的大多数称量。

2. 分析天平

分析天平的准确度通常可以达到 $\pm 0.1\text{mg}$,在要求保留四位,甚至更多的有效数字时使用。

二、称量的不同类型

在实验过程中,质量数值的表示形式通常有以下几种。

(1)“称出约 2g 的……”这种表述是指应当称取近似 2g ,其质量的准确度要求不高,托盘天平就可以满足要求。

(2)“准确称量约 0.2g 的……”这种表述是指应当使用分析天平称量接近 0.2g 的该物质,确切称样量必须达到 $\pm 0.1\text{mg}$ 的准确度。注意,这并不要求称样量准确至 0.2000g ,在 0.1900g 至 0.2100g 之间都符合要求。无论怎样,必须知道最接近十分之一毫克的量。重复称量三次样品时,并不要求三次称量结果完全相同实际上也没有必要。

三、电子分析天平使用规则

称量是实验室最常进行的操作之一,使用的仪器是分析天平。各厂商的各种不同

型号的分析天平可供使用。以 Mettler AT261 Delta Range 天平为例说明电子分析天平的使用规则。

1. 电子分析天平简介

电子分析天平最主要的部件包括称量盘、天平箱门、显示屏、控制面板、水平脚和水平仪（图 1-1）。

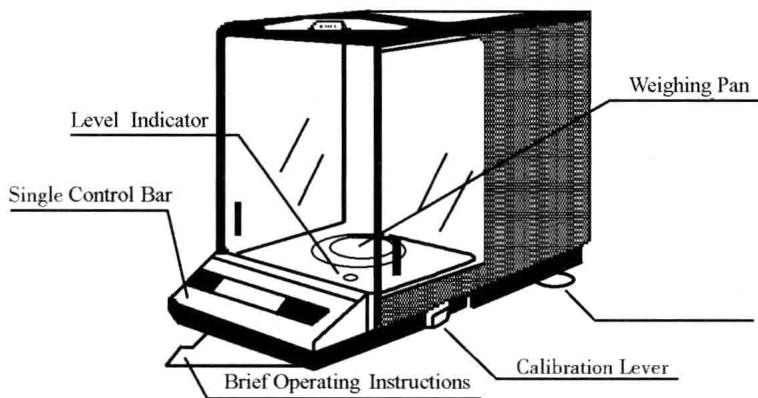


图 1-1 电子分析天平

2. 天平放置

称量结果的准确度（或可靠性）与天平所处的环境密切相关。实验台应该水平、防震。必要时可将天平置于一较重的抗磁材料上，如石头（不可以是金属板）；天平应远离静电电荷（无塑料或玻璃），应与墙壁保持一定距离（防止由于墙体或地板震动对天平产生影响）。

3. 称量容器选择

（1）称量待加热的液体时通常选择烧杯，而在反应中会产生气体的物质时应使用锥形瓶进行称量。塑料称量船（蒸发皿）只用于称量固体，称量少量固体时也可使用称量纸。

（2）尽量使用较小的容器进行称量。

（3）确保称量器皿干燥清洁，因为容器附着物可能引起称量结果偏高。

4. 天平开启

（1）检查天平称量盘上及周围有无散落物质，用专用的天平清理刷清扫称量盘及天平箱内部。将称量盘垂直提起，检查有无散落物质，用清理刷清理后，小心地将称量盘安置原位。

（2）水平仪上的空气泡应处于中央，必要时可通过旋转水平脚来校正。

（3）插好天平插头。

（4）关好天平门，轻按 control 键后松开，控制面板将显示如下并持续几秒钟。

8.8.8.8.8.8.8.8. g

接着天平显示为



0.0000 通常在开启天平时显示，如果没有如上显示或者数字出现缓慢，应确认天平是否处于防震、防气流环境下以确保稳定的零点。

(5) 使用前，保持天平接通电源并开启一段时间，使系统达到热平衡。

5. 去皮和读数

(1) 选择合适的量程，称量容器置于称量盘，关闭天平门。

(2) 按下红色的 Tare 按键去皮，可多次进行直到显示数字为零。

(3) 将待称量样品置于称量盘中央或者称量容器中。

(4) 待显示器读数稳定并显示出质量单位 g (mg) 时可以读数。

(5) 读数后移出样品。

6. 天平清理并关闭

(1) 离开天平前，使用清理刷清扫散落的物质并擦干液体。

(2) 清理结束后，关闭天平门，清零，使天平处于备用状态，方便其他操作者使用。

7. 注意事项

(1) 称量过程中多称的物质应回收到一个废液缸，不可放回原容器，以免造成整瓶试剂的污染。

(2) 称量物体时，为了防止气流干扰读数，务必关上天平门。完成称量时，为了防止灰尘进入天平，操作者应该关上门。

(3) 称量时不要用手直接接触待测物。手指上的湿气、油脂和灰尘会影响待测物的质量。

(4) 为了称量准确，所有物品的温度应当是室温。温度较高的物体会提高天平外壳的运流电流，会导致测定结果偏低。天平内的热空气密度小于原本室温下空气的密度，这是产生负误差的原因之一。

(5) 不要让待测的化学物质直接接触天平托盘。使用容器称量，如烧杯、容量瓶，或者称量瓶。

(6) 从干燥器里取出的物体会吸湿而使质量增加，操作者应当养成在相同的时间间隔进行称量的习惯。例如，如果进行称量坩埚至恒重的操作，操作者每次读数的时间都应当保持在将坩埚放入天平盘后 5 秒的时间点，以此最大程度减少因吸湿产生的影响。

(7) 勿将化学物质溅入天平内。如果不慎溅入，立刻清理。

Section 2 Protocol for Using Balance

1. Types of balances

During the experiment, you need to make a variety of weighings. It is important for you to realize with what sort of accuracy these weighings should be made. Depending on the desired accuracy, you should use the proper balance to make your weigh-

ings. There are two types of balances available :

1.1 Top-loading balances

These will weigh to an accuracy of ± 1 mg and are suitable for most weighings of amounts that are specified to only two or three significant figures.

1.2 Analytical balances

These will weigh to an accuracy of ± 0.1 mg and must be used whenever you desire four or more significant figures accuracy.

2. Various types of weighing

When mass amounts are specified in experiment procedures, the following terms are commonly used.

2.1 “Weigh out about 2g of……” means that you are required to weigh an amount of approximately two grams. The accuracy to which this mass amount needs is not high and the top-loading balance will suffice.

2.2 “Accurately weigh out about 0.2g of……” means that you should, with the aid of the analytical balance, weigh out an amount that is close to 0.2g, but you must know the exact amount to an accuracy of ± 0.1 mg. Note that it does not mean that you must weigh out exactly 0.2000g. An amount between 0.1900g and 0.2100g is perfectly acceptable. However, you must know the exact amount to the nearest tenth of a milligram. When weighing out triplicate samples, it is not necessary that all three weights be exactly the same, indeed, it is poor procedure to attempt to do so.

3. Protocol for using the electronic analytical balance

Weighing is one of the most frequently performed procedures in the lab. Several different models of balance exist to accomplish this operation and may be obtained from their respective manufacturers. But this protocol will specifically refer to Mettler AT261 Delta Range as an example.

3.1 Description of the electronic analytical balance

The most important parts of the balance are the balance pan, the balance doors (draft shield), the digital display, the control bar, the level indicator and leveling screws.

3.2 Location

The accuracy or reliability of weighing results is closely associated with the location of the balance. The weighing bench should not sag and should transmit as few vibrations as possible. If necessary, place the balance on a heavy block of antimagnetic material, such as stone (NOT a steel plate). The balance should be protected against electrostatic charges (no plastic or glass), and should be situated away from the wall

(avoidance of simultaneous transmission of vibrations from wall and floor).

3.3 Choosing a weighing vessel

A beaker may be appropriate for weighing liquids to be heated, and an Erlenmeyer flask may be appropriate for weighing substances that will generate a gas in subsequent reactions. A plastic weighing boat can only be used for weighing solids. Weighing paper may also be used for small quantities of solids.

Always use the smallest possible weighing vessel.

Be sure that the weighing vessel is clean and dry. Contaminants adhering to the vessel will cause its mass to be abnormally high.

3.4 Start-up

Inspect the balance for scattered chemicals on or near the balance. Use a small artist's brush to clean the pan and the inside of the balance chamber. Do check for chemicals under the balance pan by lifting it vertically off the pedestal. Brush the chemicals out and carefully replace the pan upon the pedestal.

Check that the air bubble is in the center of the level and, if necessary, correct this by turning the leveling feet.

Make sure the balance is plugged in.

Close all balance doors. Lightly press the control bar down and then release. Immediately the digital mass display will show the following for a few seconds.

8.8.8.8.8.8.8.8. g

This display will then be automatically followed by

0.0000 g

This cycle will normally take place only when turning on the balance. If 0.0000g is not displayed or is slow in its appearance on the digital mass display, vibrations and/or air currents have prevented a stable zero point.

Before using, leave the balance connected to the power supply and switched on for some time, so that a thermal equilibrium can be established.

3.5 Taring and taking readings

Place weighing vessel on balance pan. Close all balance doors.

Push on the large, red square labeled "Tare", if re-zeroing is necessary. Repeat until only zeros are on the display.

Place object in the center of the pan.

Allow display to stabilize; "g" will appear in the unit area of the display.

Read(record) the mass, remove object from pan.

3.6 Cleaning up and shutting down the balance

Before leaving the balance, use a brush to clean up all solids from the balance pan, and wipe up any liquids.

When you have finished cleaning the area, it is courteous to close the balance doors and re-zero the display so that the balance is ready for the next person to use.

3.7 Notes

Dispose of any spilled or excessive chemicals in an appropriate waste container, instead of the former container, to avoid contamination.

Close the balance door while weighing an object in order to prevent air currents from disturbing the reading. When finished, the operator should close the balance door to prevent dust and dirt from entering the balance.

Do not handle objects to be weighed with bare hands. Moisture, grease and dirt on your fingers will affect the weight of the objects.

To be weighed accurately, all objects must be at room temperature. A warm object sets up convection currents inside the balance enclosure, which will make an object appear lighter than it really is. Also, warm air inside the enclosure is less dense than the air that it displaces, which also leads to a negative determinate error.

Never weigh chemicals directly in contact with the balance pan. Use containers, such as beakers, flasks or weighing bottles.

All objects and materials that have recently been removed from a desiccator will absorb moisture and thereby gain weight. It is therefore good practice to record weights after identical time intervals. For example, if you are taking crucibles to constant weight, always record the weight of the crucible exactly 5 seconds after having placed it on the balance pan. In this way, it is possible to minimize the effect of moisture absorption.

Do not spill chemicals inside the balance enclosure. If a spill occurs, clean it up immediately.

第三节 有效数字的修约

一、有效数字

有效数字应反映结果的精确度，有效数字位数越多，精确度越高。有效数字表明数据中有意义的信息。

二、有效数字位数确定

如果数据中有欠准确的数值位数，那么该数据最好用科学计数法表示（例如， $x. xxx \times 10^y$ ）。