医药高等职业教育课程改革实验教材

（供医药类各专业使用）

医药职业英语

Special English for Pharmaceutical Profession

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河海大学出版社

内 容 提 要

本书教学部分共分 8 个单元，每单元包括一篇对话、一篇医药应用文及两篇补充阅读材料。其中，第一单元介绍了制药过程中的针剂和片剂两种剂型的生产过程及常用制药设备的英语表达；第二单元为药物滥用内容的英语科技文章及 OTC 药物简介；第三单元介绍英文药品说明书的阅读方法；第四单元介绍美国药典的阅读与翻译；第五单元介绍药品生产质量管理规范；第六单元教给医药类专业学生如何写英文求职信；第七单元为医药商品营销专业学生选学内容，主要介绍医药市场发展状况及英文药品购销合同样本；第八单元为中药制药专业学生选学内容，主要介绍中药研究方面的英文科技报道及中草药在国际市场发展概况。全书涉及了医药各专业英语词汇及各类型相关专业英语文章。每个单元中有词汇注解、课文注解和理论联系实际的课后习题。为了在有限的单元内尽量拓展本学科的英语知识，在各课文后附有帮助课文理解的补充阅读材料和相关知识说明。在 8 个单元的教学内容后面为实用生产记录样本，主要列举了实际生产过程中的生产指令和生产记录，这些材料将会对学生的实际生产实践起到很大的帮助作用。教材最后部分为附录：总词汇表。

本书以职业实际需求为准，突出职业教育特点，理论联系实际，利于学生学习，教学内容符合职业英语教学的需求。

图书在版编目(CIP)数据

医药职业英语 / 张红云主编. —南京：河海大学出版社，2006.8

医药高等职业教育课程改革实验教材

ISBN 7-5630-2283-X

Ⅰ.医… Ⅱ.张… Ⅲ.医药学—英语—高等学校：技术学校—教材 Ⅳ.H31

中国版本图书馆 CIP 数据核字(2006)第 096183 号

书　　名 / 医药职业英语
书　　号 / ISBN 7-5630-2283-X/R·67
责任编辑 / 谢业保
封面设计 / 张世立
出　　版 / 河海大学出版社
地　　址 / 南京市西康路 1 号(邮编：210098)
电　　话 / (025)83737852(总编室)　(025)83722833(发行部)
经　　销 / 江苏省新华书店
印　　刷 / 南京工大印务有限公司
开　　本 / 787 毫米×1092 毫米　1/16
印　　张 / 9.5
字　　数 / 231 千字
版　　次 / 2006 年 8 月第 1 版　2006 年 8 月第 1 次印刷
定　　价 / 20.00 元

编 写 说 明

本教材是江苏联合职业技术学院徐州医药分院根据医药高等职业教育的培养目标和要求组织编写的医药高等职业课程改革实验教材。在编写中，遵照国家教育部提出的教材必须具备“思想性、科学性、先进性、启发性和适用性”的指导原则，以从事医药生产岗位所必需的基本职业技能、专业知识、职业素质为主线，注重实际操作技能的培养，为学生今后从事医药类相关岗位的工作奠定坚实的基础。

本教材借鉴国外职业教育的先进经验，结合我国的国情，在体系和内容上均有所创新。教材编写过程中注重理论联系实际，能针对专业学生今后的工作岗位，紧扣生产实践，以“必须、够用”为尺度，以职业实际需求为准则，强调基本技能的培训，彻底打破了学科教育的模式，突出了职业技术教育的特点，在职教教材编写上有较大突破。本教材可操作性强、专业基础知识突出、语言简练。

本教材适合医药高等职业教育专业教学使用，也可作为企业各类医药相关工种以及其他相关专业员工培训教材和参考书使用。

本教材由江苏联合职业技术学院徐州医药分院张红云同志任主编，中国矿业大学化工学院牟杰博士任副主编，江苏联合职业技术学院徐州医药分院英语教师王忠水同志也参加了编写工作。全书主要内容由张红云及牟杰同志合作编写；王忠水同志分担编写了2、3、5、6、7单元的对话部分内容。

本教材得到原国家药品监督管理局科教司司长、北京大学药理学教授、博士生导师苏怀德教授的大力支持和指导；同时为了提高编写质量，特邀澳大利亚 Ken McMurtrie 先生对本书英文部分作了细致的总体校对和修正，在此一并表示感谢。

由于主编水平有限，且成稿时间仓促，书中定有疏漏和不妥之处，诚请读者及同行专家批评指正。

编 者

2006.4

总　　序

近几年来，中国医药高等职业教育发展迅速，已构成医药高等教育的半壁河山，为医药行业培养了大批实用性人才，得到了社会的认可。

医药高等职业教育承担着培养高素质、高技能型人才的任务，为了实现高等职业教育服务地方经济的功能，贯彻理论必需、够用，突出职业能力培养的方针，就必须具有先进的职业教育理念和培养模式。因此，形成各个专业先进的课程体系是办好医药高等职业教育的关键环节之一。

江苏联合职业技术学院徐州医药分院十分注重课程改革与建设。在对工作过程系统化课程理论学习、研究的基础上，按照培养方案规定的课程，组织了一批具有丰富知识、教学经验和第一线实际工作经历的教师及企业的技术人员，第一批编写了《药物制剂技术》、《中药制药专门技术》、《药品经营与管理》、《医院、药店药品管理与技术》、《药物新剂型与新技术》、《药物分析技术基础》、《药物合成技术》、《医药职业英语》、《医药应用数学》、《医药应用物理》、《医药应用文》等高职教材。

江苏联合职业技术学院徐州医药分院教育定位是培养拥护党的基本路线，适应生产、管理、服务第一线需要的德、智、体、美各方面全面发展的医药技术应用性人才。紧扣地方经济、社会发展的脉搏，根据行业对人才的需求设计专业培养方案，针对职业要求设置课程体系。在课程改革过程中，组织者、参与者认真研究了工作过程系统化课程和其他课程模式开发理论，并在这批教材编写中进行了初步尝试，因此，这批教材有如下几个特点：

1. 以完整职业工作为主线构建教材体系，按照医药职业工作领域不同确定教材种类，根据职业工作领域包含的工作任务选择教材内容，对应各个工作任务的内容既保持相对独立，又蕴涵着相互之间的内在联系。

2. 教材内容的范围与深度与职业的岗位群相适应，选择生产、服务中的典型工作过程作为范例，安排理论与实践相结合的教学内容，并注意知识、能力的拓展，力求贴近生产、服务实际，反映新知识、新设备与新技术，并将 *SOP* 对生产操作的规范、《中国药典》对药品质量的要求、*GMP*、*GSP* 等法规对生产与服务工作质量的要求引入教材内容中。项目教学、案例教学将是本套教材较为适用的教学方法。

3. 参加专业课教材编写的人员多数具有生产或服务第一线的经历，并且从事多年教学工作，使教材既真实反映实际生产、服务过程，又符合教学规律。

4. 教材体系模块化，各种教材既是各个专业选学的模块，又具有良好的衔接性；每种教材内容的各个单元也形成相对独立的模块，每个模块一般由一个典型工作任务构成。

5. 此批教材既适合于职业教育使用，又可作为职业培训教材，同时还可作为医药行业职工自学读物。

此批教材虽然具有以上特点，但由于时间仓促和其他主、客观原因，尚有种种不足之处，需要经过教学实践锤炼之后加以改进。

承蒙全国医药职业教育研究会苏怀德会长、化工出版社编辑、河海大学出版社编辑等的鼎力支持，这批教材才得以顺利出版，在此，表示诚挚的谢意。

医药高等职业教育实验教材编写委员会

2006 年 3 月 13 日

目　　录

（Content）

Unit One Techniques in Medicine Production

Part One Pharmaceutical Conversation

Talking about The Pharmaceutical Practice

A: Haven't seen you for half a month! Where have you been?

B: We've had our pharmaceutical practice. The teacher says that's necessary for every student who wants to be qualified in pharmaceutical industry in the future.

A: Then, have you been working in a pharmaceutical plant?

B: Er, some of my classmates worked in the pharmaceutical plant, some of them went to the hospital pharmacy, but I stayed in the pharmaceutical training workshop of our college.

A: What did you learn there?

B: Well, our workshop is a multi-functional workshop where we learned techniques and skills in the manufacture of tablets, especially the manufacturing methods of granulations, including the dry methods of direct compression, compression granulation, and wet granulation. These three methods are established methods for tablet compression. The teacher also showed us techniques and skills in cleaning various instruments, etc.

A: Do you think the practice is very helpful with your pharmaceutical learning?

B: Certainly! The faculty provides us exercises to ensure our knowledge comprehension. We'd like to spend some time every term in experiential rotations to learn how to prepare for an exciting career.

New Words and Expressions

technique [tekˈniːk] *n.* 技术，技巧，方法，表演法，手法
pharmaceutical [ˌfɑːməˈsjuːtikəl] *n.* 药物 *adj.* 制药(学)上的
pharmacy [ˈfɑːməsi] *n.* 药房，药剂学，制药业
training workshop 实训车间，实训工场

manufacture [ˌmænju'fæktʃə] *vt.* 制造，加工　*n.* 制造，制造业，产品
granulation [ˌgrænju'leiʃən] *n.* 使成粒状，有粒的表面，粗糙
compression [kəm'preʃ(ə)n] *n.* 浓缩，压缩
faculty ['fækəlti] *n.*（大学的）系科
rotation [rəu'teiʃən] *n.* 旋转

Part Two　Pharmaceutical Application Article

Some Necessary Components In the Process of Injection Manufacture

The initial processing step of the Injection Manufacture is the procurement of acceptable components. In a plant, the majority of components are requisitioned from tested and approved stock, and are then subjected to whatever processing steps are required to prepare them for use. A few components, such as Water for Injection, are manufactured to specifications as needed.

Water for Injection

Water for Injection (WFI)① usually is prepared by distillation in a still specifically designed to produce the high-quality water required. Reverse osmosis②, however, is a method that is now approved by the USP, and it is receiving increasing attention and use.

The specifications for a still should include:

(1) prepurification of feed water by chemical softening, deionization, or filtration to improve the quality of the distillate and reduce the frequency of required cleaning due to insoluble scale in the boiler,

(2) removal of entrained contaminants from the vapor before it is condensed by passage through an efficient baffle system③,

(3) ejection of volatile constituents from the top of the system before the vapor is cooled so that they will not redissolve and appear in the condensate,

(4) construction of all surfaces that will come in contact with the vapor and condensate of a material that will not dissolve in even trace amounts, preferably pure tin, 304 stainless steel, or borosilicate glass.

In addition to conventional stills, two types of stills frequently used for the production of large volumes of water are the "vapor compression stills" and the "multiple effect stills". While they operate on somewhat different principles, both utilize initially heated feed water and steam to conserve on energy consumption and

cooling water. Both types are capable of producing high purity water at rates of 50 to 1000 or more gallons per hour.

Reverse osmosis system functions by applying pressure (usually 200 to 400 PSI) to raw water sufficient to force the permeation of water through a select semipermeable membrane④ in the opposite direction from natural osmosis⑤. The membranes most commonly used are composed of cellulose esters or polyamides (nylon) and are effective in retaining all macromolecules and 85% or more of small ions such as Na^+ and Cl^-. Since pyrogens are macromolecules, they should be retained as well as such viable particles as microorganisms. Greater efficiency and reliability are achieved by passing the water through two membranes in series. The acceptance of reverse osmosis for the preparation of Water For Injection is increasing as experience is gained with the system and its characteristics are understood more fully.

Cleaning Equipment and Containers

Equipment and containers to be used in the processing of a sterile product must be scrupulously clean. New, unused containers and equipment are contaminated principally with dust, fibers, and chemical films, which usually are relatively easy to remove, often by rinsing only. Debris that is more dangerous and more difficult to remove may be present as a residue from a previous use. Such debris usually must be removed by vigorous treatment with hot detergents.

In general, equipment used previously should be scrubbed by hand immediately after use with an effective detergent that does not leave a residue of its own. Whenever possible, equipment should be disassembled so that each part can be thoroughly scrubbed and cleaned with particular attention given to screw threads, joints, and other dirt-collecting structures. Live steam can sometimes be used to loosen debris effectively, particularly in areas that are not easily accessible. After cleaning, the equipment should be rinsed several times, with a final rinse with WFI. Just prior to reuse, large clean tanks and similar equipment should be rinsed thoroughly with WFI. Reserving equipment for use with only one type of product reduces cleaning problems.

Filling Equipment for Liquids

Certain fundamental features are found on all machines used for filling containers with liquids. A means is provided for repetitively forcing a measured volume of the liquid through the orifice of a delivery tube designed to enter the constricted opening of a container. The size of the delivery tube is governed by the

opening in the container to be used, the viscosity and density of the liquid, and the speed of delivery desired. The tube must freely enter the neck of the container and deliver the liquid deep enough to permit air to escape without sweeping the entering liquid into the neck of the container. To reduce the resistance to the flow of the liquid, the tube should have the maximum possible diameter. Excessive delivery force causes splashing of the liquid and troublesome foaming, if the liquid has a low surface tension.

The delivery of relatively small volumes of liquids is usually obtained from the stroke of the plunger of a syringe. The stroke of the syringe forces the liquid through a two-way valve that provides for an alternate filling of the syringe from a reservoir and delivery to a container. For heavy, viscous liquids a sliding piston valve provides more positive action.

Filling Equipment for Solids

Sterile solids, such as antibiotics, are more difficult to subdivide accurately and precisely into individual dose containers than are liquids. The rate of flow of solid material tends to be slow and irregular, particularly if finely powdered. Small, granular particles flow most evenly. Containers with a relatively large opening must be used. Even so, the filling rate is slow, and the risk of spillage is ever present. For these reasons, the tolerances permitted for the content of such containers must be relatively large. Suggested tolerances may be found tabulated in the USP.

Sterile solids can be subdivided into containers by individual weighting. The operation can use a scoop that holds a volume approximately equal to the weight required, but the quantity filled into the container is finally weighed on a balance. This is a slow process.

When the solid is obtainable in a relatively free-flowing form, machine methods of filling may be employed. In general, these methods involve the measurement and delivery of a volume of the solid material, which has been calibrated in terms of the weight desired. Among the major problems in the use of such machines are stratification of particles due to varying particle sizes, the development of electrostatic charge within the mass of dry solid particles, the formation of air pockets, and uneven flow due to clumping of the particles. These all result in uneven filling of the container. The problems usually can be minimized if uniform particle size of the solid is achieved and a small electric current is used to neutralize the developing charge.

Excerpted from Lachman Leon et al. *The Theory and Practice of Industrial Pharmacy*, 3*rd ed.*, Lea and Febiger, Philadelphia, 1986.

New Words and Expressions

injection [in'dʒekʃən] *n.* 注射，注射剂
procurement [prə'kjuəmənt] *n.* 获得
baffle ['bæfl] *n.* 挡板
prepurification ['pri:pjurifi'keiʃən] *n.* 预纯化
scale [skeil] *n.* 锅垢
ejection [i'dʒekʃən] *n.* 排斥，喷出
volatile ['vɔlətail] *a.* 易挥发的
borosilicate [ˌbɔ:rəu'silikit] *n.* 硼硅酸盐
still [stil] *n.* 蒸馏器，蒸馏
consumption [kən'sʌmpʃn]; [kən'sʌmpʃən] *n.* 消耗
raw water *n.* 生水
permeation [ˌpə:mi'eiʃən] *n.* 渗透，充满
cellulose ['seljuləus] *n.* 纤维素
polyamide [pɔli'æmaid] *n.* 聚酰胺
macromolecule [ˌmækrəu'mɔlikju:l] *n.* 大分子
reliability [riˌlaiə'biliti] *n.* 可靠度
scrupulously ['skru:pjuləsli] *adv.* 审慎地，严格地
debris ['debri:; 'deib-] *n.* 碎片
scrub [skrʌb] *vt.* 擦净
disassemble [ˌdisə'sembl] *vt.* 拆卸，分解
screw [skru:] *n.* 螺丝，螺孔 *vt.* 调节，拧紧
thread [θred] *n.* 针，丝，罗纹
orifice ['ɔrifis] *n.* 孔，口
viscosity [vis'kɔsiti] *n.* 粘性，粘滞性
splash [splæʃ] *vt.* 溅污
troublesome ['trʌblsəm] *a.* 令人烦恼的
foaming ['fəumiŋ] *n.* 发泡，起泡
syringe ['sirindʒ] *n.* 注射器，注射
subdivide ['sʌbdi'vaid] *vt.* 把……再分，分装
spillage ['spilidʒ] *n.* 溢出，洒落
tolerance ['tɔlərəns] *n.* 忍受，耐受性，耐(药)性
stratification [ˌstrætifi'keiʃən] *n.* 分层
clump [klʌmp] *vi.* 结块，结团

Notes:

① **Water For Injection (WFI)** 注射用水
② **reverse osmosis** 反向渗析

③ **an efficient baffle system**　有效的挡板系统
④ **a select semi-permeable membrane**　选择性的半渗透膜
⑤ **the opposite direction from natural osmosis**　与自然渗透相反的方向

Part Three　Further Reading

（1）Tablets（The Pharmaceutical Tablets Dosage Form）

Role in Therapy

The oral route of drug administration is the most important method of administering drugs for systemic effects. Except in cases of Insulin therapy, the parenteral route is not routinely used for self-administration of medication. The topical route of administration has only recently been employed to deliver drugs to the body for systemic effects, with two classes of marketed products: Nitroglycerin for the treatment of angina and scopolamine for the treatment of motion sickness. Other drugs are certain to follow, but the topical route of administration is limited in its ability to allow effective drug absolution for systemic drug action. The parenteral route of administration is important in treating medical emergencies in which a subject is comatose or cannot swallow, and in providing various types of maintenance therapy for hospitalized patients. Nevertheless, it is probable that at least 90% of all drugs used to produce systemic effects are administered by the oral route. When a new drug is discovered, one of the first questions a pharmaceutical company asks is whether or not drug can be effectively administered for its intended effect by the oral route. If it cannot, the drug is primarily relegated to administration in a hospital setting or physician's office. If patient self-administration cannot be achieved, the sales of the drug constitute only a small fraction of what the market would otherwise be. Of drugs that are administered orally, solid oral dosage forms represent the preferred class of product. The reasons for this preference are as follows. Tablets and capsules represent unit dosage forms in which one usual dose of the drug has been accurately placed. By comparison, liquid oral dosage forms, such as syrups, suspensions, emulsions, solutions, and elixirs, are usually designed to contain one dose of medication in 5 to 30 ml. The patient is then asked to measure his or her own medication using a teaspoon, tablespoon, or other measuring device. Such dosage measurements are typically in error by a factor ranging from 20% to 50% when the drug is self-administered by the patient.

Liquid oral dosage forms have other disadvantages and limitations when compared with tablets. They are much more expensive to ship (one liquid dosage weighs 5 g or more versus 0.25 to 0.4 g for the average tablet), and breakage or leakage during shipment is a more serious problem with liquids than with tablets. Taste masking of the drug is often a problem (if the drug is in solution even partially). In addition, liquids are less portable and require much more space per number of doses on the pharmacist's shelf. Drugs are in general less stable (both chemically and physically) in liquid form than in a dry state and expiration dates tend to be shorter. Careful attention is required to assure that the product will not allow a heavy microbiologic burden to develop on standing or under normal conditions of use once opened (preservation requirements). There, are basically three reasons for having liquid dosage forms of a drug: (1) The liquid form is what the public has come to expect for certain types of products (e.g. cough medicines). (2) The product is more effective in a liquid form (e.g. many adsorbents and antacids). (3) The drug(s) are used fairly commonly by young children or the elderly, who have trouble swallowing the solid oral dosage forms.

Properties

The objective of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the proper form at or over the proper time and in the desired location, and to have its chemical integrity protected to that point. Aside from the physical and chemical properties of the medicinal agent(s) to be formulated into a tablet, the actual physical design, manufacturing process, and complete chemical makeup of the tablet can have a profound effect on the efficacy of the drug(s) being administered.

A tablet, (1), should be an elegant product having its own identity while being free of defects such as chips, cracks, discoloration, contamination, and the like, (2), should have the strength to withstand the rigors of mechanical shocks encountered in its production, packaging, shipping and dispensing and (3), should have the chemical and physical stability to maintain its physical attribute over time. Pharmaceutical scientists now understand that various physical properties of tablets can undergo change under environmental or stress conditions, and that physical stability, through its effect on bioavailability in particular, can be of more significance and concern in some tablet systems than chemical stability.

On the other hand, the tablet, (1), must be able to release the medicinal agent (s) in the body in a predictable and reproducible manner and (2), must have a

suitable chemical stability over time so as not to allow alteration of the medicinal agent(s). In many instances, these sets of objectives are competing. The design of a tablet that emphasizes only the desired medicine effects may produce a physically inadequate product. The design of a tablet emphasizing only the physical aspects may produce tablets of limited and varying therapeutic effects. As one example of this point, Meyer and associates present information on 14 Nitrofurantoin products, all of which passed the compendia physical requirements, but showed statistically, significant bioavailability differences.

Excerpted from Lachman Leon et al. *The Theory and Practice of Industrial Pharmacy*, 3*rd ed.*, Lea and Febiger, Philadelphia, 1986.

(2) Tablet Compression Operation and Tablet Compression Machines

Tablets are made by compressing a formulation containing a drug or drugs with excipients on stamping machines called presses. Tablet compression machines or tablet presses are designed with the following basic components:

1. hopper(s) for holding and feeding granulation to be compressed,
2. dies that define the size and shape of the tablet,
3. punches for compressing the granulation within the dies,
4. cam tracks for guiding the movement of the punches,
5. a feeding mechanism for moving granulation from the hopper into the dies.

Tablet presses are classified as either single punch or multi-station rotary presses.

Multi-station presses are termed rotary because the head of the tablet machine that holds upper punches, dies, and lower punches in place rotates. As the head rotates, the punches are guided up and down by fixed cam tracks, which control the sequence of filling compression, and ejection. The portions of the head that hold the upper and lower punches are called the upper and lower puncher turrets respectively, and the portion holding the dies is called the die table. At the start of the compression cycle granulation stored in a hopper (not shown), empties into the feed-frame (A) which has several interconnected compartments. These compartments spread the granulation over a wide area to provide time for the dies (B) to fill. The pull-down cam (C) guides the lower punches to the bottom of their vertical travel, allowing the dies to overfill. The punches then pass over a weight control cam (E), which reduces the fill in the dies to the desired amount. A wipe-off blade (D) at the end of the feed-frame removes the excess granulation and directs it around the turret and back into to the front of the feed-frame. Next, the lower punches travel over the