



GAODENG XUEXIAO ZHUANYE JIAOCAI

• 高等学校专业教材 •

[高校教材]

生物制药工程 专业英语

汤鲁宏 编著

SPECIAL ENGLISH FOR
BIOPHARMACEUTICAL ENGINEERING



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前 言

生物技术药物作为人类抗击肿瘤、传染性疾病、心血管系统疾病等严重威胁人类健康的重大疾病的一种新的有效手段,研究异常活跃,发展非常迅猛,已经成为与天然药物、合成药物并驾齐驱的药物新品种。生物制药工程,作为一种建立在医学、生物学与生物技术和化学工程学基础上的,以生物技术为主要手段,以生物技术药物为主要研究对象的新兴交叉学科便应运而生。

经过全世界的科学家和工程研究人员 20 多年的不懈努力,已经有越来越多的生物技术药物获得了美国 FDA 等药物监管部门的批准,上市销售,年销售额在 10 亿美元以上的实例有促红细胞生成素(EPO)、重组人胰岛素(rh-Insulin)、干扰素(α -IFN)、白介素(IL-2)等。我国的科研工作者紧紧追踪这一国际生物技术领域的研究热点,在生物技术药物的长效化等方面积极地参与国际竞争,进行了卓有成效的工作,在生物制药工程技术领域诞生了一批生物技术药物研发和生产企业,越来越多的生物技术药物正在实现国产化。

由于生物制药工程技术涉及医学、分子生物学、生物化学、蛋白质化学以及化学工程等诸多学科,现有的专业英语往往仅限于上述学科中的某一科,无法满足和适应从事生物制药工程领域的学习和研究的广大本专科学生、研究生和工程技术人员需要。为此,编者根据自己近年来在国内外从事生物制药工程技术领域研究的经验和体会,参考和借鉴了国外有关的生物制药工程的教材,以及新近发表的专利和综述等参考文献编写此书。希望能够为医学、药学、制药工程、生物化工、生物技术等相关领域中有志于从事生物制药工程领域的研究的本科生、研究生及相关的科研人员提供有关生物制药工程的英语基础知识以及该领域的基本概念和发展动向等其他相关信息。

全书共 39 课,由 7 个大致独立的结构单元组成。

第一单元为生物技术药物导论,包括第 1~2 课,介绍生物技术药物的定义、特征以及生物技术药物的迅猛发展和光明的未来。

第二单元为生物技术药物的研发,包括第 3~7 课,详细介绍从先导物的表征到新药的申请等整个生物技术药物的研发过程,其中包括先导物的表征、知识产权保护、临床前研究、临床试验、新药的临床试验申请与新药申请。

第三单元为生物技术药物的生产,包括第 8~17 课,系统介绍从 GMP 要求到生产设施的验证等涉及生物技术药物生产的整个过程,其中包括药厂设计的 GMP 要求、洁净室及清洗,净化与消毒、生物技术药物生产所必需的文档资料和 GMP 关于记录和报告的要求、生物技术药物源、细胞库、下游过程综述、高解析度柱色谱纯化、生物技术药物的药剂学、制剂的罐装与冷冻干燥、生物技术药物的药物分析和生物技术药物生产设施的验证。

第四单元为生物技术药物详述,包括第 18~32 课,详细介绍了从细胞因子到反义核酸等已批准使用和正在进行临床试验的主要生物技术药物种类,其中包括干扰素、白介

素、肿瘤坏死因子、造血因子、促红细胞生成素、胰岛素样生长因子、胰岛素、人生长激素、促性腺激素、血液制品、抗凝血剂、溶栓剂、药用酶、多克隆抗体、单克隆抗体、疫苗、佐剂,以及基因治疗和反义核酸技术。

第五单元为生物技术药物的知识产权保护,包括第33~35课,提供了用于保护新物质、新工艺或新用途的三种不同类型的专利的实例,意在为增强我国学生的知识产权保护意识,提高他们的国际专利写作技巧打下基础。限于篇幅,只摘录了原专利申请文献中的部分内容作为本教材的内容,有兴趣的读者可以自行到网上去搜寻和下载相应的全文。

第六单元涉及生物技术药物的药物经济学,包括第36~38课,给出了投资成本估算和操作成本估算的有关内容,并给出了生物技术药物行业商务开发和产品生产工艺开发的案例。

第七单元,由第39课组成,涉及国外高等职业教育中非常重要的一项内容:职业道德教育,给出了与生物制药工程教育密切相关的药剂师与工程师的职业道德准则。

广大读者可根据自己的兴趣和学习需要,选读本教材中的内容。各位从事专业英语教学的教师在教学实践中也可结合各个学校的专业特点,自行决定取舍。

本书在材料组织上,充分考虑了生物制药工程专业的专业英语词汇方面的需要,当代大学生通过计算机网络自主学习、查找信息的能力和通过了大学4级、6级英语考试的学生们的基本英语水平,并兼顾了基础英语水平较高的学生们进一步提高英语阅读水平的愿望,所选材料起点高,难度大,实用性强。每一课均由Text A、Text B和阅读材料组成。其中的Text A为必须掌握的基本内容,涵盖了从事生物制药工程领域的学习和研究所必须掌握的英语词汇和常见的英语表达方式,并给出了参考译文。学生们应当在充分预习的基础上,能够诵读,最好是背诵全文,作为专业英语口语交流能力培养的启蒙。Text B为在Text A基础上对阅读能力的进一步训练,一方面重复已经出现的单词,同时也强调独立的翻译能力的训练。学生们应当在掌握了Text A的基础上,通篇阅读Text B,并独立完成练习。阅读材料部分系专为学有余力的同学安排的课后自学内容,课上不做要求。

生物制药工程涉及的范围很广,并且处在知识的不断更新之中,新靶点、新药物、新技术和新方法不断地涌现出来。编者进行了大量详细的取材和精心的编写工作,力求反映生物制药工程的发展方向,体现该技术领域的发展前沿。由于时间紧迫,加之编者自身的业务水平所限,不足之处在所难免,望专家同仁和广大读者在使用过程中提出宝贵的批评和建议。

汤鲁宏

2009.1月于江南大学医药学院

Contents

Lesson 1	1
Text A Introduction to Pharmaceutical Products	1
参考译文 药品简介	3
Text B The Age of Biopharmaceuticals	
生物技术药物时代	5
Exercises	6
Reading Material Introduction to Biopharmaceuticals	
生物技术药物简介	7
Lesson 2	10
Text A The Business of Biopharmaceuticals	10
参考译文 生物技术药物的市场	11
Text B The Future of Biopharmaceuticals	
生物技术药物的未来	11
Exercises	13
Reading Material Abstract of China Pharmaceutical Industry Report, 2006—2007	
中国制药工业 2006—2007 年度报告摘要	13
Lesson 3	16
Text A Initial Product Characterization	16
参考译文 先导物的表征	18
Text B Characterization of Recombinant Thioesterase and Acyl Carrier Protein (ACP)	
Domains of Chicken Fatty Acid Synthase Expressed in <i>Escherichia coli</i>	
大肠杆菌中表达的重组鸡脂肪合成酶的硫酯酶与酰基载体蛋白域的表征	19
Exercises	21
Reading Material Characterization of Recombinant Thioesterase and Acyl Carrier Protein Domains of Chicken Fatty Acid Synthase Expressed in <i>Escherichia coli</i> (continue)	
大肠杆菌中表达的重组鸡脂肪合成酶的硫酯酶与酰基载体蛋白域的表征 (续)	22
Lesson 4	26
Text A What Is Patent and What Is Patentable?	26
参考译文 什么是专利? 什么可以申请专利?	27
Text B Patent in Biotechnology	
生物技术领域的专利	28

Exercises	30
Reading Material Background, Summary and Claims of U. S. Patent 20080005807 (Transgenic Animals) 美国专利 USP 20080005807 (转基因动物) 的背景、概要与 权利要求	30
Lesson 5	34
Text A Pre-Clinical Trials	34
参考译文 临床前试验	36
Text B Toxicity Studies 毒理学研究	37
Exercises	39
Reading Material Immunogenicity of Recombinant Proteins 重组蛋白质的免疫原性	40
Lesson 6	43
Text A Clinical Trials	43
参考译文 临床试验	44
Text B Clinical Trials (continue) 临床试验 (续)	46
Exercises	48
Reading Material Clinical Trials (continue) 临床试验 (续)	48
Lesson 7	51
Text A The Food and Drug Administration of United States	51
参考译文 美国食品与药品管理局	53
Text B The Food and Drug Administration of United States (continue) 美国食品与药品管理局 (续)	55
Exercises	56
Reading Material The Investigational New Drug Application and The New Drug Application 新药的临床试验申请与新药申请	56
Lesson 8	61
Text A Introduction to Current Good Manufacturing Practice	61
参考译文 GMP 简介	62
Text B GMP Design Requirement 药厂设计的 GMP 要求	63
Exercises	66
Reading Material Guides to Good Manufacturing Practice GMP 指南	67

Lesson 9	70
Text A Clean-rooms	70
参考译文 洁净室	72
Text B Cleaning, Decontamination and Sanitation (CDS)	
清洗, 净化与消毒	73
Exercises	75
Reading Material Generation of Purified Water and WFI	
纯水与注射用水的制备	76
Lesson 10	79
Text A Essential Documents for Biopharmaceuticals Production	79
参考译文 生物技术药物生产所必需的文档资料	81
Text B GMP Requirement for Records and Reports (partly)	
GMP 关于记录和要求的要求 (部分)	83
Exercises	84
Reading Material GMP Requirement for Records and Reports (partly) (continue)	
GMP 关于记录和要求的要求 (部分) (续)	85
Lesson 11	88
Text A Sources of Biopharmaceuticals	88
参考译文 生物技术药物源	89
Text B Yeast, Fungus and Transgenic Animals	
酵母, 霉菌和转基因动物	91
Exercises	92
Reading Material <i>E. coli</i> As a Source of Recombinant, Therapeutic Proteins	
作为药用重组蛋白源的大肠杆菌	93
Lesson 12	96
Text A Cell Bank Systems	96
参考译文 细胞库系统	97
Text B Fermentation	
发酵	98
Exercises	100
Reading Material Important Design Considerations for Good Fermenter Operation	
设计符合 GMP 要求的发酵罐时需要考虑的重要因素	101
Lesson 13	103
Text A Overview of the Downstream Processing	103
参考译文 下游过程综述	105
Text B High-Resolution Chromatographic Purification	
高解析度柱色谱纯化	107
Exercises	108
Reading Material Final Purification Process of Rhinsulin	

重组人胰岛素的纯化工艺	108
Lesson 14	111
Text A Some Influences Which Can Alter the Biological Activity of Proteins	111
参考译文 可导致蛋白质生物活性改变的某些影响因素	113
Text B Some Influences Which Can Alter the Biological Activity of Proteins (continue) 可导致蛋白质生物活性改变的某些影响因素 (续)	114
Exercises	116
Reading Material Some Influences Which Can Alter the Biological Activity of Proteins (continue) 可导致蛋白质生物活性改变的某些影响因素 (续)	116
Lesson 15	119
Text A The Challenges of Improving the Formulation and Delivery of Biopharmaceuticals	119
参考译文 生物技术药物配方与给药系统的改进方面所面临的挑战	120
Text B Stabilizing Excipients Used in Final Product Formulation 制剂配方用稳定化赋形剂	121
Exercises	123
Reading Material Final Product Fill and Freeze-Drying 制剂的灌装与冷冻干燥	123
Lesson 16	126
Text A Detection of Protein-based Product Impurities	126
参考译文 蛋白类产品杂质的检出	127
Text B Pyrogen Detection 热源的检测	128
Exercises	130
Reading Material Detection of DNA and Viral Contaminants DNA 与病毒类污染物的检出	130
Lesson 17	133
Text A Introduction of the Validation	133
参考译文 验证简介	135
Text B Validation Master Planning 验证方案	136
Exercises	138
Reading Material Validation Master Planning (continue) 验证方案 (续)	138
Lesson 18	142
Text A The Cytokines	142
参考译文 细胞因子	144
Text B Leukocytes, Their Range and Function	

白细胞及其范围与功能	146
Exercises	147
Reading Material Cytokines as Biopharmaceuticals and Their Receptors 生物技术药物细胞因子及其受体	148
Lesson 19	150
Text A The Interferons (IFN)	150
参考译文 干扰素	152
Text B The Biochemistry of Interferons 干扰素的生物化学	153
Exercises	155
Reading Material The Biological Effect of Interferons 干扰素的生物学效用	155
Lesson 20	158
Text A Interleukin	158
参考译文 白介素	159
Text B Interleukin-2 (IL-2) 白介素-2	161
Exercises	162
Reading Material Interleukin-2 (continue) 白介素-2 (续)	163
Lesson 21	165
Text A Tumor Necrosis Factor (TNF)	165
参考译文 肿瘤坏死因子	166
Text B TNF Receptors TNF 的受体	167
Exercises	168
Reading Material Biological Activities of TNF TNF 的生物活性	169
Lesson 22	172
Text A Haemopoietic Growth Factors	172
参考译文 造血生长因子	173
Text B Haemopoietic Growth Factors (continue) 造血生长因子 (续)	174
Exercises	176
Reading Material Clinical Application of CSFs 集落刺激因子的临床应用	176
Lesson 23	179
Text A The Erythropoietin (EPO)	179
参考译文 促红细胞生成素	180

Text B The Erythropoietin (continue)	
促红细胞生成素 (续)	181
Exercises	183
Reading Material Therapeutic Applications of EPO	
EPO 的临床应用	184
Lesson 24	187
Text A Growth Factors	187
参考译文 生长因子	188
Text B Insulin-like Growth Factors (IGFs)	
胰岛素样生长因子	190
Exercises	191
Reading Material Biological Effects of IGFs	
胰岛素样生长因子的生物学效用	192
Lesson 25	195
Text A The Introduction of Hormones of Therapeutic Interest	195
参考译文 药用激素简介	196
Text B Insulin	
胰岛素	197
Exercises	199
Reading Material Human Growth Hormone and Gonadotrophins	
人生长激素和促性腺激素	199
Lesson 26	202
Text A Blood Products	202
参考译文 血液制品	204
Text B Whole Blood, Platelets, Red Blood Cells and Albumin	
全血, 血小板, 红细胞和白蛋白	205
Exercises	207
Reading Material Haemostasis	
止血	207
Lesson 27	211
Text A Anticoagulants	211
参考译文 抗凝血剂	213
Text B Thrombolytic Agents	
溶栓剂	214
Exercises	216
Reading Material Thrombolytic Agents (continue)	
溶栓剂 (续)	216
Lesson 28	220
Text A Enzymes of Therapeutic Value	220

参考译文 药用酶的价值	222
Text B Enzymes of Therapeutic Value (continue)	
药用酶的价值 (续)	223
Exercises	224
Reading Material Enzymes of Therapeutic Value (continue)	
药用酶的价值 (续)	225
Lesson 29	228
Text A Polyclonal Antibody Preparations	228
参考译文 多克隆抗体制剂	230
Text B Polyclonal Antibody Preparations (continue)	
多克隆抗体制剂 (续)	232
Exercises	233
Reading material Monoclonal Antibodies	
单克隆抗体	234
Lesson 30	237
Text A Vaccine Technology	237
参考译文 疫苗技术	238
Text B Vaccine Technology (continue)	
疫苗技术 (续)	239
Exercises	241
Reading Material The Impact of Genetic Engineering on Vaccine Technology	
基因工程对疫苗技术的影响	241
Lesson 31	244
Text A Adjuvant Technology	244
参考译文 佐剂技术	245
Text B Adjuvant Technology (continue)	
佐剂技术 (续)	246
Exercises	248
Reading Material Adjuvant Technology (continue)	
佐剂技术 (续)	249
Lesson 32	253
Text A Gene Therapy	253
参考译文 基因治疗	255
Text B Gene Therapy and Cancer	
基因治疗与癌症	256
Exercises	258
Reading Material Antisense Nucleic Acid Technology	
反义核酸技术	259
Lesson 33	262

Text A	The Background of the Invention and Outline of Detailed Description of U. S. Patent 20080003202 (Modified Interferon- β (IFN- β) Polypeptides)	262
参考译文	美国专利 USP 20080003202 [改性 β -干扰素 (IFN- β) 多肽] 的发明背景与详细描述部分的提纲	264
Text B	Example: Analysis of the Activity of the Modified IFN- β Polypeptides	
	实例: 改性 IFN- β 多肽的活性分析	266
	Exercises	267
Reading Material	Example: Evaluation of IFN- β Variants	
	实例: IFN- β 变种的评价	268
Lesson 34		271
Text A	Claims of U. S. Patent 20070298052 (Drying Process for Preserving an Active Agent as a Highly Viscous Liquid)	271
参考译文	美国专利 USP 20070298052 (用于保藏高黏度液体活性物质的干燥工艺) 的权利要求书	272
Text B	Claims of U. S. Patent 20070298052 (Drying Process for Preserving an Active Agent as a Highly Viscous Liquid) (continue)	
	美国专利 USP 20070298052 (用于保藏高黏度液体活性物质的干燥工艺) 的权利要求书 (续)	273
	Exercises	275
Reading Material	Description of U. S. Patent 20070298052 (Drying Process for Preserving an Active Agent as a Highly Viscous Liquid)	
	美国专利 USP 20070298052 (用于保藏高黏度液体活性物质的干燥工艺) 的描述	275
Lesson 35		278
Text A	The Background and Summary of the Invention of U. S. Patent 20070202131 (Use of Mycobacterial Vaccines in CD4 ⁺ or CD8 ⁺ Lymphocyte-Deficient Mammals)	278
参考译文	美国专利 USP 20070202131 (肺结核疫苗在 CD4 ⁺ 或 CD8 ⁺ 淋巴细胞缺乏型哺乳动物中的应用) 的发明背景与概要	279
Text B	The Background and Summary of the Invention of U. S. Patent 20070202131 (Use of Mycobacterial Vaccines in CD4 ⁺ or CD8 ⁺ Lymphocyte-Deficient Mammals) (continue)	
	美国专利 USP 20070202131 (肺结核疫苗在 CD4 ⁺ 或 CD8 ⁺ 淋巴细胞缺乏型哺乳动物中的应用) 的发明背景与概要 (续)	280
	Exercises	281
Reading Material	Example: Vaccine Efficacy of a Lysine Auxotroph of <i>M. tuberculosis</i> (part)	
	实例: 一株赖氨酸缺陷型肺结核菌的疫苗功效 (部分)	282
Lesson 36		285

Text A	Evolution from Technology Provider to Product Developer: A Case Study in Business Development	285
参考译文	从技术提供商向产品开发商的进化: 商业开发的一个案例	286
Text B	Evolution from Technology Provider to Product Developer: A Case Study in Business Development (continue) 从技术提供商向产品开发商的进化: 商业开发的一个案例 (续)	287
Exercises		288
Reading Material	Evolution from Technology Provider to Product Developer: A Case Study in Business Development (continue) 从技术提供商向产品开发商的进化: 商业开发的一个案例 (续)	289
Lesson 37		292
Text A	Capital Cost Estimation	292
参考译文	投资成本估算	294
Text B	Capital Cost Estimation (continue) 投资成本估算 (续)	295
Exercises		296
Reading Material	Operating Cost Estimation 操作成本估算	297
Lesson 38		301
Text A	Case Study: Production of a Therapeutic Monoclonal Antibody	301
参考译文	案例分析: 一种药用单抗的生产	302
Text B	Case Study: Production of a Therapeutic Monoclonal Antibody (continue) 案例分析: 一种药用单抗的生产 (续)	303
Exercises		304
Reading Material	Case Study: Production of a Therapeutic Monoclonal Antibody (continue) 案例分析: 一种药用单抗的生产 (续)	305
Lesson 39		308
Text A	Pharmacist's Code of Ethics and Oath of a Pharmacist	308
参考译文	药剂师的职业道德准则与宣誓誓言	310
Text B	Code of Ethics for Engineers 工程师的职业道德准则	311
Exercises		313
Reading Material	Code of Ethics for Engineers (continue) 工程师的职业道德准则 (续)	313
主要参考文献		316

Lesson 1

Text A Introduction to Pharmaceutical Products

Pharmaceutical substances form the backbone of modern medicinal therapy. Most traditional pharmaceuticals are low-molecular-mass organic chemicals. Although some (e. g. aspirin) were originally isolated from biological sources, most are now manufactured by direct chemical synthesis. Two types of manufacturing companies thus comprise the 'traditional' pharmaceutical sector: the chemical synthesis plants which manufacture the raw chemical ingredients in bulk quantities, and the finished product pharmaceutical facilities which purchase these raw bulk ingredients, formulate them into final pharmaceutical products, and supply these products to the end-user.

In addition to chemical-based drugs, a range of pharmaceutical substances (e.g. hormones and blood products) are produced by/extracted from biological sources. Such products, some major examples of which are listed in Table 1.1, may thus be described as products of biotechnology. In some instances, categorizing pharmaceuticals as products of biotechnology or chemical synthesis becomes somewhat artificial. For example, certain semi-synthesis antibiotics are produced by chemical modification of natural antibiotics produced by fermentation technology.

Table 1.1 **Some pharmaceuticals which may be obtained by direct extraction from biological source material**

Substance	Medical application
Blood products (e. g. coagulation factors)	Treatment of blood disorders such as haemophilia A or B
Vaccines	Vaccination against various diseases
Antibodies	Passive immunization against various diseases
Insulin	Treatment of diabetes mellitus
Enzymes	Thrombolytic agents, digestive aids, debriding agents (i. e. cleansing of wounds)
Antibiotics	Treatment against various infections agents
Plant extractives (e. g. alkaloids)	Various, including pain relief

Many of the protein-based pharmaceuticals mentioned above are now also produced by genetic engineering.

The term ‘biologic’ (biological medicinal product) forms part of the pharmaceutical vocabulary. While it might be assumed that ‘biological’ refers to any pharmaceutical product produced by biotechnological endeavor, its definition is more limited. In pharmaceutical circles, ‘biologic’ generally refers to medicinal products derived from blood, as well as vaccines, toxins and allergen products. Thus, some traditional biotechnology-derived pharmaceu-

tical products (e. g. hormones, antibiotics and plant metabolites) fall outside the strict definition.

Biomedical research continues to broaden our understanding of the molecular mechanisms underlying both health and disease. Research undertaken since the 1950s has pinpointed a host of biomolecules produced naturally in the body which have obvious therapeutic applications. Examples include the interferons and interleukins which, for example, regulate the immune response factors such as erythropoietin (which stimulates red blood cell production), and neurotrophic factors, which regulate the development and maintenance of neural tissue.

While the pharmaceutical potential of these regulatory molecules was generally appreciated, their widespread medical application was in most cases rendered impractical due to the tiny quantities in which they were naturally produced. The advent of recombinant DNA technology (genetic engineering) and monoclonal antibody technology (hybridoma technology) overcame many such difficulties, and marked the beginning of a new era of the pharmaceutical sciences.

Recombinant DNA technology has facilitated the production of almost unlimited quantities of virtually any protein, hence overcoming problems of source availability. Another major advantage of the technology is the generation of a product which is likely free from infectious agents. Direct extraction of such products from contaminated biological material in the past sometimes resulted in the unwitting transmission of disease. Examples include the transmission of blood-borne pathogens such as hepatitis B and HIV to haemophiliacs via infected blood products, and the transmission of Creutzfeldt-Jakob disease to persons of short stature receiving human growth hormone derived from human pituitaries.

Hybridoma technology facilitates the generation of large quantities of monospecific (monoclonal) antibodies. Many such monoclonal antibodies are now finding therapeutic application particularly in the diagnosis and treatment of some tumor types.

The twin techniques of genetic engineering and hybridoma technology were developed in the mid-1970s. Between them, they have subsequently facilitated large-scale production of hundreds of proteins of actual or potential therapeutic use. Any such pharmaceutical substance produced specifically via genetic engineering or hybridoma technology is generally termed a biopharmaceutical. The first biopharmaceutical product to come on the market was recombinant human insulin, produced in *Escherichia coli* cells. This product (trade name Humulin) was granted a marketing license by the Food and Drug Administration (FDA) in October 1982.

Until recently, all biopharmaceutical products were protein based. However, during the 1990s, nucleic acid-based biopharmaceuticals have also come to prominence, being employed in gene therapy and antisense technology.

Notes

backbone

骨干, 中坚

pharmaceutical

制药学上的

organic	有机的	manufacture	生产, 制造
synthesis	合成	comprise	包含, 包括
ingredient	成分, 要素	formulate	用公式表示
end-user	终端用户	hormone	激素, 荷尔蒙
extract	提取, 分离出	biotechnology	生物技术
artificial	人工的, 人造的	antibiotic	抗生素
modification	修饰, 改良	fermentation	发酵
genetic engineering	基因工程	coagulation	凝固作用, 凝结物
disorder	失调; 混乱	haemophilia	血友病
vaccine	疫苗	immunize	使免疫
insulin	胰岛素	diabetes mellitus	糖尿病
enzyme	酶	thrombolytic agent	溶栓剂
digestive	可消化的	debriding agent	清创剂
cleaning	净化	treatment	治疗
infection	感染; 传染病	antibody	抗体
alkaloid	生物碱, 植物碱基	pain relief	镇痛, 疼痛缓解
endeavor	努力, 尽力	toxin	毒素, 毒质
allergen	过敏原, 变应原	metabolite	代谢产物
biomedical	生物医学的	molecular	分子的
mechanism	机制	biomolecule	生物分子
interferon	干扰素	interleukin	白介素
regulate	调节, 调控	immune response	免疫反应
erythropoietin	促红细胞生成素	stimulate	刺激
neurotrophic	神经营养的	maintenance	维持; 供给
neural tissue	神经组织	potential	潜能, 潜力
recombinant	重组	monoclonal	单克隆
facilitate	助长, 促进	virtually	实际上, 事实上
contaminate	污染; 损害	unwitting	不知不觉的, 无意的
transmission	传递, 传导	blood-borne	血源性的
pathogen	病原体	hepatitis	肝炎
stature	身长, 身材	derive	衍生, 导出
pituitary	脑垂体	diagnosis	诊断
hybridoma	杂交瘤细胞	therapeutic	治疗上的
biopharmaceutical	生物制药的	<i>escherichia coli</i>	大肠杆菌
protein	蛋白质	nucleic acid	核酸
prominence	显著, 突出, 杰出	antisense	反义
creutzfeldt-Jakob disease	克雅病		

参 考 译 文

药 品 简 介

药物是现代医学治疗手段中不可或缺的主心骨。大多数传统药物是小分子有机物。