目录

「公司简介」

上海复旦张江生物医药股份有限公司，一九九六年十一月创建于上海浦东张江高科技园区，上海医药集团股份有限公司、新企二期创业投资企业、上海张江高科技园区开发股份有限公司和上海复旦资产经营有限公司等知名企业和大学为公司股东。

本着“ 我们多一分探索，人类多一分健康 ”的信念，公司主要从事生物医药的创新研究、开发、生产和销售，力求成为一家以知识产权为核心源泉的生物医药创新企业。经过多年的不懈努力，公司在基因工程药物、光动力药物及纳米药物等领域不断推出新技术及产品，形成了明显的竞争优势预计未来将陆续有新药投放市场。

凭籍在生物医药领域的实力，公司多次担纲国家级研发项目，包括国家重点科技项目计划和国家高技术研究发展计划（八六三计划）、“ 国家 “ 重大新药创制 ” 科技重大专项 ” 等。一九九八年以来，公司被连续认定为 “ 高新技术企业 ” ；一九九九年，公司被国家人事部批准为 “ 企业博士后科研工作站 ” 。二〇〇二年八月，公司在香港创业板成功上市（股票代码：8231）。

公司现控股上海摩根谈国际生命科学中心有限公司、上海靶点药物有限公司、泰州复旦张江药业有限公司、上海溯源生物技术有限公司，参股上海先导药业有限公司。公司人力资源丰富，技术力量强大，约400名高素质的员工将推动公司不断创新，实现飞跃。

Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd. (“FDZJ”), established in November 1996, is located in Zhangjiang Hi-Tech park, Pudong, Shanghai. The shareholders of the company are well-known companies and universities, such as Shanghai Pharmaceuticals Holding Co., Ltd., China New Enterprise Investment Fund II, Shanghai Zhangjiang Hi-Tech Park Development Co., Ltd., and Shanghai Fudan Asset Operating Limited, etc.

Bearing the idea of “the more we explore, the healthier human beings will be” in mind, aiming at the establishment of an innovative bio-pharmaceutical company with the core capacity of the intellectual properties creation, the company is principally engaged in research, development, manufacture and sale of innovative bio-pharmaceutical products. After years of the unremitting efforts, the company has developed new technologies and products in the fields of genetic engineering drugs, photodynamic drugs and nano-drugs which created competitive advantages. It is planned to launch new drugs gradually in future.

Depends on the strong R&D strength of bio-pharmaceutical areas, the company has played a leading role in the execution of the national R&D projects, including “National Key Project on Development of Science and Technology” (Project 865), “National Key Project on Important Medicine Innovation”, etc. The company has been recognized as a hi-tech enterprise since 1998 and authorized as “The Post-doctoral Station of Research” since 1999. The company was listed in HK GEM in August 2002 (code No: 8231).

Shanghai Morgan-Tan International Center for Life Sciences Co., Ltd., Shanghai Ba Dian Medicine Co., Ltd., Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd. and Shanghai Tracing Bio-technology Co., Ltd are the subsidiaries of FDZJ. Shanghai Lead Discovery Limited Company is the associate of FDZJ. FDZJ has rich human resource and strong technique power. About 400 high-quality employees will lead the R&D of new drugs forward for the greater progress.

上海复旦张江生物医药有限公司
FUDAN ZHANGJIANG

我们的股东
Shareholders

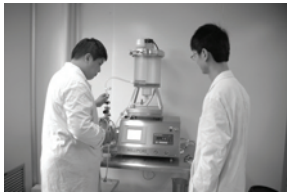
集团股东

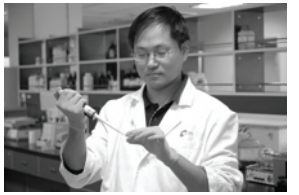
上海医药集团股份有限公司
Shanghai Pharmaceuticals Holding Co., Ltd.

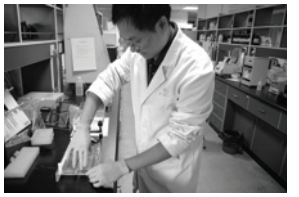
新企二期创业投资企业
China New Enterprise Investment Fund II

上海浦东科技投资有限公司
Shanghai Pudong Science And Technology Investment Co., Ltd.

上海复旦资产经营有限公司
Shanghai Fudan Asset Operating Limited







公司实行董事会领导下的总经理负责制
按职能分为五大体系

Under the leadership of the board of directors, the company adopts the system of general manager responsibility. The system is divided into five major functional divisions as follows.

研究开发体系
R & D Division

基因工程药物研发部
Genetic Engineering Drug Department

化学药物研发部
Chemical Drug Department

医学部
Medical Department

生产体系
Production Division

制造部
Manufacture Department

物流部
Logistic Department

设备管理部
Equipment Department

营销体系
Marketing Division

销售部
Sales Department

商务部
Commercial Department

市场部
Marketing Department

营销中心办公室
Office of Marketing Centre

管理保障体系
Management Supporting Division

营运策划部
Business Planning Department

行政人事部
Admin and HR Department

财务部
Financial Department

质量保障体系
Quality Control Division

质量管理部
Quality Management Department

纳米药物研发平台

Platform of R & D Based on Nano-Drugs

纳米药物（Nano - Drugs）研发平台是利用脂质体、纳米粒和微乳等纳米给药技术，改善药物的理化性质、药代动力学性质和药理毒理性质，使普通制剂具有缓释、控释和靶向等特性，以提高原有制剂的治疗效果、降低其毒副作用和改善依从性。

The technology to prepare the drugs of nanometer grade is studied on the platform, such as liposomal technology, nanometer particle, micro-emulsions and so on, to improve drug's chemical or physical properties, pharmacokinetic properties, pharmacological properties and toxicological properties, to give new characteristics, such as suspended releasing, controlled releasing, targeting and so on to the original drugs and then to increase the efficacy, reduce the toxicities, lessen the occurrence rate of the reverse reactions and improve the compliance of the conventional drugs.

纳米药物研发平台

Platform of R & D Based on Nano-Drugs

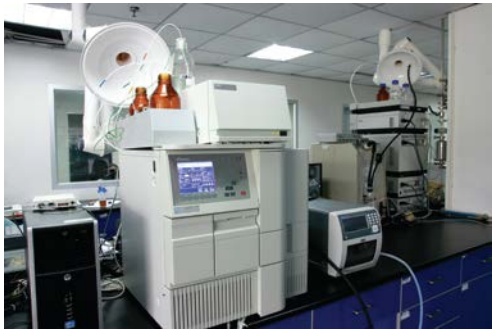
脂质体、纳米粒、微乳等缓控释制剂是高端药物制剂，具有很高的技术壁垒，可以有效避免大量重复和同质化竞争。复旦张江采用国际标准，开发出系列脂质体及纳米粒抗肿瘤药物制剂，突破了缓控释高端制剂的大规模生产技术，建成了具有国际水平的脂质体药物生产线。

The preparation of the drugs characteristic of sustended releasing or control releasing based on the technology relating to liposome, nanometer particle and micro-emulsions are regarded as high-technology which performs as a barrier for the further development of these drugs and makes the products confront less competitions in the market. Following the international standard, FDZJ developed a series of liposomal or nanometer graded new antitumor drug agents and manufactured in production scale in the processing line which met the international requirement.

纳米药物研发平台开发的项目包括：

The projects carried on this platform include

- 盐酸多柔比星脂质体注射液（Doxil仿制药, 用于治疗肿瘤）：于2009年实现上市，商品名里葆多®
  Doxorubicin Hydrochloride Liposome Injection (antitumor, generic) listed in market since 2009, with the brand name of LIBOd ®
- 注射用硫酸长春新碱脂质体浓溶液（用于治疗肿瘤）：已进入临床研究
  Vincristin Sulfate Liposome Concentrate Solution for Injection(antitumor), in the stage of clinical trial phase Ⅰ
- 紫杉烷类药物纳米制剂（用于治疗肿瘤）：临床前研究
  Taxan nanometer injection (antitumor), in the stage of pre–clinical studies
- 两性霉素 B 脂质体制剂（Amphotec仿制药，用于治疗深部真菌感染）：已完成临床前研究
  Amphotericin B Liposome for Injection (antifungal, generic as Amphotec), pre–clinical completed



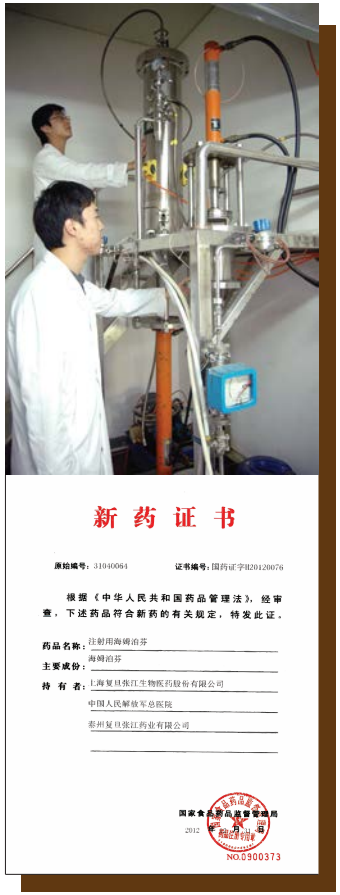
光动力药物研发平台

Platform of R & D of Photodynamic Drugs

光动力治疗（photodynamic therapy, PDT）是极具特色的医药领域，在治疗血管增生性疾病、表浅性肿瘤方面，具有选择性高、副作用小的优势，近年来在国际上形成新的开发热潮。这一疗法的基础是：某些特定药物（光敏剂）进入患者体内后，富集到生长旺盛的组织（如肿瘤、鲜红斑痣、眼底黄斑病变及尖锐湿疣等），在一定波长激光辐照下，光敏剂发生光化学反应而产生单线态氧（ $^1O_2$ ）等活性物质，在照射部位产生光毒性，杀伤靶细胞，产生治疗效果。由于光敏剂释放的单线态氧等自由基寿命非常短，只能在产生的部位（光照的部位）发挥作用，因而具有极好的靶向性。

Photodynamic therapy (PDT) is especially significant to treat vascular proliferative disease and superficial tumors with the advantages of higher selectivity and less reverse reactions. Attention has been paid to the R & D of new drug for PDT internationally. The mechanism of the PDT has been elucidated. The vigorously grown cells or tissues, e.g. those on sites of tumor, port wine stain, fundus macular lesion and condyloma acuminatum, undergo a series of photochemical reactions caused by the radiation of certain laser with a suitable wave length, when a particular drug (photosensitive drug) is administrated. Some active substances as singlet oxygen are produced in the photoreactions and produce photo-toxicities on the site radiated to injure the cells or tissues and then to bring therapeutic efficacy. The therapy is highly targeted because the photo-reaction is only taking place on the site radiated and the active substances have a very short life.

光动力药物研发平台
Platform of R & D of Photodynamic Drugs



复旦张江是国内最早开展光动力药物研究的公司，在这个平台上已开发出3个光动力新药，涉及5个适应症，拥有10多项发明专利，已成为国际上最具实力的光动力治疗药物研发机构之一。

FDZJ is the first company to deal with the R & D of photodynamic drugs and regarded as the one of the most powerful companies for the R & D of photodynamic drugs. Three new photodynamic drugs with 5 indications and more than ten patents developed in the platform.

光动力研发平台上开发的药物包括：
The projects carried on this platform include

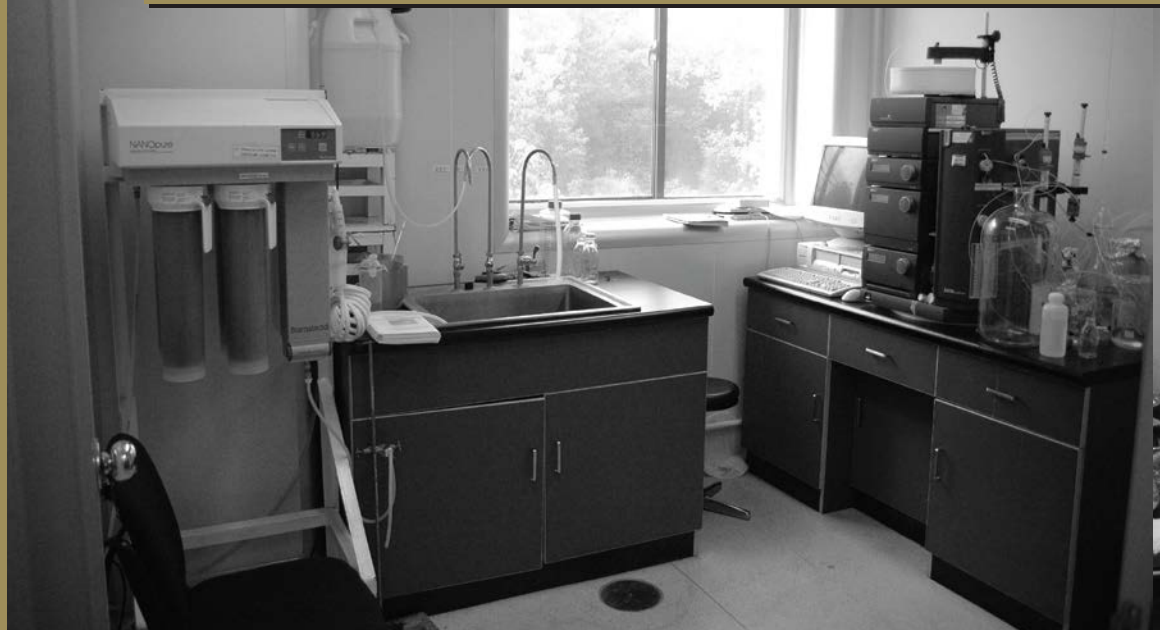
- 盐酸氨基酮戊酸（Aminolevulinic acid, ALA）新药（治疗尖锐湿疣）：2007年实现上市，商品名艾拉®
  Aminolevulinic acid (ALA) to treat condyloma, listed in market since 2007, with the brand name of ALA®
- 盐酸氨基酮戊酸（Aminolevulinic acid, ALA）化妆品（治疗中重度痤疮）：2010年实现上市，商品名易妍®
  Aminolevulinic acid (ALA) to treat acne, listed in market since 2010, with the brand name of YIYAN®
- 盐酸氨基酮戊酸（Aminolevulinic acid, ALA）新药（治疗宫颈癌前病变），工期临床研究
  Aminolevulinic acid (ALA) to treat cervical precancerous lesions, phase I clinnical trial
- 海姆泊芬（Hemoporfin）新药（治疗鲜红斑痣）：上市准备
  Hemporfin to treat port wine stain, pre-marketing
- 多替泊芬（Deuteporfin）新药：已进入临床 II 期研究
  Deuteporfin to treat tumor, in the stage of clinical trial phase II

基因工程药物研发平台

Platform of Genetic Engineering Drugs

基因工程药物是指将功能已经明确的基因根据预防和治疗疾病的需要，采用计算机辅助模拟技术和DNA重组技术，对其改造后导入宿主中表达，以生产供人体治疗用的多肽或蛋白质药物。

Based on the genes whose functions have been clearly recognized and the needs of disease prevention and treatment, the R & D of the genetic engineering drugs adopts computer-assisted design technique and DNA recombination technique for modification of the genes and expression in the host to prepare polypeptide or protein drugs.



基因工程药物研发平台

Platform of Genetic Engineering Drugs

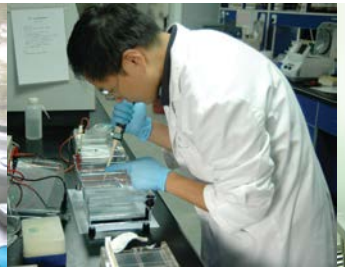
复旦张江已经建立了原核细胞表达系统和哺乳动物细胞表达系统两大技术体系，在细菌和哺乳动物细胞的高密度发酵与表达、蛋白质大规模复性和纯化技术上有突出创新研究。该平台共承担国家级研究课题3项，其中国家863项目2项（新型淋巴毒素的开发研究2001AA215051、新型淋巴毒素的临床研究2002AA2Z3309/2005AA2Z3G10），国家“重大新药创制项目”1项（哺乳动物细胞大规模培养及药物制备关键技术研究，2009ZX09503–012）。

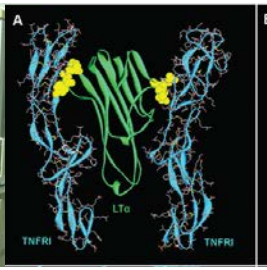
Two technique systems have been constructed in FDZJ: prokaryote cells expression and mammalian cells expression. Outstanding results on high density fermentation and expression of bacteria or mammalian cells, recovery of protein on big scale and purification have been obtained. The studies on three national topics are carried out on the platform: two projects of “863” (The Development of New Type of Lymph-toxin, 2001AA215051, The Clinical Trial of New Type of Lymph-toxin, 2002AA2Z3309/ 2005AA3Z3G10) and one project of “Key Project of New Drug R & D”(The Studies on Big Scale Culture of Mammalian Cells and the Key Technique of Drug Preparation,2009ZX09503-012).

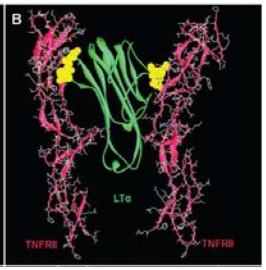
基因工程药物研发平台研发的基因工程药物包括：

The projects carried on this platform include

- 重组人淋巴毒素α衍生物（LT, 治疗肿瘤）：已完成II期临床研究
  Recombinant derivatives of human lymph–toxin (LT, antitumor), finished the stage of clinical trial phase II
- 重组人组织型纤溶酶原激酶衍生物（Reteplase, 治疗心肌梗死）：已获准上市
  Recombinant derivatives of human tissue plasminogen activator (rhTPA, Reteplase, for the treatment of Myocardial infarction), listed in market already
- 重组人TNF受体75–Fc融合蛋白（Etanercept,治疗类风湿性关节炎）：已申报新药证书
  Recombinant human TNF receptor 75 – Fc fusion protein (Etanercept, for the treatment of rheumatoid arthritis), submitted to apply for the Certificate of New Drug
- 重组人TNF受体75–Fc融合蛋白突变体（Hitanercept, 治疗类风湿性关节炎）：已申报临床研究批文
  The mutant of recombinant human TNF receptor 75 – Fc fusion protein (Hitanercept, for the treatment of rheumatoid arthritis), submitted to apply for the permission of clinical trial







我们的生产线

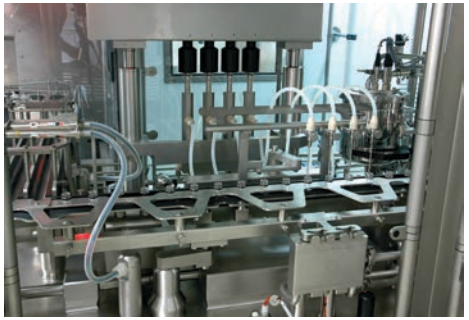
Three Processing Lines

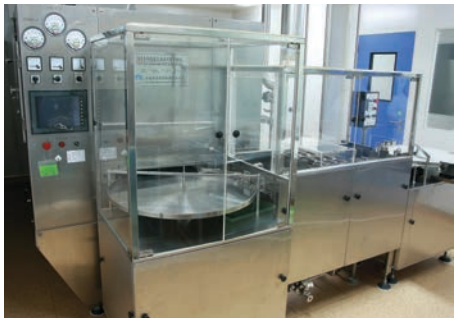
小容量注射剂车间

Small Capacity Injection Workshop

小容量注射剂车间：一条小容量注射剂（抗肿瘤药）生产线，2013年上半年通过国家新版GMP认证，获得小容量注射剂（抗肿瘤药）生产的GMP证书。配备德国进口的洗、灌、封全自动生产设备洁净程度达到B+A级别，全线安装有限制进出隔离系统（RABS），在线清洗（CIP），在线灭菌（SIP）。现在主要生产盐酸多柔比星脂质体注射液（商品名为里葆多）。

Small Capacity Injection Workshop: a small volume injection (anti-tumor) product line which obtained the GMP certificate in 2013.It outfits with automatic production equipment imported from Germany, for washing, filling and capping, and the cleanliness can reach B+A Air grades. The full lines have been equipped with restrictive access barrier system,equipped with CIP cleansing function and SIP sterilizing function. Currently, the main product is Doxorubicin hydrochloride liposome injection (Trade Name: “LIBOd”).





外用固体制剂车间

Exterior Solid Dosage Workshop

外用固体制剂车间，一条D级洁净级别的外用固体制剂生产线，2012年通过国家新版GMP认证，获得外用固体制剂生产的GMP证书。现在主要生产散剂：外用盐酸氨酮戊酸散（商品名为艾拉）。

Exterior Solid Dosage Workshop: a grade D environment production line which was designed to produce the solid dosages. It obtained the GMP certificate of 2010 version in 2012. Now it primarily produces external use Aminolevulinic Acid hydrochloride Dose. (Trade Name: “ALA”).

原料药车间

Bulk Drug Workshop

原料药车间，一条D级洁净级别的原料药生产线，2012年通过国家新版GMP认证，获得原料药生产的GMP证书。现在主要生产盐酸氨酮戊酸，艾拉的原料药。

Raw Materials Workshop: a grade D environment Raw Material production line which was built in accordance to the latest 2010 version of the national GMP and obtained the GMP certificate in 2012. The main product of this line is Aminolevulinic Acid hydrochloride, raw material of ALA.

销售体系-以学术推广为主的营销模式

Team of Marketing and Sales with the Ability of Academic Promotion

我们是这样的一群人——怀揣着同一个梦想：做大中国企业自己的创新药；秉承着同一种创业理念：专心、专业、专注；实践着同一种销售模式——顾问式销售；铸就了共同的丰碑：探讨和建立了医院、科室、医生、患者、公司的共赢模式。这就是复旦张江营销团队！

We are such a group of people
- With a same dream: trying our best to enlarge the market size of the innovative medicine developed by our own Chinese company.
- Uphold the same business philosophy: concentrating , professional and focusing.
- Practice the same kind of sales model: playing a part of a sales consultant.
- Construct a common monument: exploring and setting up a win-win model between hospital, departments, doctors, patients and the company.

This is our sales team of FDZJ!




销售体系

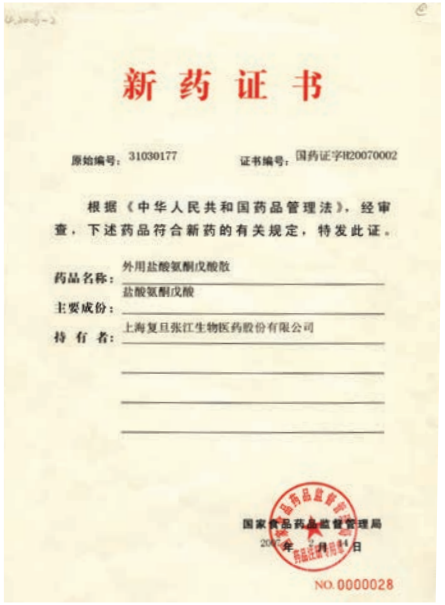
销售团队

现在的复旦张江，以“解决临床实际问题”和“提升患者生活质量”为己任，业务覆盖国内顶级医院近1000家，与全国近10000名临床医生通力合作，以专业化的学术推广为导向，并建立了高质量的客户服务系统。

Today’s business of FDZJ, in order to take “solving practical clinic problems and improving life quality of patients ” as its mission, has covered a domestic area with nearly 1000 top class hospitals and worked with nearly 10000 clinical doctors across the country. A high quality customer service system has been constructed under the guidance of the concept of professional academic promotion.

未来的复旦张江，将与时俱进，利用先进的传播手段，和我们的客户共同建立中国光动力治疗的金标准，成为中国自主创新药物的第一品牌和市场领导者，傲立于世界之巅！

Future’s FDZJ will keep pace with the progress of modern drug R&D, use the latest advanced communication tool, collaborate with all of our customers to set up the gold standard of photodynamic therapy in China, and become the first brand of China's innovative drugs and a market leader to stand on the top of the world!



新 药 证 书

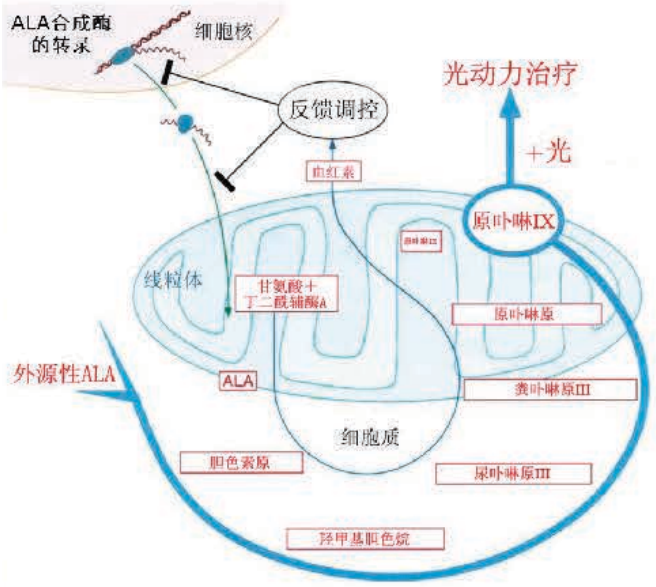
原始编号：31030177　　证书编号：国药证字H20070002

根据《中华人民共和国药品管理法》，经审查，下述药品符合新药的有关规定，特发此证。

药品名称：外用盐酸氨酮戊酸散
主要成份：盐酸氨酮戊酸
持 有 者：上海复旦张江生物医药股份有限公司

国家食品药品监督管理局
二〇〇七年十一月十一日

NO.0000028



光学动力治疗药物
艾拉 外用盐酸氨酮戊酸散

Photodynamic Drug

ALA®, aminolevulinic acid

5–盐酸氨酮戊酸（5–ALA）是近年来开发的第2代光敏剂，是一种体内合成血红素的前体物。正常情况下，ALA在细胞内的量很小、本身不产生光敏性。外源性ALA进入体内后，可被增生活跃的细胞选择性吸收并积累，并转化为原卟啉IX（PpIX）等卟啉类物质。PpIX是一种活性很强的光敏剂，经过特定波长的红光照射后即发生光动力反应，产生活性氧如单线态氧等而杀死增生活跃的细胞，而邻近正常组织则不受任何影响。

复旦张江在研究了大量有关ALA的科学资料的基础上，根据中国疾病谱和市场特点，选择人类乳头瘤病毒（HPV）感染引起的传染病——尖锐湿疣作为开发方向，在国际上率先将ALA治疗尖锐湿疣的新适应症推向临床研究。临床试验结果表明，ALA–光动力治疗用于尖锐湿疣，疣体清除率达98.42%；治疗后复发率仅为10.77%。同时，病人耐受性好，安全性高，不留疤痕，不良反应发生率也仅为7.67%。专家一致认为，艾拉光动力治疗将成为尿道口尖锐湿疣的首选疗法和尿道外尖锐湿疣的一线疗法。

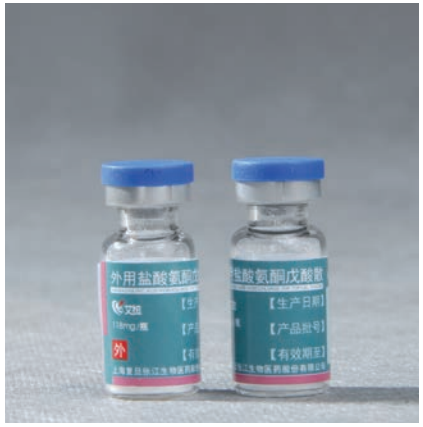
5 - Aminolevulinic acid (5 – ALA) is the second generation of photosensitive reagents recently developed. It is a precursor existing in the heme synthesis process in vivo. The quantity of ALA normally existing inside body is very small and does not show any photosensitivity. The exogenous ALA administrated can be selectively absorbed by cells, accumulated and then transferred to PpIX inside the cells, which is a strong photosensitive reagent. When a red light with a certain wave length is radiated, a photodynamic reaction takes place to produce active oxygen, e.g. singlet oxygen, and then to injure hyperplasia cells while the nearby cells remain unaffected.

On the bases of the studies of the information of ALA, considering the disease spectrum and market feature in China, the researchers in FDZJ choose condyloma, a disease caused by HPV infection, as the indication to deal with, and carry out the clinical studies to treat condyloma with ALA® photodynamic therapy. The results of the clinical trial showed that the clearance rate reached 98.42% and the recurrence rate reduced to 10.77%. At the meantime, better tolerance and higher safety were also observed. The treatment left no scar on the treated site. The occurrence rate of the reverse reactions was only 7.67%. It is commonly regarded that ALA® PDT will be the first choice for the treatment of condyloma sited on urinary meatus and the first line treatment for condyloma outside of urethral.

经国家食品药品监督管理总局（CFDA）批准，复旦张江光动力新药“艾拉”（国药准字H20070027）于2007年2月14日获得新药证书、生产批文，并于2007年5月上市销售。

艾拉目前临床适应症：尖锐湿疣。尖锐湿疣细胞有着增生活跃等与癌细胞相似的特点艾拉能够选择性地在尖锐湿疣细胞中分布和累积，加以特定波长和能量的光波照射，可以选择性地杀死尖锐湿疣细胞，而不损害周围正常组织细胞。尤其对亚临床感染和潜伏感染也能清除，从而降低复发率。

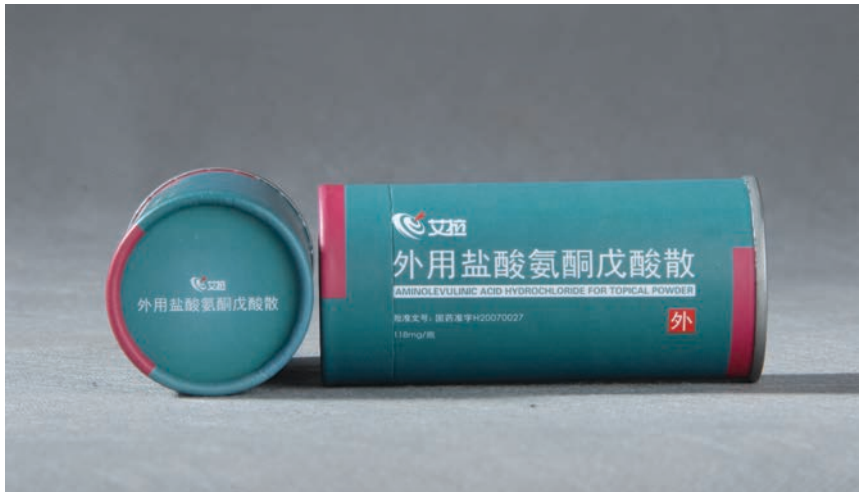
艾拉光动力药品的研制成功，给传统的尖锐湿疣治疗领域提供了全新的治疗手段，填补了尿道口尖锐湿疣长期缺乏有效治疗的空白，成为治疗尖锐湿疣的首选疗法。



Approved by CFDA, ALA® (register No. GYZ H20070027) received the Certificate of New Drug and the License of Manufacture on 14th, February, 2007 and listed in market in May, 2007.

The indication of ALA® is condyloma which has the same characteristic of hyperplasia cells. ALA selectively distributes and accumulates in condyloma infected cells and selectively kills these cells to clear the subclinical infection and latent infection, and then reduces the reoccurrence rate of the disease, when the radiation with certain wave length and energy takes place and the nearby cells remain unaffected.

The successful development of ALA® brought a totally new therapy for the treatment of condyloma. Effective method to treat condyloma sited on urinary meatus has been lacked for a long time. ALA® PDT filled in the gaps and is regarded as the first line treatment for condyloma.



里葆多
盐酸多柔比星脂质体注射液

LIBOd®
Doxorubicin Hydrochloride Liposome Injection

公司采用革命性的隐匿脂质体传输技术生产的盐酸多柔比星脂质体注射液（里葆多®）已经获得中国国家食品药品监督管理总局（CFDA）批准于2009年7月在国内上市，是国内第一个也是唯一一个成功投产的PEG脂质体化疗药物。

里葆多® 具有与多柔比星完全不同的药代动力学特点，增加药物在体内的循环时间，保证药物能靶向性地向癌灶局部富集，通过控制药物粒径，大大增强药物的抗肿瘤活性，同时减少了药物原有的心脏、骨髓以及脱发等毒副反应，是目前较理想的蒽环类化疗药物。

本品是一种脂质体制剂，系将盐酸多柔比星包封于聚乙二醇化(PEG化)的脂质体中，可以保护脂质体免受单核巨噬细胞系统（MPS）识别，从而延长其在血液循环中的时间。

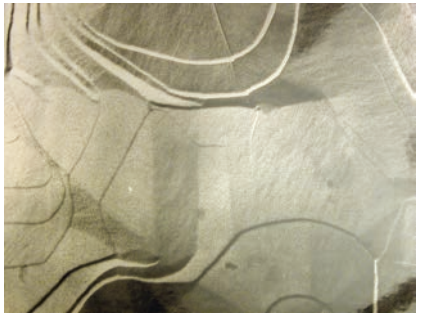
本品为无菌、半透明红色混悬液，每瓶10ml，含盐酸多柔比星2mg/ml，是用于单剂量静脉滴注的浓缩液。本品活性成份为盐酸多柔比星，是从一种波塞链霉菌表灰变种 (Streptomyces peucetius var.caesius)培养液中提取得到的蒽环类细胞毒性抗生素。

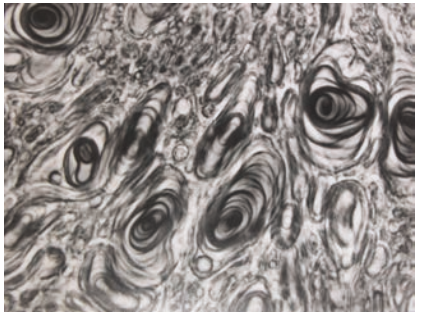
LIBOd®, prepared with the advanced technology of stealth liposome, has received the manufacture license issued by CFDA and is the first PEG product made in China and listed in China market.

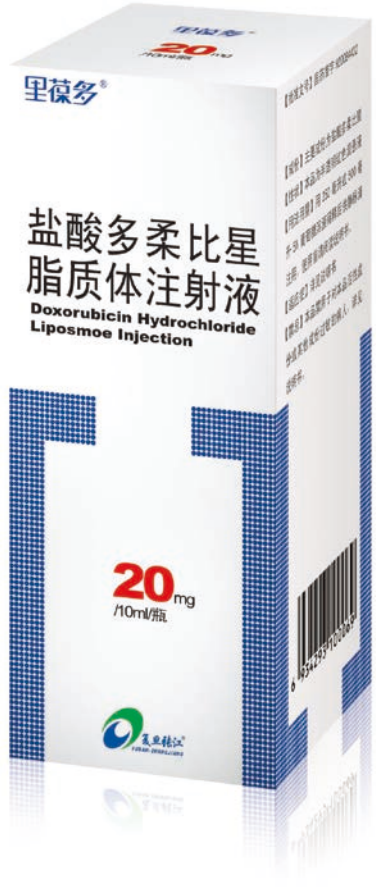
LIBOd® possesses a totally different pharmacokinetic property compared with the conventional doxorubicin hydrochloride preparation. The duration of the circulation of the new drug inside body is increased to ensure the targeted accumulation of the drug in the lesion area. The particle size is controlled to increase the efficacy and decrease the toxicity on the heart and bone marrow and occurrence of the reverse reactions, such as hair loss. It is regarded as an ideal anthracycline drug used in chemotherapy.

LIBOd® is a liposomal reagent. Doxorubicin hydrochloride is encapsulated in pegylated liposome (PEG) whose surface is covered with methoxypolyethylene glycol MPEG molecules, which protect the liposome to avoid the identification by the mono-nuclear macrophages （MPS）. The duration of the circulation in blood is then extended.

It is a sterile, semitransparent and red suspension. 10 ml / vial, each ml contains 2 mg of doxorubicin hydrochloride. It is a concentrate of single dose for intravenous infusion. Doxorubicin hydrochloride is an anthracycline antibiotic with cytotoxicity and extracted from the culture medium of streptomyces peucetius var.caesius.





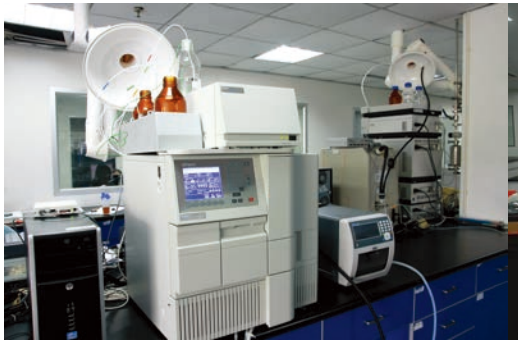


【药品批准文号】
国药准字H20084432
【适应症】
本品可用于低CD_4（＜200CD_4淋巴细胞/mm^3）及有广泛皮肤粘膜内脏疾病的与艾滋病相关的卡波氏肉瘤（AIDS-KS）病人。
本品可用作一线全身化疗药物，或者用作治疗病情有进展的AIDS-KS病人的二线化疗药物，也可用于不能耐受下列两种以上药物联合化疗的病人长春新碱、博莱霉素和多柔比星（或其他蒽环类抗生素）。
盐酸多柔比星脂质体注射液在国外还被批准用于乳腺癌、卵巢癌和多发性骨髓瘤等恶性肿瘤。
【规格】20mg/10ml/瓶

[Register No.] GYZ H20084432

[Indication] This product is indicated for treatment of patients with AIDS-related Kaposi's sarcoma (AIDS-KS) who has a low CD4 (<200CD4 lymphocytes/mm3) and a wide range of mucocutaneous and visceral diseases.
This prodcut can be used as first-line systemic chemotherapy or used as the second-chemotherapeutic drug in AIDS-KS patients with progressive disease. It can also be used in patients who are intolerable to chemotherapy combined with more than two of the following drugs: vincristine, bleomycin and doxorubicin (or other anthracycline antibiotics).

[Strength] 20 mg / 10 ml / vial




公司下属子公司及联营公司
Subsidiaries & Associates

泰州复旦张江药业有限公司
Taizhou Fudan–Zhangjiang Pharmaceutical Co., Ltd.

上海靶点药物有限公司
Shanghai Ba Dian Medicine Co., Ltd.

上海摩根谈国际生命科学中心有限公司
Shanghai Morgan–Tan International Center for Life Sciences Co., Ltd.

上海溯源生物技术有限公司
Shanghai Tracing Bio–technology Co., Ltd.

上海先导药业有限公司
Shanghai Lead Discovery Limited Company

泰州复旦张江药业有限公司简介

Introduction of Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd.

泰州复旦张江

子公司泰州复旦张江药业有限公司（简称“泰州复旦张江”）成立于2007年3月，注册资本8600万元人民币，位于泰州医药高新技术产业园内，占地面积100亩，作为集团的产业化基地，未来研发的新药将逐步纳入该生产基地实现产业化生产。

泰州复旦张江一期工程建设一条冻干/水针生产线及配套设施，根据集团产品的上市时间和种类还将分期建造口服制剂、大输液及抗肿瘤等生产线，逐步发展成为集多种剂型、多种规格为一体、以创新产品为主的现代化药品生产制造基地。主要生产线从德国、美国等国家进口，硬件及软件的设计和实施完全按照国家新版GMP和欧盟、美国FDA的标准进行，工厂今后的目标是能通过美国FDA认证，使产品质量和内部管理达到国际化水准。

Taizhou Fudan -Zhangjiang Pharmaceutical Co., Ltd.

Taizhou Fudan-Zhangjiang Pharmaceutical Co., Ltd. (“Taizhou FDZJ”), a subsidiary of FDZJ, was founded in March 2007 with the registered capital of RMB 86 million. It is located in Taizhou medicine high-tech industrial park, covers an area of 17 acres. As the group’s industrial base, the new drugs will be gradually assigned to Taizhou for industrialization in the future.

Taizhou FDZJ installed a frozen dry/aqueous injection production line and relative facilities in phase I of the construction. Oral preparation production line, fusion preparation production line and antitumor drug preparation line will be conducted according to the launch time and categories of the new products of the group. Taizhou FDZJ will be gradually developed into a modern drugs production base which is competent to produce drugs, focusing on innovative drugs , with various doses, forms and strengths. The main production lines are imported from Germany, United States and so on. The hardware and software are designed and implemented in accordance with the latest version of national GMP, EU and US FDA standards. When the construction completed, Taizhou FDZJ will apply for the attestation of US FDA to meet the international standards of products quality and internal management.

「大事记」

1 1996年11月
上海复旦张江生物医药有限公司由复旦大学、上海浦东新区经贸国有资产经营公司及上海张江高新技术发展促进中心等共同投资设立。
November, 1996
Shanghai Fudan–Zhangjiang Bio–Pharmaceutical Co.,Ltd. (FDZJ) was established in November 1996, by Fudan University, Shanghai Pudong New District Economy and Trade State–own Asset Management Co. Ltd. and Zhangjiang Hi–tech Promotion Centre.

2 1997年12月
上海张江高科技园区开发股份有限公司（SH600895）增资成为公司新股东。
December, 1997
Shanghai Zhangjiang Hi–Tech Park Development Co.,Ltd. (SH600895) became a new investor of FDZJ.

3 1998年8月
上海复旦张江生物医药有限公司控股的上海摩根谈国际生命科学中心有限公司成立。
August, 1998
FDZJ established Shanghai Morgan–Tan International Center for Life Sciences Co.,Ltd. as a Subsidiary.

4 1998年11月
被上海市政府认定为“高新技术企业”。
November, 1998
FDZJ was identified as "Hi–Tech Enterprise" by Shanghai Municipal Government.

5 1999年5月
被国家人事部批准为“企业博士后科研工作站”。
May, 1999
FDZJ was designated as "Enterprise Postdoctoral Research Workstation" by the Ministry of Human Resources of PRC.

6 1999年8月
上海市医药股份有限公司（SH600849）受让股权成为公司第一大股东。
August, 1999
Shanghai Pharmaceutical Group Co. Ltd. (SH600849) became the largest shareholder through an equity transaction.

7 2000年3月
承担国家重点科技项目计划。
March, 2000
FDZJ undertook the National Key Science and Technology Project Plan Project.

8 2000年9月
中国通用技术（集团）控股有限责任公司受让股权成为公司第二大股东。于2013年2月27日，该股权转让给新企二期创业投资企业。
September, 2000
China General Technology(Group) Holding Limited. became the second largest shareholder through an equity transaction.
The share has been transferred to China New Enterprise Investment Fund II on 27 Feb.2013.

「大事记」

9 2000年10月
整体变更为股份有限公司，全称“上海复旦张江生物医药股份有限公司”。
October, 2000
FDZJ was transformed into a joint stock company with limited liability, and the full name is “Shanghai Fudan Zhangjiang Bio-Pharmaceutical Co. Ltd.”

10 2001年12月
承担国家高技术研究发展计划（八六三计划）项目。
September, 2001
FDZJ undertook the National High Technology Research and Development Program (863 Program).

11 2002年6月
第一个新药“重组人淋巴毒素-α衍生物（rhLT）”被国家药品监督管理局批准进入临床试验。
June, 2002
The first new drug “Derivatives of Recombinant Human Lymphotoxin-alpha (rhLT)” was approved to conduct clinical trial.

12 2002年7月
全新研发基地落成。
July, 2002
The new research and development base was built with full function.

13 2002年8月
在香港创业板上市，股票代码8231。
August, 2002
IPO in Hong Kong GEM, stock code: 8231.

14 2002年12月
复旦张江参股的上海先导药业有限公司成立。
December, 2002
Shanghai Lead Discovery Limited Company was established as an associate of FDZJ.

15 2003年6月
复旦张江控股的上海靶点药物有限公司成立。
June, 2003
Shanghai Ba Dian Medicine Co., Ltd. was established as a subsidiary of FDZJ.

16 2004年3月
第一次将药物技术转让给境外企业。
March, 2004
Drug technology was transferred to oversea firm for the first time.

「大事记」

17 2004年3月
“ 唐氏综合症产前筛查系统 ” 获国家食品药品监督管理局颁发的药品注册批件。该药品是中国开展 “ 出生缺陷干预工程 ” 以来第一个被批准用于临床的产品。
March, 2004
"Down Syndrome Prenatal Screening System" was approved by SFDA. It is the first drug selected by the national "Birth Defects Intervention Project".

18 2004年7月
通过国家食品药品监督管理局GMP认证。
July, 2004
FDZJ was awarded the national GMP certification of the SFDA.

19 2005年10月
完成第一项药物临床试验 - 外用盐酸氨酮戊酸散（ALA - 艾拉® ）。
October, 2005
FDZJ completed the first clinical trial of Aminolevulinic Acid(ALA®)

20 2006年11月
公司成立十周年，举行十周年回顾和庆典活动。
November, 2006
Ten year anniversary celebration of FDZJ was held.

21 2007年2月
“ 外用盐酸氨酮戊酸散（艾拉®） ” 获国家食品药品监督管理局颁发的药品注册批件，随后上市销售。
February, 2007
Drug License for Aminolevulinic Acid (ALAR) Issued by SFDA in Feb., 2007 and sale started thereafter.

22 2007年3月
治疗艾滋病的尼非韦罗获得国家食品药品监督管理局批准，进入临床研究。
March, 2007
Nifivoc, a drug for the Treatment of HIV/AIDS was approved to conduct the clinical trial by the SFAD.

23 2007年3月
复旦张江在江苏泰州注册成立全资子公司泰州复旦张江药业有限公司
March, 2007
FDZJ established a wholly - owned subsidiary: Taizhou Fudan - Zhangjiang Pharmaceutical Co., Ltd. in Jiangsu Province.

「大事记」

24 2008年10月
“盐酸多柔比星脂质体注射液（里葆多®）”获国家食品药品监督管理局颁发的药品注册批件，随后上市销售。
October, 2008
Drug License for “The Doxorubicin Hydrochloride Liposome Injection” was issued by SFDA in Oct 2008 and sale started thereafter.

25 2009年12月
入选国家科技重大专项“重大新药创制----企业创新药物孵化基地建设”计划并获资助。
December, 2009
FDZJ was elected by the National Science and Technology Program as "Significant New Drug Creation----Enterprises Innovation Incubation Base" with funding support.

26 2010年2月
重组人肿瘤坏死因子受体突变体-Fc融合蛋白研制的国际学术文章在美国科学研究杂志获得发表。
February, 2010
The paper “Recombinant Mutant Human Tumor Necrosis Factor Receptor-FC Fusion Protein in Development” by FDZJ was published in the Science Journal of United States.

27 2010年8月
一类新药光动力药物“海姆泊芬”完成临床研究并申请新药证书。
August, 2010
Category 1 New Drug (NDA): “Hemoporfin” was completed clinical trial and was submitted for application of new drug certificate.

28 2011年2月
复旦张江与上海医药签订创新药物研发战略合作协议。
February, 2011
A strategic cooperation agreement on innovative drug research and development (R&D) was signed between and FDZJ.

29 2012年7月
外用盐酸氨酮戊酸散（艾拉®）获得“2011年度上海市高新技术成果转化项目百佳”称号，名列第24位，医疗产品类第3位，药品类第1位。
July, 2012
Aminolevulinic acid (ALA®), received the title of “100 Best Results of the Industrialization of Shanghai Hi-tech Projects in 2011”,ranked on the 1st place in the classification of drugs, the 3rd in medical products and 24th in all nominated.

30 2012年11月
子公司上海溯源生物科技有限公司成立
November,2012
Shanghai Tracing Biotech Co.,Ltd was established in Nov,2012 as a subsidiary of FDZJ.


新 药 证 书

原始编号：31040083　　证书编号：国药证字H20120079

根据《中华人民共和国药品管理法》，经审查，下述药品符合新药的有关规定，特发此证。

药品名称：海姆泊芬
主要成份：海姆泊芬
持 有 者：上海复旦张江生物医药股份有限公司
中国人民解放军总医院
泰州复旦张江药业有限公司

国家食品药品监督管理局
2012 年 7 月 11 日
NO.0900387

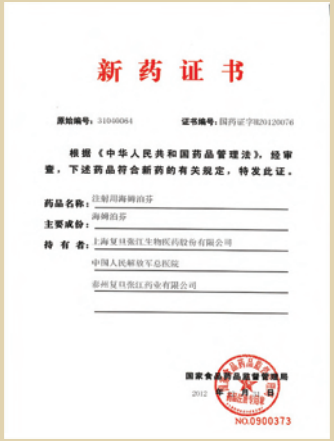
新 药 证 书

原始编号：31030177　　证书编号：国药证字H20070002

根据《中华人民共和国药品管理法》，经审查，下述药品符合新药的有关规定，特发此证。

药品名称：外用盐酸氨酮戊酸散
主要成份：盐酸氨酮戊酸
持 有 者：上海复旦张江生物医药股份有限公司

国家药品监督管理局
2007 年 11 月 14 日
NO. 0000028

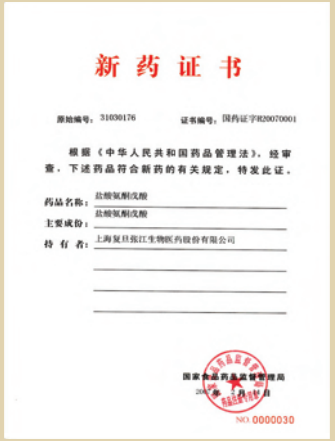

新 药 证 书

原始编号：31040084　　证书编号：国药证字H20120076

根据《中华人民共和国药品管理法》，经审查，下述药品符合新药的有关规定，特发此证。

药品名称：注射用海姆泊芬
主要成份：海姆泊芬
持 有 者：上海复旦张江生物医药股份有限公司
中国人民解放军总医院
泰州复旦张江药业有限公司

国家食品药品监督管理局
2012 年 7 月 11 日
NO.0900373


新 药 证 书

原始编号：31030176　　证书编号：国药证字H20070001

根据《中华人民共和国药品管理法》，经审查，下述药品符合新药的有关规定，特发此证。

药品名称：盐酸氨酮戊酸
主要成份：盐酸氨酮戊酸
持 有 者：上海复旦张江生物医药股份有限公司

国家药品监督管理局
2007 年 11 月 14 日
NO. 0000030