中华人民共和国
（江苏）省（自治区、直辖市）食品药品监督管理局
出口欧盟原料药证明文件
PEOPLE'S REPUBLIC OF CHINA
(JIANGSU) FOOD AND DRUG ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no.(given by the issuing regulatory authority): JS130019
证明文件编号:JS130019

1. Name and address of site (including building number, where applicable):
工厂名称与地址(包括建筑物门牌号):

Name: Changzhou Pharmaceutical Factory
公司名称：常州制药厂有限公司
Address:No.518 Laodong East Road，Changzhou，Jiangsu
公司地址:江苏省常州市天宁区劳动东路 518 号

2.Manufacturer's licence number(s): SU 20110138
《药品生产许可证》编号：苏 20110138

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE
项目 1 所列生产企业生产的下列用于出口欧盟的人用原料药

Active substance(s) 原料药名称（药品通用名）	Activity(ies) 加工方法	Chinese drug approval number 中国药品批准文号
卡托普利 Captopril	化学合成 Chemical synthesis	国药准字 H32021671

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:
兹证明：

This manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice (= GMP of EU，WHO/ICH Q7);
该企业所实施的 GMP 符合中国药品 GMP 要求，等同于欧盟、世界卫生组织组织以及 ICH Q7 药品 GMP 要求；

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure the protection of public health ,which is at least equivalent to that in the EU; and

该生产工厂接受定期、严格和透明的监管以及有效地执行药品 GMP 监管措施，包括反复的飞行检查，确保保护公众健康，其水平与欧盟相当；并且

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.
如发现不合规情况，将会及时通报欧盟有关部门。

Date of inspection of the plant under (1): May 30th –June 4th, 2013
对该生产工厂检查的日期：2013 年 5 月 30 日至 2013 年 6 月 4 日

This written confirmation remains valid until: July 21th, 2016
本证明文件的有效期：有效期至 2016 年 7 月 21 日

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
关于本证明文件的可靠性可向本局查询确认。

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Chinese law and Directive 2001/83/EC.
按照中国相关法律以及欧盟 2001/83/EC 指令，生产者应对药品质量负责，本证明不影响生产者履行该职责。

Address of the issuing regulatory authority: No.5 Gulou Street, Nanjing, Jiangsu Province
签发部门地址：江苏省南京市鼓楼街 5 号，210008

Name and function of responsible person: Yaoyu Ye, Deputy Director
负责人姓名及职务：叶耀宇 副局长

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Signature 签字 叶耀宇	Stamp of the authority and date:2013-7-22 签发部门盖章与日期:2013-7-22