中华人民共和国
江苏省药品监督管理局
出口欧盟原料药证明文件
PEOPLE'S REPUBLIC OF CHINA
JIANGSU DRUG ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no.(given by the issuing regulatory authority): JS200015
证明文件编号: JS200015

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:Joyang Laboratories
公司名称:江苏九阳生物制药有限公司
Address:No.9,HaiduNorthRoad,SheyangEconomicDevelopmentZone
公司地址:射阳经济开发区海都北路9号;

2.Manufacturer's licence number(s): SU20160342
《药品生产许可证》编号:苏20160342

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
夫西地酸 (Fusidic acid)	生物制备工艺 (Biological processes)	无

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): Aug 20, 2019-Aug 22, 2019;
对该生产工厂检查的日期：2019年08月20日至2019年08月22日;

This written confirmation remains valid until: Feb 27, 2023
本证明文件的有效期：有效期至 2023年02月27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: Meng Yu, Director of Drug Safety
负责人姓名及职务：于萌 药品安全总监

E-mail, Telephone no., and Fax no.:anjc@jsfda.gov.cn;025-83209367;025-83273702
电子邮箱、电话、传真：anjc@jsfda.gov.cn;025-83209367;025-83273702

Signature 签字 于萌	Stamp of the authority and date:2020-02-28 签发部门盖章与日期:2020-02-28