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

Confirmation no.(given by the issuing regulatory authority): HB1900010
证明文件编号: HB190010
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):
HuangShi Shixing Pharmaceutical Co.,Ltd
黄石世星药业有限责任公司
NO.73 East Jinshan Road, Huangjinshan Development Zone,Huangshi,Hubei,China.
湖北省黄石市黄金山开发区金山大道东 73 号
Manufacturer's licence number(s): 鄂 20160125
《药品生产许可证》编号: 鄂 20160125

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[1] 中国药品批准文号
阿奇霉素 Azithromycin	化学合成 Chemical synthesis	国药准字 H20067135
琥乙红霉素 Erythromycin Ethylsuccinate	化学合成 Chemical synthesis	国药准字 H42020280
克拉霉素 Clarithromycin	化学合成 Chemical synthesis	国药准字 H20067159
罗红霉素 Roxithromycin	化学合成 Chemical synthesis	国药准字 H20067151
依托红霉素 Erythromycin Estolate	化学合成 Chemical synthesis	国药准字 H20003111
右酮洛芬氨丁三醇 Dexketoprofen Trometamol	化学合成 Chemical synthesis	国药准字 H20061277
右旋酮洛芬 Dexketoprofen	化学合成 Chemical synthesis	国药准字 H20061230

[1]仅供出口的原料药在此栏填写“无”。
Record “none” in case where there is for export-only active substance.

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): September 17th, 2015
对该生产工厂检查的日期：2015 年 09 月 17 日

This written confirmation remains valid until: July 12nd, 2022
本证明文件的有效期：2022 年 7 月 12 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.19 Gongzheng Road, Wuchang District, Wuhan City, Hubei Province 430071
签发部门地址：湖北省武汉市武昌区公正路 19 号 430071

Name and function of responsible person: Liu Wenbin, deputy director of the Hubei Medical Products Administration
负责人姓名及职务：刘文斌，湖北省药品监督管理局副局长

E-mail, Telephone no., and Fax no.:
电子邮箱、电话、传真：
hbanjian@163.com, 027-87111518

Signature 签字	Stamp of the authority and date 签发部门盖章与日期
刘文斌	湖北省药品监督管理局 2019.7.15