中华人民共和国
山东省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
SHANDONG FOOD AND DRUG ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no.(given by the issuing regulatory authority):
证明文件编号:
SD130001

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):
Shandong Xinhua Pharmaceutical Company Limited, 14 Dongyi Road, Zhangdian District, Zibo, Shandong, P.R.China
山东新华制药股份有限公司,中国山东淄博市张店区东一路 14 号

2.Manufacturer's licence number(s):
《药品生产许可证》编号:
鲁 20100102

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
Acetylsalicylic Acid (Aspirin) 阿司匹林	Chemical synthesis 化学合成	H37020354
Hydrocortisone 氢化可的松	Chemical synthesis 化学合成	H37020355
Metamizole Sodium 安乃近	Chemical synthesis 化学合成	H37023630
Phenazone (Antipyrine) 安替比林	Chemical synthesis 化学合成	H37020359
Propyphenazone 异丙安替比林	Chemical synthesis 化学合成	H19990058
Hydrocortisone Acetate 醋酸氢化可的松	Chemical synthesis 化学合成	None 无
Metamizole Magnesium 安乃近镁	Chemical synthesis 化学合成	None 无
Acetylsalicylic Acid Granulated 阿司匹林颗粒	Chemical synthesis 化学合成	None 无
Calcium Carbonate Granule 碳酸钙颗粒	Chemical synthesis 化学合成	None 无
Ibuprofen Dc Grade 布洛芬颗粒	Chemical synthesis 化学合成	None 无
Metamizole Sodium Dc Grade 安乃近颗粒	Chemical synthesis 化学合成	None 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

[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.

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):
对该生产工厂检查的日期:
May 17th,2013
2013 年 5 月 17 日
This written confirmation remains valid until:
本证明文件的有效期:
June 4th, 2016
2016 年 6 月 4 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:
签发部门地址:
No.11, Jiefang Road, Jinan
济南市解放路 11 号,250013

Name and function of responsible person:
负责人姓名及职务:
Haiyan Wang, Deputy Director
王海燕 副局长
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wanghaiyan@sdfda.gov.cn,+86-0531-88562007,+86-0531-88562057

Signature 签字 王海燕	Stamp of the authority and date 签发部门盖章与日期 2013.6.14