

中华人民共和国
浙江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
ZHEJIANG FOOD AND DRUG ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no.(given by the issuing regulatory authority):ZJ200122
证明文件编号:ZJ200122

1. Name and address of site (including building number, where applicable):Hangzhou Huadong Medicine Group Zhejiang Huayi Pharmaceutical Co., Ltd. No.15 Shuangfeng Road, Fotang,Zhejiang, China

工厂名称与地址(包括建筑物门牌号):杭州华东医药集团浙江华义制药有限公司 浙江省义乌市佛堂镇双峰路15号

2.Manufacturer's licence number(s):浙 20000396
《药品生产许可证》编号:浙 20000396

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
Febuxostat,非布司他	Chemical synthesis,化学合成	Y20170001633
Solifenacin succinate,琥珀酸索利那新	Chemical synthesis,化学合成	Y20180000737
Mirabegron,米拉贝隆	Chemical synthesis,化学合成	Y20190000765

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.



Empagliflozin,恩格列净	Chemical synthesis,化学合成	Y20190021274
Canagliflozin hemihydrate,卡格列净	Chemical synthesis,化学合成	Y20200001023
Tofacitinib citrate,枸橼酸托法替布	Chemical synthesis,化学合成	Y20200001214
Ciprofloxacin HCl,盐酸环丙沙星	Chemical synthesis,化学合成	国药准字 H20023625
Omeprazole,奥美拉唑	Chemical synthesis,化学合成	国药准字 H20055742
Duloxetine hydrochloride,盐酸度洛西汀	Chemical synthesis,化学合成	无
Levetiracetam ,左乙拉西坦	Chemical synthesis,化学合成	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): 不要在此处直接录入, 请点击本页上方的“修改”图标录入并保存检查日期。

对该生产工厂检查的日期: 不要在此处直接录入, 请点击本页上方的“修改”图标录入并保存检查日期。



This written confirmation remains valid until: Dec 13th, 2023
本证明文件的有效期：2023年12月13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: 27Wenbei Lane Mogansan Road Hangzhou 310012 P.R.China

签发部门地址：杭州莫干山路文北巷 27 号

Name and function of responsible person: He JinHua , Deputy Director

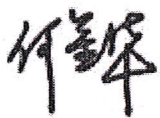
负责人姓名及职务：何金华，副处长

E-mail, Telephone no., and Fax no.:

ypsc@zjfda.gov.cn, (+86)0571-88903348, (+86)0571-88903273

电子邮箱、电话、传真：

ypsc@zjfda.gov.cn, (+86)0571-88903348, (+86)0571-88903273

Signature  签字	Stamp of the authority and date Dec 14 th , 2020 签发部门盖章与日期 2020年12月14日
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