



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)HB230032

证明文件编号: HB230032

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):

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

湖北葛店人福药业有限责任公司

No.25, Juxian Road, Gedian Economic Development District, E-zhou City, Hubei Province, P. R. China

湖北省鄂州市葛店经济技术开发区聚贤路25号

2. Manufacturer's licence number(s):鄂20200196

《药品生产许可证》编号:鄂20200196

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
非那雄胺 Finasteride	化学合成 Chemical synthesis	Y20180000714 Y20180000714
布地奈德 Budesonide	化学合成 Chemical synthesis	Y20190009886 Y20190009886
左炔诺孕酮 Levonorgestrel	化学合成 Chemical synthesis	Y20190007482 Y20190007482
黄体酮 Progesterone	化学合成 Chemical synthesis	Y20190008306 Y20190008306

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 EUWHO/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

仅供出口的原料药在此栏填写“无”。

Record “none” in casewhere there is for export-only active substance.

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。

This written confirmation remains valid until: November 12nd 2026

本证明文件的有效期：2026-11-12

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。

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

Wang Lulu, deputy director of the Hubei Medical Products Administration

负责人姓名及职务：王璐璐，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：

yp87111686@163.com, 027-87111686

Signature

签字



Stamp of the authority and date

签发部门盖章与日期

2023-11-13

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