

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



号码 No. 191100B0/068747

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of
DOCUMENT is in conformity with the original.

China Council for the Promotion
of International Trade

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授权签字:

Authorized
Signature: Zhang Dianming

日期: 2019年09月29日

(Date: Sep. 29, 2019)

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):ZJ190020
证明文件编号:ZJ190020

1. Name and address of site (including building number, where applicable):Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan Duqiao,Linhai,Zhejiang,317016
工厂名称与地址(包括建筑物门牌号):浙江华海药业股份有限公司 浙江省临海市杜桥镇川南, 317016

2.Manufacturer's licence number(s):浙 20000311
《药品生产许可证》编号:浙 20000311

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
Telmisartan,替米沙坦	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

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.

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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): Feb 14th, 2019
对该生产工厂检查的日期：2019 年 02 月 14 日

This written confirmation remains valid until: Mar 7th, 2021
本证明文件的有效期：2021 年 03 月 07 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: Ju Bo, Deputy Director
负责人姓名及职务：鞠波，副处长

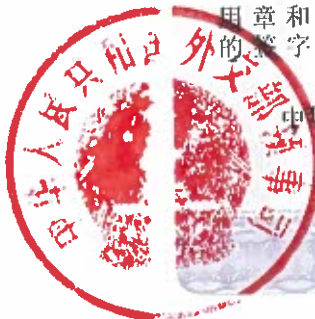
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Signature 签字	Stamp of the authority and date Mar 8 th , 2019 签发部门盖章与日期 2019 年 03 月 08 日
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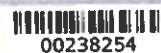


兹证明前面文书上中国国际贸易促进委员会商事证明专用章和授权签字人(张典明)的签字属实。



中华人民共和国外交部
领事司一等秘书
二〇一九年十月九日

张典明



CONSULADO DE CHILE EN BEIJING
R.P. CHINA

EL CONSUL DE CHILE QUE SUSCRIBE CERTIFICA LA AUTENTICIDAD DE LA FIRMA ELECTRONICA DEL OFICIAL DEL DEPARTAMENTO CONSULAR DE LEGALIZACIONES DEL MINISTERIO DE RELACIONES EXTERIORES DE LA R.P. CHINA.

NO. ACTUACION: 4233 ARANCEL ART. N° 4/10
DERECHOS US\$: 12.00 DIFERENCIA 10% US\$ 1.20
TOTAL PERCIBIDOS EN US\$ 13.20
PAGADO EN MONEDA DEL PAIS ¥ 86.00
BEIJING, 11 DE OCTUBRE DE 2019

JOSÉ MIGUEL GONZÁLEZ S.
MINISTRO CONSEJERO
CONSUL DE CHILE EN BEIJING



TODA DOCUMENTO LEGALIZADO EN ESTE CONSULADO DEBE SER REVALIDADO ANTE EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE. (De esta forma, su documento será reconocido por las autoridades chilenas).

Para ello, cuando llegue a Chile, dirijase al Departamento de Legalizaciones del Ministerio de Relaciones Exteriores, ubicado en calle Agustinas 1320 (esquina Teatinos), Santiago. El horario de atención es de 9:00 a 14:00 horas. El trámite no tiene costo.

Si usted es de provincia, lo invitamos a acercarse a su Gobernación más cercana y solicitar la legalización en el Ministerio de Relaciones Exteriores de Chile. Ellos enviarán a Santiago sus documentos, los que serán legalizados y enviados de regreso a la Gobernación, sin costo alguno.

