National Authority Of Medicines And Health Products

CERTIFICATE NUMBER: ***FT096/MH/001/2023***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:
The manufacturer: ***Jiangsu Hengrui Pharmaceuticals Co. Ltd.***
Site address: ***Dongjin Road Port Industry Area, Economic And Technological Development Zone, Lianyungang, 222069, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011688*** / ***LOC-100061536***
DUNS Number: ***42-132-4417***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-12-16***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

- Complete Address: No.2 Dongjin Road, Port Industry Area, Economic and Technological Development Zone, Lianyungang, Jiangsu 222069, China.

2023-10-02

Name and signature of the authorised person of the Competent Authority of Portugal

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Confidential
National Authority Of Medicines And Health Products
Tel:***Confidential***
Fax:***Confidential***

Jiangsu Food and Drug Administration

Approval Notification of Drug Registration Renewal

Receipt No.: CYHZ2111036SU Notification No.: 2021R045566

Drug name	General name: Ethiodized Poppyseed oil Injection English/Latin name: Ethiodized Poppyseed oil Injection		
Main ingredients	Ethiodized Poppyseed oil		
Dosage form	Injection	Application item	Domestic drug registration renewal
Strength	10 ml, 480mg/ml	Application type	Chemical drugs
Registration standard	YBH01972016	Original Drug Certificate No.	H20163348
Packaging	Medium borosilicate glass ampoule: 1 amp/box; 5 amps/box	Shelf life	24 months
Review conclusion	After review, this product complies with the relevant provisions of the *Measures for the Administration of Drug Registration* and is approved for renewal.		
Marketing Authorization Holder	Name: Jiangsu Hengrui Pharmaceuticals Co., Ltd. Address: 38 Huanghe Road, Economic & Technological Development Zone, Lianyungang, Jiangsu, China		
Manutacturer	Name: Jiangsu Hengrui Pharmaceuticals Co., Ltd. Address: Dongjin Road, Port Industry Area, Economic & Technological Development Zone, Lianyungang, Jiangsu, China		
Drug Certificate No.	H20163348	Valid to	2026-05-25
Original copy sent to	Jiangsu Hengrui Pharmaceuticals Co., Ltd.		
Copied to			
Remarks			

Stamped by Jiangsu Food and Drug Administration

Date: 26th May, 2021

江苏省药品监督管理局

药品再注册批准通知书

受 理 号：CYHZ2111036苏　　通知书编号：2021R045566

药品名称	药品通用名称： 罂粟乙碘油注射液 英文名/拉丁名： Ethiodized Poppyseed oil Injection		
商品名称			
主要成分	罂粟乙碘油		
剂　型	注射剂	申请事项	境内生产药品再注册
规　格	10ml（含碘（I）480mg/ml）	注册分类	化学药品
药品注册标准编号	YBH01972016	原药品批准文号	国药准字H20163348
包装规格	中硼硅玻璃安瓿瓶：1支/盒。5支/盒。	药品有效期	24个月
审批结论	经审查，本品符合《药品注册管理办法》的有关规定，同意再注册。		
上市许可持有人	名称：江苏恒瑞医药股份有限公司 地址：连云港经济技术开发区黄河路38号		
生产企业	名称： 江苏恒瑞医药股份有限公司 地址：连云港经济技术开发区临港产业区东晋路		
药品批准文号	国药准字H20163348	药品批准文号有效期	至 2026-05-25
主送	江苏恒瑞医药股份有限公司		
抄送			
备注			

江苏省药品监督管理局

2021-05-26