Federal Agency For Medicines And Health Products

CERTIFICATE NUMBER: ***BE/GMP/2024/014***

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 Belgium confirms the following:
The manufacturer: ***Quercus Labo***
Site address: ***Wijmenstraat 21p, Mariakerke, 9030, Belgium, GPS: 51.086739, 3.667284***
OMS Organisation Id. / OMS Location Id.: ***ORG-100016672*** / ***LOC-100025475***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1843 H*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-02-22***, it is considered that it complies with::

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

2024-06-12

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

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Confidential
Federal Agency For Medicines And Health Products
Tel:***Confidential***
Fax:***Confidential***

Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 24/2051556***

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 Netherlands confirms the following:
The manufacturer: ***Hainan Poly Pharmaceutical Co. Ltd.***
Site address: ***Guilinyang Economic Development Zone, Meilan, Haikou, 571127, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100024397*** / ***LOC-100033569***

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 ***2024-03-15***, it is considered that it complies with::

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.13 Tablets
	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* *1.6.4 Biological*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Building 2	***Injection workshop I***			***confidential***
Building 2	***Oral Solid Dosage workshop, rooms F1077 and F1078 for granulating; room F1069 for blending; room F1021 for tabletting; room F1036 for tablet coating and room F1087 for blistering***			***confidential***
Building 10	***Injection workshop II***			***confidential***
Building 10	***Injection workshop III***			***confidential***
Building 10	***Injection workshop IV***			***confidential***
Building 20	***Injection workshop V***			***confidential***
Building 20	***Injection workshop IX***			***confidential***

2024-08-14

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

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Confidential
Health And Youth Care Inspectorate
Tel:***Confidential***
Fax:***Confidential***

(https://www.cbg-meb.nl)

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Geneesmiddeleninformatiebank (https://www.geneesmiddeleninformatiebank.nl/

Zoeken (/ords/f?p=111:search:0:::RP,1:P0_DOMAIN,P0_LANG,P1_SORT,P1_RESPPG:H

Eptifibatide AFTPharm 2 mg/ml oplossing voor injectie

Over dit geneesmiddel | **Details handelsvergunning** | **Rapporte**

Werkzame stof:	EPTIFIBATIDE 2 mg/ml
ATC:	B01AC16 - Eptifibatide
Hulpstoffen:	CITROENZUUR 1-WATER (E 330) NATRIUMHYDROXIDE (E 524) WATER VOOR INJECTIE
Farmaceutische vorm:	Oplossing voor injectie
Toedieningsweg:	Intraveneus gebruik

Informatie over Eptifibatide op Farmacotherapeutisch Kompas (https://www.farmacotherapeutischkompas.nl/bladeren/preparaatteksten/atc/B01AC16

Samenvatting van de productkenmerken (SmPC)

SmPC Datum van herziening van de tekst: Laatste gedeeltelijke wijziging betreft april 2024.

(https://www.geneesmiddeleninformatiebank.nl/smpc/h120247_smpc.pdf)

Patiëntenbijsluiter (https://www.geneesmiddeleninformatiebank.nl/bijs

Informatie voor de patiënt

› In rubriek 1 van de bijsluiter staat wat dit medicijn is en waarvo gebruikt:

Betrouwbare websites van het Netwerk Patiënteninformatie

Informatie over Eptifibatide op Apotheek.nl (https://www.apotheek.nl/medicijnen/ep

Informatie over Eptifibatide op Lareb.nl (https://www.lareb.nl/nl/databank/Result?formGroup=&atc=B01AC16)

Heeft u last van een bijwerking? Meld dit dan bij het Bijwerkingencentrum Lareb. Ik melden. (https://meldformulier.lareb.nl/Forms/ReportForm)

Wilt u meer weten over ziekte en gezondheid? Kijk dan op Thuisarts.nl. (https://ww

Goede medicijnen goed gebruikt.

Sitemap (/ords/f?p=111:sitemap:0::NO)
Toegankelijkheid (/ords/f?p=111:toegankelijkheid:0
Cookies (/ords/f?p=111:cookies:0::NO)
Abonneren op nieuwsservice (http://bit.ly/2OJklfP)
Contact (https://www.cbg-meb.nl/contact)

English (https://www.geneesmiddeleninformatiebank.nl/en/)