

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.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is 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 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>
	1.6.4 <i>Biological</i>
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.2 <i>Microbiological: non-sterility</i>
	2.1.3 <i>Chemical/Physical</i>
	2.1.4 <i>Biological</i>
2.2	Batch certification of imported medicinal products
	2.2.1 <i>Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>

2024-06-12

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

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.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is 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
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

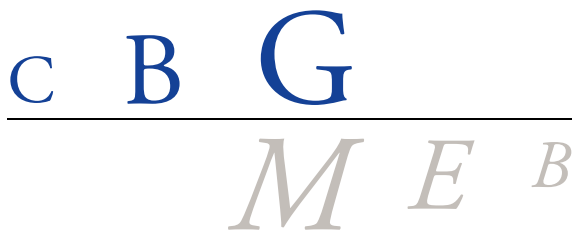
Any restrictions related to the scope of this certificate:

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 tableting; 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

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



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GENEESMIDDELEN

[_ \(https://www.cbg-](https://www.cbg-)

[meb.nl\).](https://www.geneesmiddeleninformatiebank.nl/)

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

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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)
(<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 waarvoor gebruikt:**

Betrouwbare websites van het Netwerk Patiënteninformatie

➤ [Informatie over Eptifibatide op Apotheek.nl \(https://www.apotheek.nl/medicijnen/eptifibatide\)](https://www.apotheek.nl/medicijnen/eptifibatide)

➤ [Informatie over Eptifibatide op Lareb.nl \(https://www.lareb.nl/nl/databank/Result?formGroup=&atc=B01AC16\)](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. \(https://meldformulier.lareb.nl/Forms/ReportForm\)](https://meldformulier.lareb.nl/Forms/ReportForm)

Wilt u meer weten over ziekte en gezondheid? Kijk dan op ➤ [Thuisarts.nl. \(https://www.thuisarts.nl\)](https://www.thuisarts.nl)

*Goede medicijnen
goed gebruikt.*

Sitemap

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Toegankelijkheid

(/ords/f?

p=111:toegankelijkheid:0

Cookies

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➤ Abonneren

op

nieuwsservice

(http://bit.ly/2OJklfP)

➤ Contact

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

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



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Eptifibatide AFTPharm 0,75 mg/ml oplossing voor infusie

About this medicine

Details marketing authorisation

Report

Active substance:	EPTIFIBATIDE 0.75 mg/ml
ATC:	B01AC16 - Eptifibatide
Excipients:	CITROENZUUR 1-WATER (E 330) NATRIUMHYDROXIDE (E 524) WATER VOOR INJECTIE
Pharmaceutical form:	Oplossing voor infusie
Route of Administration:	Intraveneus gebruik

[Information about Eptifibatide on Farmacotherapeutisch Kompas](#)
(<https://www.farmacotherapeutischkompas.nl/bladeren/preparaatteksten/atc/B01AC16>)



Summary of the Product Characteristics (SmPC)

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

(https://www.geneesmiddeleninformatiebank.nl/smpc/h120246_smpc.pdf)



Patient information leaflet

(<https://www.geneesmiddeleninformatiebank.nl/bijsluiters/h120246.pdf>)

Patient information

➤ **Paragraph 1 of the Leaflet shows the purpose of this medicine and**

Patient information

➤ [Information about Eptifibatide on Apotheek.nl](https://www.apotheek.nl/medicijnen) (<https://www.apotheek.nl/medicijnen>,

➤ [Information about Eptifibatide on Lareb.nl](https://www.lareb.nl/nl/databank/ResultformGroup=&atc=B01AC16) (<https://www.lareb.nl/nl/databank/ResultformGroup=&atc=B01AC16>).

Are you experiencing adverse events? Please report to the Adverse Events Centre Lareb [an adverse event](https://meldformulier.lareb.nl/Forms/ReportForm) (<https://meldformulier.lareb.nl/Forms/ReportForm>).

Do you need more information on sickness and health? Take a look at ➤ [Thuisarts.nl](https://thuisarts.nl).

*Good medicines
used better.*

Sitemap

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Dutch (<https://www.geneesmiddeleninformatiebank.nl/nl/>)