NOTARIUS PUBLICUS IN GÖTEBORG, PARTILLE AND ÖCKERÖ

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. **Country** Sweden

   This attached public document

2. **has been signed by** Christoffer Mangelus
3. **acting in the capacity of** the Notary Public of Göteborg, Partille and Öckerö, Sweden
4. **bears the seal/stamp of** the Notary Public of Göteborg, Partille and Öckerö, Sweden

CERTIFIED

5. **at** Göteborg, Sweden
6. **this** 8th day of July 2019
7. **by** Sten Westman

   Deputy Notary Public of Göteborg, Sweden

8. **No.** 190708-006
9. **Seal/Stamp**

NOTARIUS PUBLICUS
GÖTEBORG

10. **Signature**

Stockholm
Göteborg
Malmö
Linköping
Norrköping

Advokatfirman Delphi
Östra Hamngatan 29
411 10 Göteborg
Tel 031 10 72 00
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LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***6.2.1-2018-089592***

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 Sweden confirms the following:
The manufacturer: ***Recipharm Uppsala AB***
Site address: ***Björkgatan 30, Uppsala, 751 82 Uppsala, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***6.2.1-2018-089592*** 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 ***2018-11-28*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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. 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 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.12 Suppositories 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.12 Suppositories 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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Clarifying remarks (for public users)

Quality control can also be performed in building 22, Rapsgatan 7, Uppsala. (Analysverksamhet får även utföras i hus 22, Rapsgatan 7, Uppsala.) Warehousing of products can also be done at Hyvelgatan 26, Knivsta. (Lagerhållning av läkemedel får även ske på Hyvelgatan 26, Knivsta.)

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2019-05-02

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

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency
Tel: ***+46 18 174600***
Fax: ***+46 18 548566***

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GÖTEBORG PARTILLE ÖCKERÖ

Notarization, see overleaf

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NOTARIUS PUBLICUS IN GÖTEBORG, PARTILLE AND ÖCKERÖ

I, the undersigned, CHRISTOFFER MANGELUS, Notary Public of Göteborg, Partille and Öckerö, Sweden, do hereby certify that this is a copy of a Certificate of GMP Compliance of a Manufacturer, for Recipharm Uppsala AB with certificate number 6.2.1-2018-089592, issued by the Swedish Medical Products Agency (Sw. Läkemedelsverket).

Göteborg, this 5th day of July 2019
Ex Officio:

CHRISTOFFER MANGELUS

Exp. No: 190705-005

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Apostille, see overleaf

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