LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Digitally signed by Margină Veaceslav
Date: 2019.03.07 17:10:40 EET
Reason: MoldSign Signature
Location: Moldova

NOTARIUS PUBLICUS MIKAEL BRATT
STOCKHOLM

Medical Products Agency

CERTIFICATE NUMBER: *6.2.1-2017-037959*

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
Art. 15 of Directive 2001/20/EC

The competent authority of Sweden confirms the following:
The manufacturer: ***Octapharma AB***
Site address: ***Lars Forssells gata 23, Stockholm, 112 75, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***6.2.1-2017-037959*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-10-05*** , 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.

[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.*

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

OCTAPHARMA
QC Assessment & Release
If this is green this
is an approved copy

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 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
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.1 Blood products 1.3.1.8 Other: Other(en)
	1.3.2 Batch Certification (list of product types) 1.3.2.1 Blood products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
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*

Clarifying remarks (for public users)

1.3.1.1 Manufacturing of products from human plasma. (1.3.1.1 Tillverkning av produkter från humanplasma) 1.3.1.8 Filling, freezedrying and inspection of recombinant products. (1.3.1.8 Fyllning, frystorkning och syning av rekombinanta produkter). Manufacturing of sterile water for injection. (Tillverkning av sterilt vatten för injektion.)

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

2018-05-04

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*

NOTARIUS PUBLICUS MIKAEL BRATT * STOCKHOLM *
pto

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

I, MIKAEL BRATT, a Notary Public at Stockholm, Sweden, hereby certify that Ms Lydia Weldai has signed her name on this document.

Stockholm, November 1, 2018

Ex officio:

Notary Public
Grünberger Advokater AB
www.grunberger.se

NOTARIUS PUBLICUS MIKAEL BRATT * STOCKHOLM *

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Sweden
   This public document
2. has been signed by Mikael Bratt
3. acting in the capacity of Notary Public
4. bears the seal/stamp of Notary Public Mikael Bratt, Stockholm

Certified

5. at Stockholm
6. the 1st of November, 2018
7. by Deputy Notary Public Carsten Angsmark
8. Nº 3590/18
9. Seal/stamp:
10. Signature:

BITR. NOTARIUS PUBLICUS CARSTEN ANGSMARK * STOCKHOLM *