Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00104018***

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 Denmark confirms the following:
The manufacturer: ***Novo Nordisk A/S***
Site address: ***Hallas Alle, Kalundborg, 4400, Denmark***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***36313*** 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 ***2018-05-24*** , 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*

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
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 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*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

2018-08-02

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

Mr. Claus Mortensen
Danish Medicines Agency
Tel: *+45 2093 9054*
Fax:

APOSTILLE (Convention de La Haye du 5 octobre 1961)			
1. Country: Land:	**Denmark** Danmark		
This public document Dette offentlige dokument			
2. has been signed by er underskrevet af	**Helle Wendt**		
3. acting in the capacity of i egenskab af	**Administrative officer** Administrativ medarbejder		
4. bears the seal/stamp of er forsynet med segl/stempel af	**Danish Medicines Agency** Lægemiddelstyrelsen		
Certified Attesteret			
5. at i	**Copenhagen** København	**6. the** den	**21 Aug 2018** 21 aug 2018
7. by af	**Ministry of Foreign Affairs of Denmark** Udenrigsministeriet		
8. No nr.	**9A411FCB**		
9. Seal/stamp: Segl/stempel:	MINISTRY OF FOREIGN AFFAIRS	**10. Signature:** Underskrift:	Michael Madsen

MINISTRY OF FOREIGN AFFAIRS

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.

To verify the issuance of this Apostille, scan the QR code or visit the following website:

https://e-register.um.dk

Danish Medicines Agency

Certificado Nº: ***DK IMP 00104018***

CERTIFICADO DE CUMPLIMIENTO DE NCF DE UN FABRICANTE [1, 2]

Parte 1

Emitido en virtud de una inspección según el
Art. 15 de la Directiva 2001/20/CE

La autoridad competente de Dinamarca confirma lo siguiente:
El fabricante: ***Novo Nordisk A/S***
En su planta ubicada en: ***Hallas Alle, Kalundborg, 4400, Dinamarca***

Ha sido inspeccionado dentro del programa nacional de inspecciones y en relación con la autorización de laboratorio farmacéutico número ***36313*** de acuerdo con Art. 13 de la Directiva 2001/20/CE .

En base a la información obtenida en las visitas de inspección a este fabricante, la última de ellas realizada en ***2018-05-24*** , se considera que el mismo cumple con :

- los principios y directrices de las Normas de Correcta Fabricación establecidas en la Directiva 2003/94/CE(1) [3]

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de tres años desde esa fecha de inspección. Sin embargo, este período de validez podrá verse reducido o ampliado mediante el empleo de la herramienta de análisis de riesgos, debiendo incluirse en el correspondiente campo de Restricciones y Aclaraciones. Este certificado es válido sólo cuando se presente con todas las páginas y las Partes 1 y 2. La autenticidad de este certificado puede ser verificada en EudraGMDP. Si éste no aparece, por favor, contacte con la autoridad emisora

---

[1] *El certificado al que se hace referencia en el párrafo 111(5) de la Directiva 2001/83/CE y 80(5) de la Directiva 2001/82/CE, deberá ser también requerido en las importaciones*

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

[3] *Estos requisitos cumplen con las NCF de la OMS*

Parte 2

Medicamentos en investigación de uso humano

1 Operaciones de Fabricación	
1.3	**Medicamentos biológicos**
	1.3.1 Medicamentos biológicos 1.3.1.5 Productos Biotecnológicos
1.6	**Control de calidad**
	1.6.1 Microbiológico: estéril *1.6.2 Microbiológico: no-estéril* *1.6.3 Químico/ Físico* *1.6.4 Biológico*

2018-08-02

Nombre y firma de la persona autorizada de la Autoridad Competente de Dinamarca

---

Confidencial
Danish Medicines Agency
Tel: ***Confidencial***
Fax: ***Confidencial***