Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00096518***

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: ***Novo Allé, Bagsværd, 2880, Denmark***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***35926*** 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 ***2017-09-28*** , 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.

[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) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 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
1.6	**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	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *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
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products

Clarifying remarks (for public users)

Batch release responsibility for all Novo Nordisk A/S owned medicinal products is conducted from the legal address Novo Allé, DK-2880 Bagsværd. 1.1.3 Including batch release of lyophilisates and terminally sterilised small volume liquids.

2018-01-30

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

Ms. Kathrine Ask Asmussen
Danish Medicines Agency
Tel: ***+45 93514252***
Fax

APOSTILLE (Convention de La Haye du 5 octobre 1961)			
1. Country: Land:	**Denmark** Danmark		
This public document Dette offentlige dokument			
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3. acting in the capacity of i egenskab af	**Medical secretary** Lægesekretær		
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	**05 Mar 2018** 05 mar 2018
7. by af	**Ministry of Foreign Affairs of Denmark** Udenrigsministeriet		
8. No nr.	**91FD3E53**		
9. Seal/stamp: Segl/stempel:	MINISTRY OF FOREIGN AFFAIRS	**10. Signature:** Underskrift:	Louise Dahm

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MINISTRY OF FOREIGN AFFAIRS

Danish Medicines Agency

Certificado Nº: ***DK H 00096518***

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

Parte 1

Emitido en virtud de una inspección según el
Art. 111(5) de la Directiva 2001/83/CE modificada

La autoridad competente de Dinamarca confirma lo siguiente:
El fabricante: ***Novo Nordisk A/S***
En su planta ubicada en: ***Novo Allé, Bagsværd, 2880, Dinamarca***

Ha sido inspeccionado dentro del programa nacional de inspecciones y en relación con la autorización de laboratorio farmacéutico número ***35926*** de acuerdo con Art. 40 de la Directiva 2001/83/CE .

En base a la información obtenida en las visitas de inspección a este fabricante, la última de ellas realizada en ***2017-09-28*** , 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

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[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 de uso humano

1 Operaciones de Fabricación	
1.1	**Productos Estériles**
	1.1.1 Preparación aséptica (operaciones de procesamiento de las siguientes formas farmacéuticas) 1.1.1.4 Líquidos de pequeño volumen
	1.1.3 Certificacion de lotes
1.2	**Productos no estériles**
	1.2.2 Certificacion de lotes
1.3	**Medicamentos biológicos**
	1.3.1 Medicamentos biológicos 1.3.1.5 Productos Biotecnológicos
	1.3.2 Certificación de lotes (lista de tipos de productos) 1.3.2.5 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*

2 IMPORTACION DE MEDICAMENTOS	
2.1	**Actividades de control de calidad de medicamentos importados**
	2.1.1 Microbiológico: estéril *2.1.2 Microbiológico: no-estéril* *2.1.3 Químico/ Físico* *2.1.4 Biológico*

2.2	**Certificación de lotes de medicamentos importados**
	2.2.1 Productos Estériles 2.2.1.1 Fabricación aséptica 2.2.1.2 Esterilización terminal
	2.2.2 Productos no estériles
	2.2.3 Medicamentos biológicos 2.2.3.5 Productos Biotecnológicos

Aclaraciones (para el público general)

Batch release responsibility for all Novo Nordisk A/S owned medicinal products is conducted from the legal address Novo Allé, DK-2880 Bagsværd. 1.1.3 Including batch release of lyophilisates and terminally sterilised small volume liquids.

2018-01-30

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

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

To Whom It May Concern

For registration purposes in Chile, please find attached the GMP certificate for:

Catalent Belgium SA
Font Saint Landry 10, Bruxelles,
1120, Belgium

Bagsvaerd, 15 August 2017

NOVO NORDISK A/S

A. Desjardins

Annick Desjardins
Submission Coordinator
Publishing & Submission Management

The Danish Chamber of Commerce do hereby confirm that the company is a member of our organization and know to us as worthy of confidence.

16 AUG 2017

Danish Chamber of Commerce
Secretary: Pernille Hellesøe

Novo Nordisk A/S

Novo Allé
DK-2880 Bagsvaerd
Denmark

Telephone:
+45 4444 8888

Internet:
www.novonordisk.com

CVR Number:
24 25 67 90

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. **Land: Danmark**
   Country: Denmark

   Dette offentlige dokument / This public document
2. **er underskrevet af /** has been signed by
   Pernille Hellesøe
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   Sekretær / Secretary

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   Dansk Erhverv / Danish Chamber of Commerce

Attesteret / Certified

5. **i København**
   at Copenhagen
6. **den 16. august 2017**
   the 16 August 2017
7. **af Udenrigsministeriet**
   by the Ministry of Foreign Affairs of Denmark
8. **Nr. / N° DNK-00578879**
9. **Segl/stempel /** Seal/stamp:

MINISTRY OF FOREIGN AFFAIRS

10. **Underskrift /** Signature:

AmalieDavidsen

Amalie Davidsen

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2017/044***

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: ***Catalent Belgium SA***
Site address: ***Font Saint Landry 10, Bruxelles, 1120, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***314 H*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-04-06*** , 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.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 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) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted 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*

2017-07-10

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***


OF FOREIG

- AUTHORISED COPY -
Danish Medicines Agency
Axel Heides Gade 1
2300 København S

Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00085017***

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: ***Hagedornsvej 1, Gentofte, 2820, Denmark***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***34077*** 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 ***2016-12-02*** , 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.*

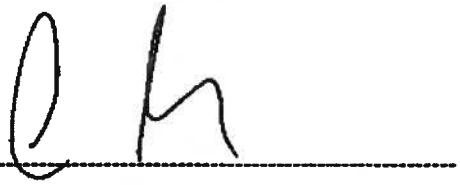
Part 2

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) 1.1.2.5 Other: Solvents(en)
	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* *1.6.4 Biological*

2017-03-07

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



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

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(Convention de La Haye du 5 octobre 1961)

1. **Land: Danmark**
   Country: Denmark

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Attesteret / Certified

5. **i København**
   at Copenhagen
6. **den 19. maj 2017**
   the 19 May 2017
7. **af Udenrigsministeriet**
   by the Ministry of Foreign Affairs of Denmark
8. **Nr. /** N° **DNK-00551659**
9. **Segl/stempel /** Seal/stamp:
10. **Underskrift /** Signature:

Michelle Ettrup

Michelle Kjøge Ettrup