styrelsen

Danish Health and Medicines Authority

Certificate No: DK H [illegible]

- AUTHORISED COPY -
Danish Health and Medicines Authority
Axel Heides Gade 1
2300 København S

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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 H. Lundbeck A/S

Site address Ottiliavej 9
2500
Valby
Denmark

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 26294 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: *(Consolidated) Medicinal Products Act, 2005, as amended.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2013/06/11–2013/06/14 and 2013/06/19-2013/06/20,it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC2.

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, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

- Authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary.
- Quality control testing and/or release and batch certification activities without manufacturing operations are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.1	**Sterile Products**
	1.1.1 Aseptically prepared *Aseptically prepared*
	1.1.1.4 Small volume liquids *Small volume liquids*
	1.1.2 Terminally sterilised *Terminally sterilised*
	1.1.2.3 Small volume liquids *Small volume liquids*
1.2	**Non-sterile products**
	1.2.1 Non-sterile products *Non-sterile products*
	1.2.1.1 Capsules, hard shell *Capsules, hard shell*
	1.2.1.6 Liquids for internal use *Liquids for internal use*
	1.2.1.13 Tablets *Tablets*
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substances/excipients/finished product: *Sterilisation of active substances/excipients/finished product:*
	1.4.2.1 Filtration *Filtration*
	1.4.2.3 Moist heat *Moist heat*
1.5	**Packaging only**
	1.5.2 Secondary packing *Secondary packing*
1.6	**Quality control testing**
	1.6.3 Chemical/Physical *Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS

- Authorised importation activities without manufacturing activity
- Authorised importation activities include storage and distribution unless informed to the contrary

2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical *Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile Products *Sterile Products*
	2.2.1.1 Aseptically prepared *Aseptically prepared*
	2.2.2 Non-sterile products *Non-sterile products*

Manufacture of active substance. Names of substances subject to inspection:
None

Any restrictions or clarifying remarks related to the scope of this certificate:
None

styrelsen
Danish Health and Medicines Authority

Date: 2013/09/19

Name and signature of the authorised person
of the competent authority of Denmark:

.....
Claus Mortensen
The Danish Health and Medicines Authority

Axel Heides Gade 1
DK-2300 København S

Tel. +45 72 22 74 00
www.sst.dk

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
   Dorte Heidelberg Lyndby
3. **i egenskab af** / acting in the capacity of
   Administrativ medarbejder / Administrator

4. **er forsynet med segl/stempel af** / bears the seal/stamp of
   Sundhedsstyrelsen / Danish Health and Medicines Authority

Attesteret / Certified

5. **i København** / at Copenhagen
6. **den** 7. december 2015 / the 07 December 2015
7. **af Udenrigsministeriet**
   by the Ministry of Foreign Affairs of Denmark
8. **Nr.** / Nº **DNK-00446747**
9. **Segl/stempel** / Seal/stamp:
10. **Underskrift** / Signature:

MINISTRY OF FOREIGN AFFAIRS

Lotte Greve

CONSULADO DE CHILE
COPENHAGUE, DINAMARCA

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Oficial de Legalizaciones del Ministerio
de Relaciones Exteriores de Dinamarca

Actuación Nro. ..1155.. Arancel Nro. 4/10
Derechos US$ ...12.. Diferencia %. ...1120....
Total percibido en US$.....13,20
Pagado en moneda del país: DKK 93,-

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2015 2 2

Mario Luis Silva
Cónsul

6 LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr(a)
28 DIC 2015
Laura DE LA VEGA FERNANDEZ
Oficial de Legalizaciones