190890

Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00072316***

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: ***H. Lundbeck A/S***
Site address: ***Ottiliavej 9, Valby, 2500, Denmark***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***30542*** 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 ***2015-11-27***, 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 EudraGMP. 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
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration 1.4.2.3 Moist heat
1.5	**Packaging**
	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**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products

2016-03-09

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

Mr. Henning Willads Petersen
Danish Medicines Agency
Tel: *+45 4488 9176*
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 Health Authority** Sundhedsstyrelsen		
Certified Attesteret			
5. at i	**Copenhagen** København	**6. the** den	**12 Dec 2017** 12 dec 2017
7. by af	**Ministry of Foreign Affairs of Denmark** Udenrigsministeriet		
8. No nr.	**8B708A94**		
9. Seal/stamp: Segl/stempel:	MINISTRY OF FOREIGN AFFAIRS	**10. Signature:** Underskrift:	Iram Ilyas

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