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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

Site address

Denmark

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) 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 2012/09/19, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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

Manufacture of active substance. Names of substances subject to inspection:

- sterile and non-sterile
- (non-sterile
-), sterile and non-sterile
- sterile and non-sterile
- sterile and non-sterile
- non-sterile

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

Date: 2013/07/05

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

Medicines Inspector (The Danish Health and Medicines Authority

Vertical handwritten text on the right side: 本証明之正本文件於原料藥

Vertical handwritten text on the right side: 許可証展延登記

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True copy certified

07 AUG 2013

Notariate of Copenhagen, Denmark

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
3. i egenskab af / acting in the capacity of
Notar / Notary Public
4. er forsynet med segl/stempel af / bears the seal/stamp of
Københavns Retskreds / Copenhagen County Court

Afleveret / Certified

5. i København
at Copenhagen
6. den 16. august 2013
the 16 August 2013
7. af Udenrigsministeriet
by the Ministry of Foreign Affairs of Denmark
8. Nr. / N°
9. Segl/stempel / Seal/stamp:
10. Underskrift / Signature:

Sabrina Hassel Boklund

