French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***HPF/FR/184/2017***

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 France confirms the following:
The manufacturer: ***GLAXO WELLCOME PRODUCTION - EVREUX***
Site address: ***Zone Industrielle n° 2, 23 rue Lavoisier, EVREUX, 27000, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 16/198*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-05-19*** , 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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: inhalation powder, hard capsule, inhalation powder, pre-dispensed(en) 1.2.1.9 Pressurised preparations
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.8 Other solid dosage forms: inhalation powder, hard capsule, inhalation powder, pre-dispensed(en) 1.5.1.9 Pressurised preparations
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

1.2.1. Manufacturing operations include also micronization of active substances --- Signatory: Mrs Mélanie Cachet, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2017-07-24

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

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Confidential
French National Agency for Medicines and Health Products Safety
Tel: ***Confidential***
Fax: ***Confidential***

RÉPUBLIQUE FRANÇAISE
LEGALISATION
(DECRET N° 2007 - 1205 DU 10 AOUT 2007)
DESTINATION DE L'ACTE (PAYS OU AUTORITE)
DATE : 27 AVR. 2018
NOM ET QUALITE DE L'AGENT : S. DAVID
BUREAU DES LEGALISATIONS
SIGNATURE
ET CACHET OBLIGATOIRE :
MINISTÈRE DES AFFAIRES ETRANGÈRES

Françoise BOURNICHE
Chief Pharmaceutical Officer GWP
Glaxo Wellcome Production, France
N°inscription à l'ordre : 81803
February, 13th 2018

Me Gaël BAILLEUL, Notaire associé
RÉPUBLIQUE FRANÇAISE
EVREUX (EURE)

Je soussigné Gaël BAILLEUL
Notaire à EVREUX, certifie
la signature de Mme BOURNICHE
apposée ci-dessus
EVREUX, le 15 FEV. 2018

Actuacion N° 2435 Arancel Articulo N° 4 L.D.
Derechos US$ 12. Diferencia 10% 1,20
Total percibido en US$ 13,20
Pagado en moneda local 11 €
Paris, 30 AVR. 2018

SERVICIO CONSULAR 2018 10 ISS CHILE ISS

SERVICIO CONSULAR 2018 2 ISS CHILE ISS

CONSULADO GENERAL DE CHILE EN PARIS

EL CONSUL GENERAL DE CHILE QUE SUSCRIBE CERTIFICA LA AUTENTICIDAD DE LA FIRMA DE DON
S DAVID
FUNCIONARIO DEL MINIST. DE RR. EE. DE FRANCIA

Hans HORMAZÁBAL R.
Ministro de Fe Pública

5 LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr. (a): Hans Hormazabal
24 MAY 2018
Patricia LÓPEZ RODRÍGUEZ
Oficial de Legalizaciones

10-915320-2178672