Ref 2018-11-29

This document is to be presented
to the competent authority in
CHILE

Merck Sharp & Dohme Limited
Shotton Lane
Cramlington
Northumberland
NE23 3JU
Telephone: +44 (0) 1670 593000

MSD

I, Pauline Chan, Senior Quality Assurance Specialist of Merck Sharp & Dohme ltd, declare that this is a true copy of the GMP Certificate.

10 Dec 2018

Signed by the above-named

Before me:-

Richard S. Appleby
Notary Public
15 Summerhill Avenue
Melton Park
Newcastle Upon Tyne NE3 5QJ
0191 2364759

F HARRIS
Authorised Signatory

Hertfordshire Chamber
Of Commerce
CERTIFYING STAMP
18 DEC 2018
THIS SIGNATURE IS AUTHENTIC
Authorised Signatory
Hertfordshire Chamber of Commerce

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	F Harris
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Official of the Chamber of Commerce, (Hertfordshire)
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	Not applicable

Certified

Attesté / Certificado

5. at á / en	London	**6. the** le / el día	19 December 2018
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs		
8. Number sous no / bajo el numero	APO-1231321		
9. Seal / stamp Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	**10. Signature** Signature Firma	N. Larrier

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Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA 25 Insp GMP/IMP 25/4061-0028

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	Merck Sharp & Dohme Limited
Site address	MERCK SHARP & DOHME LIMITED SHOTTON LANE CRAMLINGTON NE23 3JU UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 25 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/06/2018, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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. 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 only valid 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.

Certificate No: UK MIA 25 Insp GMP/IMP 25/4061-0028

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

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
Special Requirements:
Other
Bulk Granules and bulk blend for oral solution.

1.2.1.13 Tablets

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.2 Secondary packaging

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

Not Authorised

2.3 Other importation activities

Not Authorised

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA 25 Insp GMP/IMP 25/4061-0028

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Kevin Bailey
GMP Inspector
kevin.bailey@mhra.gov.uk

Date: 04/12/2018