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Chile.

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astrazeneca.com

TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

It is hereby confirmed that the attached Certificate is a true copy of the original document.

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 IEN, England,
Tel: 01753 851591

Signed: ..... Dated 14/12/18

Vicky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

20/12/18

3361/18

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	Phillip H Jones
3.	**Acting in the capacity of** agissant en qualité de quien actúa en calidad de	Notary Public
4.	**Bears the seal / stamp of** est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5.	**at** á / en London	6.	**the** le / el día 03 January 2019
7.	**by** par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs	
8.	**Number** sous no / bajo el numero	APO-1241785	
9.	**Seal / stamp** Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	
10.	**Signature** Signature Firma	J. Allsop-Ward	

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LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***5.9.1-2018-085989***

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 Sweden confirms the following:
The manufacturer: ***AstraZeneca AB***
Site address: ***Oral Solid Dosage, Gärtunavägen, Södertälje, 151 85, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***5.9.1-2018-085989*** 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 ***2018-01-25*** , 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.*

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

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) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Pellets and granules(en) 1.2.1.13 Tablets
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Buildings at Gärtunavägen: 611, 612, 614, 616, 641, 642 and 643. Buildings at Forskargatan 18: 313 and 317.

2018-11-27

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

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency
Tel: ***+46 18 174600***
Fax ***+46 18 548566***

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