Chile AZ 101b

AstraZeneca · Parklands · Alderley Park · Macclesfield · Cheshire · SK10 4TG
T: +44 (0) 1625 582828 · F: +44 (0) 1625 586495 · astrazeneca.com

AstraZeneca

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: D Wright Dated: 21/04/2015

Dawn Wright
Team Administrator

Global Operations
AstraZeneca UK
First Floor East, Parklands, Alderley Park
Macclesfield, Cheshire
SK10 4TG

27/4/15

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: 28 April 2015
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el número	K490508
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** C. Antwi-Boasiako Signature: Firma:

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK public official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

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CONSULADO GENERAL DE CHILE EN
LONDRES, GRAN BRETAÑA

El Cónsul General de Chile que suscribe certifica la autenticidad de la firma de don C. ANTWI-BOASIAKO
OFFICIAL DEL FOREIGN OFFICE
Actuación No. 1936 Arancel Art. No. 4-10
Derechos US$: 12.00 Diferencia 10%: 1.20
Total percibido en US$: 13.20
Pagado en moneda del país: £ 9.00
LONDRES, 01 de MAYO de 2015.-

CONSULADO GENERAL DE CHILE * LONDRES *

SERVICIO CONSULAR 2015 10 US$ CHILE US$ 10

SERVICIO CONSULAR 2015 2 US$ CHILE US$ 2

Sebastian Lorenzini Aracena
Cónsul de Chile

2 LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr.
17 JUN 2015
Armando PARRA CASTILLO
Oficial de Legalizaciones

Certificate No: UK API 32467 Insp GMP 32467/10116-0010

MHRA
Regulating Medicines and Medical Devices

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	ASTRAZENECA UK LIMITED
Site address	AVLON WORKS SEVERNSIDE HALLEN BRISTOL AVON BS10 7ZE UNITED KINGDOM

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: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/07/2014, it is considered that it complies with the principles of GMP for active substances

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.

Medicines and Healthcare Products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

MHRA
Regulating Medicines and Medical Devices

ROSUVASTATIN CALCIUM

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.2 Manufacture Of Crude Active Substance
3.1.3 Salt Formation/Purification Steps (e.g. Crystallisation)
CRYSTALLISATION

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
3.5.1 Physical Processing Steps
DRYING, MILLING
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing
3.6.1 Physical / Chemical testing

4 Other Activities
Not Authorised

MHRA
Regulating Medicines and Medical Devices

QUETIAPINE FUMARATE

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.1 Manufacture Of Active Substance Intermediates
3.1.2 Manufacture Of Crude Active Substance
3.1.3 Salt Formation/Purification Steps (e.g. Crystallisation)
CRYSTALLISATION

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
3.5.1 Physical Processing Steps
DRYING, MILLING
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

3.6 Quality Control Testing
3.6.1 Physical / Chemical testing

4 Other Activities
Not Authorised

MHRA
Regulating Medicines and Medical Devices

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

Mark Webb
GMP Inspector
mark.webb@mhra.gsi.gov.uk

Date: 12/09/2014