AstraZeneca UK Limited
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London, W2 6BD, United Kingdom
T: +44 (0) 20 7604 8000
F: +44 (0) 20 7604 8151

astrazeneca.com

TO WHOM IT MAY CONCERN

ood Manufacturing Practice Certificate

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

S ed: ..... Dated 14/1/16

V attie
R latory Project Assistant
R latory Project Management Group
A Zeneca UK Limited

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

18/1/16.

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 — 20 January 2016

7. by par / por — Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs

8. Number
sous no / bajo el número — K822959

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FOREIGN AND COMMONWEALTH OFFICE
LONDON

10. Signature: M. O Dell
Signature:
Firma: MO

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CONSULADO GENERAL DE CHILE EN LONDRES, GRAN BRETANA

El Cónsul General de Chile que suscribe certifica la autenticidad de la firma de don M. ODELL OFICIAL DEL FOREIGN OFFICE

Actuación No. 270 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, 22 de ENERO de 2016.-

CONSULADO GENERAL DE CHILE · LONDRES

CONSULADO GENERAL DE CHILE · LONDRES

Sebastian Lorenzini Aracena
Cónsul de Chile

[illegible] temporalmente
[illegible] estampillas consulares
[illegible] US$ 12.-
Art. Nº 42 R.C.

[illegible] DEL MINISTERIO DE RELACIONES [illegible] DE CHILE
FIRMA DEL [illegible]
- 5 FEB 2016
Armando PARRA CASTILLO
Oficial de Legalización

Certificate No: UK MIA 17901 Insp GMP/GDP/IMP 17901/10117-0029

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	SILK ROAD BUSINESS PARK MACCLESFIELD SK10 2NA UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 17901 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 15/06/2015, 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.

Medicines and Healthcare Products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.5 Solids and implants
1.1.1.6 Other aseptically prepared products
LHRH Agonist (Solids and Implants)

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.3 Small volume liquids

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
1.2.1.5 Liquids for external use
1.2.1.6 Liquids for internal use
1.2.1.13 Tablets
1.2.1.17 Other non-sterile medicinal products
Antioestrogen (Tablets)

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.8 Other solid dosage forms
1.5.1.11 Semi-solids
1.5.1.17 Other non-sterile medicinal products
Assembly of aerosol inhalers.

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

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Regulating Medicines and Medical Devices

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility
2.1.2 Microbiological: non-sterility
2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared products
2.2.1.2 Terminally sterilised 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

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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

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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

Rachel Carmichael
GMP Inspector
rachel.carmichael@mhra.gsi.gov.uk

Date: 27/08/2015