MSD
Mariano Sánchez Fontecilla 310,
piso 8. Las Condes
Santiago
Chile
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www.msdchile.cl

CERTIFICADO GMP

HYZAAR FORTE COMPRIMIDOS RECUBIERTOS

Por medio de la presente nos permitimos señalar a usted que la certificación GMP para el producto en referencia, se encuentra detallada en el punto 3.3 de los CPPs (Certificate of Pharmaceutical Product) adjuntos, la que considera todas las etapas de elaboración del producto, desde la calificación de proveedores de principios activos, excipientes y hasta la liberación final.

Ref 2015-12-01

This document is to be presented
to the competent authority in

CHILE

MHRA
Regulating Medicines and Medical Devices

MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

RESTRICTED – COMMERCIAL
Mrs N Ward
MERCK MANUFACTURING DIVISION - CRAMLINGTON
MERCK SHARP & DOHME LIMITED
SHOTTON LANE
CRAMLINGTON
NORTHUMBERLAND
NE23 3JU
UNITED KINGDOM

I, William Wharton, Quality Assurance Specialist with Merck Sharp & Dohme Limited, declare that this is a true copy of the original Certificate of GMP Compliance.

William Wharton 13Jul15

SIGNED by the above-named
at Cramlington Northumberland UK
Before me:- Richard S. Appleby

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
- 7 DEC 2015
THIS SIGNATURE IS AUTHENTIC
Authorised Signatory
Hertfordshire Chamber of Commerce

Medicines and Healthcare
Products Regulatory Agency

Certificate No: UK MIA 25 Insp GMP 25/4061-0024

MHRA
Regulating Medicines and Medical Devices

Certifica

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: 09 December 2015
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el número	K778995
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** Jovita Payne Signature: Firma:

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Medicines and Healthcare Products Regulatory Agency

CONSULADO GENERAL DE CHILE EN LONDRES, GRAN BRETANA

El Cónsul General de Chile que suscribe certifica la autenticidad de la firma de don J. PAYNE
OFICIAL DEL FOREIGN OFFICE
Actuación No. 6054 Arancel Art. No. 4-a
Derechos, US$: 12.00 Diferencia 10%. 1.20
Total percibido en US$: 13.20
Pagado en moneda del país: £ 9.20
LONDRES, 14 de DICIEMBRE de 2015

SERVICIO CONSULAR 2015 10 10 US$ CHILE US$
SERVICIO CONSULAR 2015 2 2 US$ CHILE US$

Cristian Faúndez Riquelme
Ministro de Fe Pública

3 LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr.(a)
20 ENE 2016
Víctor GOMEZ ZAPATA
Oficial de Legalizaciones

CONSULADO GENERAL DE CHILE LONDRES

Medicines and Healt

CERTIFICATE OF GMI

Part 1

Issued following an inspection in accor

The competent authority of the United King

The manufacturer	MERCK MANUFAC
Site address	MERCK SHARP & D SHOTTON LANE CRAMLINGTON NORTHUMBERLANI NE23 3JU UNITED KINGDOM

Has been inspected under the national inspec
MIA 25 in accordance with Art. 40 of Directive
Human Medicines Regulations 2012 (SI 2012/

From the knowledge gained during inspection o
on 02/03/2015, it is considered that it complies v
Manufacturing Practice laid down in Directive 20

This certificate reflects the status of the manufac
and should not be relied upon to reflect the comp
since the date of that inspection. However, this pe
regulatory risk management principles by an entry

This certificate is only valid when presented with al

The authenticity of this certificate may be verified in
the issuing authority.

Medicines and Healthcare Products Regulatory Agency

Certificate No: UK MIA 25 Insp GMP 25/4061-0024

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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 MANUFACTURING DIVISION - CRAMLINGTON
Site address	MERCK SHARP & DOHME LIMITED SHOTTON LANE CRAMLINGTON NORTHUMBERLAND 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 02/03/2015, 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.

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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

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

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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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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

Alan Moon
GMP Inspector
Alan.Moon@mhra.gsi.gov.uk

Date: 22/04/2015