

MSD

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CPP REINO UNIDO

HYZAAR FORTE COMPRIMIDOS RECUBIERTOS

Por medio de la presente nos permitimos adjuntar a usted CPP (Certificate of Pharmaceutical Product, Certificado de Producto Farmacéutico) emitido por la agencia sanitaria de Reino Unido para el producto en referencia, el que da cuenta de la certificación por parte de la misma entidad.

BE IT KNOWN THAT I, Shujaat Husain, Notary Public, duly authorised, admitted and sworn and practising at 4 Palace Court, 250 Finchley Road, London NW3 6DN and elsewhere in England and Wales,

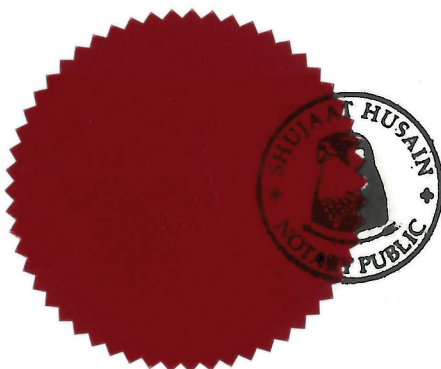
DO HEREBY CERTIFY:

THAT Abdelsalam El-Idrissi whose identity I attest and who is duly authorised to represent the Arab-British Chamber of Commerce in London has today presented me with a purported original 'Certificate of a Pharmaceutical Product' Certificate No: PP10147638 issued by the 'Medicines and Healthcare Products Regulatory Agency', which is hereunto annexed.

IN TESTIMONY WHEREOF I have hereunto set my hand and affixed my seal of office on the 15th day of February 2017.



Shujaat Husain
Notary Public



Shujaat Husain, Notary Public
4 Palace Court, 250 Finchley Road
London, NW3 6DN. ENGLAND, UK
Tel: +44 (0) 207433 3338



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	Shujaat Husain
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 à / en	London
6. the le / el día	20 February 2017
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-203488
9. Seal / stamp Sceau / timbre Sello / timbre	10. Signature Signature Firma K. Reed 



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 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.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country

To verify this apostille go to www.verifyapostille.service.gov.uk

CONSULADO GENERAL DE CHILE EN
LONDRES, GRAN BRETANA

El Cónsul General de Chile que suscribe certifica la
autenticidad de la firma de don K. R. R.

.... Oficial del Fomento

Actuación No. 542 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-

LONDRES, 06 de Mayo de 2017

SERVICIO CONSULAR

2017

10

ISS-CHILE-ISS

SERVICIO CONSULAR

2017

2

ISS-CHILE-ISS



Jayne Muñoz Sandoyal
Cónsul General

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Department of Health

CERTIFICATE OF A PHARMACEUTICAL PRODUCT⁽¹⁾

This certificate conforms to the format recommended by the World Health Organisation
(explanatory notes are attached)

Exporting (certifying) country: **UNITED KINGDOM**

Importing (requesting) country: **CHILE**

1 Name and dosage form of the product:

A) In the United Kingdom - Cozaar Comp 100mg/25mg Film-Coated Tablets, FILM-COATED TABLET

B) In CHILE - Hyzaar, FILM-COATED TABLET

1.1 Active ingredient(s)⁽²⁾ and amount(s)⁽³⁾ per unit dose:

<u>Active Ingredient(s)</u>	<u>Amount per unit dose</u>
LOSARTAN POTASSIUM	100.000 MG
HYDROCHLOROTHIAZIDE	25.000 MG

For complete qualitative composition including excipients, see attached.⁽⁴⁾

1.2 Is this product licensed to be placed on the market for use in the exporting country?⁽⁵⁾ Yes

1.3 Is this product actually on the market in the exporting country? Yes

1.4 The product is not on the market in the exporting country because

N/A





Certificate Number: **PP10147638**

1 Product Licence/Marketing Authorisation

Number ⁽⁷⁾:

PL 00025/0374

Date of Issue:

22 December 1999

2 The name and address of the Product Licence/Marketing Authorisation holder are:

Name: **MERCK SHARP & DOHME LIMITED**

Address: **HERTFORD ROAD, HODDESDON, HERTFORDSHIRE, EN11 9BU,
UNITED KINGDOM**

3 Status of the Product Licence/Marketing Authorisation holder ⁽⁸⁾:

c) is not involved in manufacturing, packaging or labelling the dosage form
but is responsible for the quality and release of the product

3.1 For categories b,c and d the names and address of the manufacturing site where the dosage
form is produced are ⁽⁹⁾:

See attached page for Manufacturers/Packagers

4 Is Summary Basis of Approval appended? ⁽¹⁰⁾ No

5 Is the attached, officially approved product information complete and consonant with the licence? ⁽¹¹⁾ Yes

6 Applicant for certificate, if different from licence holder (name and address) ⁽¹²⁾ :

Name:

Address:

Section 2B is not included because the product named in this certificate is licensed in the UK⁽⁶⁾





- 3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? ⁽¹⁴⁾ Yes

IF NO OR NOT APPLICABLE PROCEED TO QUESTION 4

- 3.1 Periodicity of routine inspections (years) 2
- 3.2 Has the manufacturer of this type of dosage form been inspected? Yes
- 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisation ? ⁽¹⁵⁾ Yes
- 4 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product including Good Manufacturing Practice (GMP)? ⁽¹⁶⁾ Yes

If No, explain

Additional Information:

NONE

Address of certifying authority:

**The Medicines and Healthcare products Regulatory Agency,
151 Buckingham Palace Road, London, SW1W 9SZ, United Kingdom**

Telephone Number: +44 (0203) 080 6593

Name of authorised person: Colin Atkinson

Signature: *Colin Atkinson*

Stamp and Date: 31 January 2017

F Harris
F HARRIS
Authorised Signatory





Certificate Number: PP10147638

Names and Addresses of Manufacturers/Packagers ⁽⁹⁾

Manufacturers

Name: MERCK SHARP & DOHME LIMITED
Address: SHOTTON LANE, CRAMLINGTON, NORTHUMBERLAND, NE23 3JU,
UNITED KINGDOM

Manufacturing Licence Holder

Name: MERCK SHARP & DOHME LIMITED
Address: HERTFORD ROAD, HODDESDON, HERTFORDSHIRE, EN11 9BU, UNITED
KINGDOM





Certificate Number: PP10147638

<u>Excipient</u>	<u>Modifier</u>	<u>Amount per unit dose</u>
MICROCRYSTALLINE CELLULOSE		
LACTOSE MONOHYDRATE		
PREGELATINISED STARCH 1500.		
MAGNESIUM STEARATE IMPALPABLE		
POWDER 1500		
HYDROXYPROPYL CELLULOSE		
METHYLHYDROXYPROPYL CELLULOSE		
TITANIUM DIOXIDE E171		
QUINOLINE YELLOW ALUMINIUM LAKE		
E104		
CARNAUBA WAX		
WATER PURIFIED	ND	

