

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 - Cardura 2mg Tablets, TABLET

B) In CHILE - Cardura 2mg Tablets, 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>
DOXAZOSIN MESYLATE	2.430 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



2A.1 Product Licence/Marketing Authorisation

Number ⁽⁷⁾: **PL 00057/0277**
Date of Issue: **22 August 1988**

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

Name: **PFIZER LIMITED**

Address: **RAMSGATE ROAD, SANDWICH, KENT, CT13 9NJ, UNITED KINGDOM**

2A.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

2A.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

2A.4 Is Summary Basis of Approval appended? ⁽¹⁰⁾ **No**

2A.5 Is the attached, officially approved product information complete and consonant with the licence? ⁽¹¹⁾ **Yes**

2A.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⁾ N/A

IF NO OR NOT APPLICABLE PROCEED TO QUESTION 4

- 3.1 Periodicity of routine inspections (years)
- 3.2 Has the manufacturer of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisation ? ⁽¹⁵⁾

- 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,
10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom**

Telephone Number: +44 (0) 20 3080 6593

Name of authorised person: Colin Atkinson

Signature: 

Stamp and Date: 11 December 2018





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	Colin Atkinson
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Official of the Medicines and Healthcare products Regulatory Agency (MHRA)
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 à / en	London
6. the le / el día	11 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-1253651
9. Seal / stamp Sceau / timbre Sello / timbre	
10. Signature Signature Firma	L. Smethurst 

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

Names and Addresses of Manufacturers/Packagers ⁽⁹⁾

Manufacturers

Name: PFIZER MANUFACTURING DEUTSCHLAND GMBH
Address: BETRIEBSSTAETTE FREIBURG, MOOSWALDALLEE 1, FREIBURG, D-79090, GERMANY

