Certificate Number: PP10158623

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:

Active Ingredient(s)	Amount per unit dose
DOXAZOSIN MESYLATE	2.430 MG
For complete qualitative compacition including an including and (4)	

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 Yes complete and consonant with the licence? (11)

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⁾



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

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 Yes certifying authority on all aspects of the manufacture of the product including Good Manufacturing Practice (GMP)? (16)

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

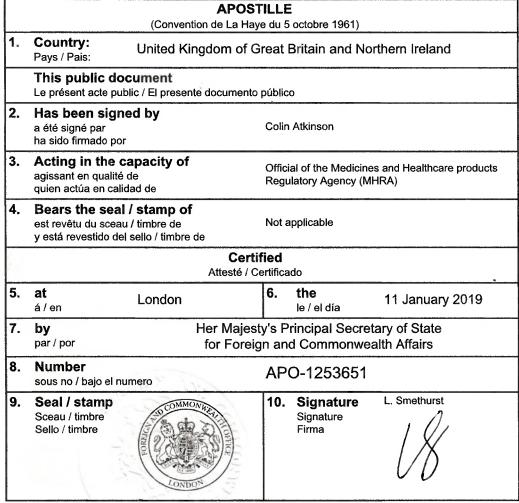
Name of authorised person: Colin Atkinson

Signature: O

Stamp and Date:

11 December 2018





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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

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Names and Addresses of Manufacturers/Packagers (9)

Manufacturers

Name:

PFIZER MANUFACTURING DEUTSCHLAND GMBH

Address:

BETRIEBSSTAETTE FREIBURG, MOOSWALDALLEE 1, FREIBURG, D-

79090, GERMANY

