Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL
Christopher Homan
BARD PHARMACEUTICALS LIMITED
UNIT 191
CAMBRIDGE SCIENCE PARK
MILTON ROAD
CAMBRIDGE
CB4 0GW
UNITED KINGDOM

SOCIETATE PE ACTIUNI, REPUBLICA MOLDOVA, mun. CHIȘINĂU
"FARMACIA CENTRALĂ FARM-PRIM" S.A.
Nr. 1002600039072

Digitally signed by Harea Ștefan
Date: 2021.09.23 14:26:25 EEST
Reason: MoldSign Signature
Location: Moldova

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA 1811 Insp GMP/GDP/IMP 1811/21989-0038

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)

The competent authority of the United Kingdom confirms the following:

The manufacturer	BARD PHARMACEUTICALS LIMITED
Site address	UNIT 191 CAMBRIDGE SCIENCE PARK MILTON ROAD CAMBRIDGE CB4 0GW UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 1811 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 14/08/2020, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended).

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 MHRA-GMDP database. 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

1.1.3 Batch Certification

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
1.2.1.13 Tablets
1.2.1.17 Other non-sterile medicinal products
Granules for suspension.

1.2.2 Batch Certification

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell
1.5.1.13 Tablets
1.5.1.17 Other non-sterile medicinal products
Granules for suspension

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

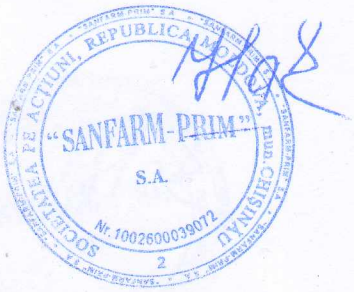
2.2.1 Sterile Products

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



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:

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. A risk-based site inspection programme remains in force.

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

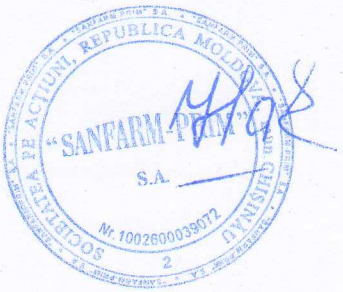
   N/A

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

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 16/02/2021