MHRA
Regulating Medicines and Medical Devices

MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

RESTRICTED – COMMERCIAL
Ms Mona Gogia
CADILA PHARMACEUTICALS LIMITED
PLOT NO. 1389 TRASAD ROAD
DHOLKA
AHMEDABAD
IN 382225
INDIA

SERIAL NO.: 1910 /2018

12 MAY 2018

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NOTARY NIKITA Y. PARGHI DIST. AHMEDABAD GUJARAT STATE REGD. NO. 8578/2011 Expires Dt. 07-09-2021 GOVERNMENT OF INDIA
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GUJARAT CHAMBER OF COMMERCE & INDUSTRY ESTD. 1949 AHMEDABAD

TUSHAR PANDYA
ASST.SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

Medicines and Healthcare Products Regulatory Agency

Certificate No: UK GMP 20872 Insp GMP 20872/14013-0007

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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	CADILA PHARMACEUTICALS LIMITED
Site address	PLOT NO. 1389 TRASAD ROAD DHOLKA AHMEDABAD IN 382225 INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) 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 22/03/2018, 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.

TUSHAR PANDYA
ASST.SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

Medicines and Healthcare Products Regulatory Agency

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)

1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell
1.5.1.13 Tablets
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

Not Authorised

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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AHMEDABAD

ESTD. 1949

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Any restrictions or clarifying remarks related to the scope of this certificate:

The inspection only covered non-sterile products manufactured in the Main Pharmaceutical Building. It did not cover the manufacture of B-lactams, cephalosporins, rifampicin or insulin, which were manufactured in other buildings on the site.

1. Building(s)/Area(s)

   The inspection only covered non-sterile products manufactured in the Main Pharmaceutical Building. It did not cover the manufacture of B-lactams, cephalosporins, rifampicin or insulin, which were manufactured in other buildings on the site.

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

NOTARY NIKITA Y. PARGHI DIST. AHMEDABAD GUJARAT STATE REGD. NO. 8578/2011 Expires Dt. 17-09-2021 GOVERNMENT OF INDIA

Name of the authorised person of the Competent Authority of the United Kingdom

Trevor Watson
GMP Inspector
Trevor.Watson@mhra.gov.uk

Date: 11/05/2018

CERTIFIED TRUE COPY
NIKITA Y. PARGHI
NOTARY
GOVT. OF INDIA

12 MAY 2018

GUJARAT CHAMBER OF COMMERCE & INDUSTRY ESTD. 1949 AHMEDABAD

TUSHAR PANDYA
ASST.SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

NOTARY NIKITA Y. PARGHI DIST. AHMEDABAD GUJARAT STATE REGD. No.8578/2011 GOVERNMENT OF INDIA

The Ministry of External Affairs accepts no responsibility for the contents of the above documents.

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by N/A

acting in the capacity of N/A

bears the seal/stamp of ASSTT. SECY, GUJARAT CHAMBER OF COMMERCE AND INDUSTRY, AHMEDABAD

Certified

at NEW DELHI, INDIA the 13-Nov-2019

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. GJAH0021604519

Seal / Stamp Signature

is issued to CADILA PHARMACEUTICALS LTD.

MINISTRY OF EXTERNAL AFFAIRS GOVT OF INDIA

(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi