



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

MHRA

151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

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.

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

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

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

**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