Medicines & Healthcare products Regulatory Agency

MHRA

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL
Mr Amit Sareen
LUPIN LIMITED - UNIT 2
UNIT-2
PLOT NO. M-2 AND M-2-A
SPECIAL ECONOMIC ZONE
PHASE-II
MISC. ZONE
APPAREL PARK
PITHAMPUR
DHAR DISTRICT
MADHYA PRADESH
IN-454775
INDIA

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 25315 Insp GMP 19930/2478460-0008

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	LUPIN LIMITED - UNIT 2
Site address	UNIT-2 PLOT NO. M-2 AND M-2-A SPECIAL ECONOMIC ZONE PHASE-II MISC. ZONE APPAREL PARK PITHAMPUR DHAR DISTRICT MADHYA PRADESH IN-454775 INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20/03/2023, 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

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

N/A

1. Building(s)/Area(s)

   OSD Facility and Central Warehouse

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   This GMP certificate applies to the manufacture and testing of oral tablets and hard shell capsules.

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

Christine E. Gray
Head of Compliance Team 2 (GMP and GDP)
inspectionplanning@mhra.gov.uk

Date: 14/08/2023