



No: WHO-GMP/2062042/ /B  
Commissioner  
Food & Drugs Control Administration,  
Gujarat State, Dr. Jivraj Mehta Bhavan,  
Block No.8, 1<sup>st</sup> floor, Gandhinagar  
Date :

19 JUN 2020

To,

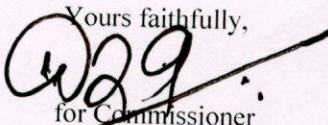
✓ M/s. LUPIN LIMITED,  
PLOT NO. 9, 123, 123/1, 124 & 125, GIDC ESTATE,  
ANKLESHWAR - 393 002  
BHARUCH

Sub :- Drugs & Cosmetics Act, 1940 & Rules thereunder.  
Issue of WHO-GMP Certificate

Sir,

Ref:- Your letter Dated : 10/02/2020

I send herewith World Health Organisation – Good Manufacturing Practices Certificate (WHO-GMP) in ONE copy as desired by you.

Yours faithfully,  
  
for Commissioner  
Food & Drugs Control Administration

No: WHO-GMP/2062042/2020/

/B Gandhinagar Date: - -2020

Copy forwarded to :-

1. Assistant Commissioner, BHARUCH
2. Copy to Dy. Drugs Controller, CDSCO, Air Cargo Complex, Ahmedabad
3. G-Branch.

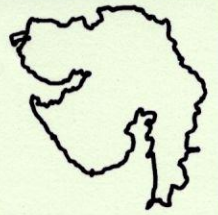
for Commissioner  
Food & Drugs Control Administration





# Food & Drugs Control Administration

BLOCK NO. 8, 1<sup>ST</sup> FLOOR, Dr. JIVRAJ MEHTA BHAVAN,  
GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010



Certificate No. : **2062042**

On the basis of the inspection carried out on **23-24/01/2020 & 28/05/2020** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of  
site :

**LUPIN LIMITED**

**PLOT NO. 9, 123, 123/1, 124 & 125, GIDC ESTATE,,  
City : ANKLESHWAR - 393 002, Dist. BHARUCH  
GUJARAT STATE, INDIA**

2 Manufacturer's  
Licence number :

**G/377**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	Beta-lactum	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **16/06/2023**. It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block  
No. 8, 1<sup>ST</sup> floor, Dr. Jivraj Mehta Bhavan,  
Gandhinagar, Gujarat State, India. – Pin :  
382010

Name & function of : (Dr. H.G. KOSHIA)  
responsible Person Commissioner

Email : [comfdca@gujarat.gov.in](mailto:comfdca@gujarat.gov.in)

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : 17/06/2020





LUPIN LIMITED

Plot No. 9,123,123/1, 124,125, GIDC Estate,

Ankleshwar - 393 002, Gujarat

Tel: +91-2646-304242, 304243, 304357

Fax: +91-2646 251868,



**List of Product for Grant of CoPP as per WHO Guidelines**

**Licence No. G/377 in Form 28 (For Export Only)**

Valid upto: \_\_\_\_\_ to \_\_\_\_\_

1. Cefadroxil IP
2. Cefadroxil Monohydrate BP
3. Cefadroxil Monohydrate EP
4. Cefadroxil USP



**For LUPIN LIMITED**

**Authorized Signatory**

FOR COMMISSIONER  
FOOD & DRUGS CONTROL ADMINISTRATION  
GUJARAT STATE.

17 JUN 2020 16 JUN 2023