F. No. ND/MA/20/000068
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan,
Kotla Road, New Delhi
Dated: 29/7/2020

To
M/s Cipla Ltd.,
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai, Maharastra, India – 400013.

Subject: Grant of permission to manufacture and market Remdesivir for Injection 100 mg/ vial (lyophilized) at the site M/s Cipla Ltd., M-61, M-62 & M-63, Verna Industrial Estate, Verna, Salcette, Goa-403722 - regarding

Reference: Your application no. ND/CT21/FF/2020/19823 dated 21.05.2020

Sir,

Please refer to the permission no.: MF-ND-109/2020 dated 20.06.2020 for manufacture and market Remdesivir for Injection 100 mg/ vial (lyophilized) granted by this office in Form CT-23 under Drugs & Cosmetics Act, 1940 and Rules there under and New Drugs and Clinical Trials Rules, 2019 there under, based on evaluation in consultation with Subject Expert Committee (SEC) as part of accelerated approval process considering the emergency situation and unmet medical need in light of Covid 19 outbreak for restricted emergency use in the country.

This office has no objection for your manufacturing and marketing of Remdesivir for Injection 100 mg/ vial (lyophilized) at additional site M/s Cipla Ltd., M-61, M-62 & M-63, Verna Industrial Estate, Verna, Salcette, Goa-403722 subject to the same conditions and restrictions as stipulated in the permission no.: MF-ND-109/2020 dated 20.06.2020.

Yours faithfully,

V.G.S.

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to: -
1. The DDC(I), Central Drugs Standards Control Organisation, West Zone, 4th Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai – 400 008.
2. Director, Food and Drug Administration, Old IPHB Complex, Altinho, panaji, Goa-403001.

Medicines & Healthcare products Regulatory Agency

MHRA

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

gov.uk/mhra

RESTRICTED – COMMERCIAL
Mr Ashwin Upasane
CIPLA LIMITED (UNIT IX)
UNIT IX
PLOT NO. L-139
S-103
M-62
VERNA INDUSTRIAL ESTATE
VERNA
GOA
IN-403 722
INDIA

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 14694 Insp GMP 14694/2017530-0006

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	CIPLA LIMITED (UNIT IX)
Site address	UNIT IX PLOT NO. L-139 S-103 M-62 VERNA INDUSTRIAL ESTATE VERNA GOA IN-403 722 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 19/08/2019, 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.

Certificate No: UK GMP 14694 Insp GMP 14694/2017530-0006

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.2 Lyophilisates
1.1.1.4 Small volume liquids

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.3 Small volume liquids

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.1 Filtration
1.4.2.3 Moist heat

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility
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

Certificate No: UK GMP 14694 Insp GMP 14694/2017530-0006

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

Sterile product manufacture approved on Lines 1 and 2. The company committed to the MHRA to improvements following this inspection and other regulatory agency findings, in particular for controls with respect to cross contamination.

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: 17/08/2020

Ph: (0832) - 2459226, 2459230
Fax: (0832) - 2459223
Website: www.dfda.goa.gov.in

No: 831/MFG/WHO-GMP/DFDA/2019/3071
Government of Goa,
Dte. of Food & Drugs Admn,
DHANWANTARI,
Opp. The Shrine Of Holy Cross,
Bambolim, Goa – 403202
Dated: 13/4/2019

CERTIFICATE

On the basis of the inspection carried out on **9th April 2019 to 11th April 2019** 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 and address of site:
   M/s Cipla Ltd. Plot No. M-61, M-62 & M-63, Verna Industrial Estate, Verna – Goa

2. Manufacturer's license number:
   704 in Form 28
   744 in Form 28-D

3. Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Liquid Injections	General	Production, Packaging, Quality Control
Lyophilized Injection	General	
Prefilled Syringe	General	

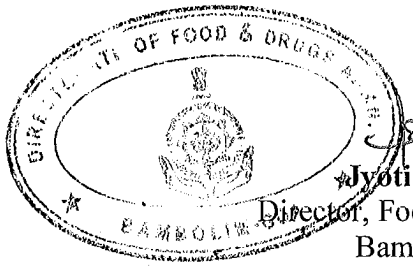
The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **20th October 2022**. 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.

Address of certifying authority:
Directorate of Food & Drugs Administration, Govt. of Goa, DHANWANTARI', Opp. Shrine of The Holy Cross, BAMBOLIM, GOA – 403202, INDIA

Name and function of responsible person:
Jyoti J. Sardesai, Director

Email: -- Telephone no.: **(0832)-2459230, 2459226** Fax no.: **(0832)-2459223**
Website: **www.dfda.goa.gov.in**



Jyoti J. Sardesai
Director, Food & Drugs Admn.
Bambolim Goa.

[1] This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Explanatory notes

(1) This certificate, which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

(2) The certification number should be traceable within the regulatory authority issuing the certificate.

(3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.

(4) Table 1
List the dosage forms, starting materials, categories and activities.
Examples give below.

Example 1

Pharmaceutical Products (s)[2]	Category(ies)	Activity(ies)
Dosage form(s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labeling
Injectables	Cefalosporin	Aseptic preparation, packaging, labeling

Example 2

Pharmaceutical Products (s)[2]	Category(ies)	Activity(ies)
Starting materials(s).[3]		
Paracetamol	Analgesic	Synthesis, purification, packing, labeling

[2] Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

Use, whenever available, International Non proprietary Names (INNs) or otherwise national nonproprietary names.

(5) The Certificate remains valid until the specifies date: The certificate becomes invalid if the activities and/or categories certifies are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organisation, Geneva and subsequent updates.

RDV LICENSE AGREEMENT

This RDV LICENSE AGREEMENT (the "**Agreement**") is made as of May 12, 2020 (the "**Effective Date**") by and between Gilead Sciences, Inc. a Delaware corporation having its principal place of business at 333 Lakeside Drive, Foster City, California 94404, USA ("Gilead"), and Cipla Limited, an Indian Corporation, and having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400013, Maharashtra, India ("**Licensee**"). Gilead and Licensee may each be referred to herein as a "**Party**" or collectively as the "**Parties**."

RECITALS

WHEREAS, Gilead wishes to facilitate access to its proprietary compound remdesivir to treat patients with coronavirus disease 2019 ("**COVID-19**") in 127 countries, as identified in this Agreement, via certain non-exclusive licenses to Licensee with respect to the manufacture and sale of remdesivir and product incorporating remdesivir; and

WHEREAS, Licensee wishes to obtain such non-exclusive licenses to facilitate patient access to Product incorporating remdesivir in such countries, all as more fully described in this Agreement below.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other good and valuable considerations, the receipt of which is hereby acknowledged, the Parties hereto mutually agree as follows:

1. Definitions

"**Affiliate**" shall mean, with respect to a Party to this Agreement, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to applicable law of the country of incorporation or domicile), as applicable.

"**Confidential Information**" shall have the meaning set forth in Section 11.1.

"Customer" shall mean any hospital, government, or alternative site of care located in the Territory that purchases Product from Licensee or a Third Party Reseller.

"**Distributor**" shall mean a third party wholesaler or distributor that is not a Gilead Distributor and that is operating under an agreement with Licensee for the distribution and sale of Product in the Territory.

IN WITNESS WHEREOF, the Parties hereto have executed this RDV License Agreement as of the Effective Date.

GILEAD:

Gilead Sciences, Inc.

By Brett a. Pletcher
Name: Brett Pletcher
Title: EVP, Corporate Affairs & General Counsel

LICENSEE:

Cipla Limited

By _____
Name:
Title:

Cipla Limited

By _____
Name:
Title:

IN WITNESS WHEREOF, the Parties hereto have executed this RDV License Agreement as of the Effective Date.

GILEAD:

Gilead Sciences, Inc.

By_____
Name: Brett Pletcher
Title: EVP, Corporate Affairs & General Counsel

LICENSEE:

Cipla Limited

DocuSigned by:
By_____ 9F7846A877E14A9...
Name: AS Kumar
Title: Global General Counsel & EVP