F. No. ND/MA/20/000074
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(New Drug Division)

FDA Bhawan, Kotla Road
New Delhi - 110 002
Dated:
22 JUL 2020

To

M/s Optimus Pharma Pvt. Ltd.,
Plot No. 73/B, 73/B/2, EPIP,
Pashamylaram (Village),
Sangareddy (District),
Hyderabad-502307, Telangana, India

Subject: Permission to manufacture and market Favipiravir 200mg - regarding

Reference: Your application no. **ND/CT21/BO/2020/19870 dated 27.05.2020.**

Sir,

Please find enclosed herewith permission no. **MF-ND-126/2020** dated 22/07/2020 in **Form CT 23** under Drugs and Cosmetics Act, 1940 and New Drugs & Clinical Trials Rules, 2019 there under granted based on evaluation in consultation with Subject Expert Committee 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.

Please acknowledge receipt of the same.

Yours faithfully,

(Dr. V. G. Somani)
Central Licensing Authority

Copy to:-

1. **The Director, Drugs Control Bhawan, Drugs Control Administration, Vengalrao Nagar, Hyderabad-500038**

2. **DDC (I), CDSCO, Zonal office, Hyderabad.**

सत्यमेव जयते

F. No. ND/MA/20/000074
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(New Drugs Division)

Diary No:
ND/CT21/BO/2020/19870
dated 27.05.2020

Form CT-23

(See rules 81, 82,83 & 84)

PERMISSION TO MANUFACTURE PHARMACEUTICAL FORMULATION OF A NEW DRUG FOR SALE OR FOR DISTRIBUTION

Number of the permission and date of issue **MF-ND-126/2020** dated __/07/2020

1. The Central Licensing Authority hereby grant permission to **M/s Optimus pharma Pvt. Ltd., Plot No. 73/B, 73/B/2, EPIP, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), Hyderabad-502307, Telangana, India, Telephone no. 040-40069400, Fax:04027174641, E-Mail:hemanth.p@optimuspharma.com** to manufacture for sale of pharmaceutical formulation manufactured by a manufacturer specified below.

2. Details of manufacturer and its manufacturing site under the license

Sr. No.	Name and address of manufacturer (Full name and address with telephone and e-mail address of manufacturer	Name and address of manufacturer (Full name and address with telephone and e-mail address of manufacturing site
01	**M/s Optimus pharma Pvt. Ltd., Plot No. 73/B, 73/B/2, EPIP, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), Hyderabad-502307, Telangana, India, Telephone no. 91-40-33889898, +91-8455-223653 Fax: 04027174641 Email: raveendra.y@optimuspharma.com**	**M/s Optimus pharma Pvt. Ltd., Plot No. 73/B, 73/B/2, EPIP, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), Hyderabad-502307, Telangana, India, Telephone no. 91-40-33889898, +91-8455-223653 Fax: 04027174641 Email: raveendra.y@optimuspharma.com**

3. Details of Pharmaceutical formulation

Name of the New Drug to be manufactured:	Favipiravir tablets
Dosage Form:	Film coated tablet
Composition	Each film coated tablet contains: Favipiravir 200mg
Indication	For the treatment of patients with mild to moderate Covid-19 disease.

CDSCO CDSCO

Shelf life with storage Condition	Initially 03 months. Store at a temperature not exceeding 30°C.

4. This is subject to the conditions prescribed in Chapter X of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: _____

Date:21/07/2020

Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Condition of permission

1. The new drugs shall conform to the specifications approved by the Central Licensing Authority;
2. The labeling of the drugs shall conform to the requirements specified in the Drugs and Cosmetics rules, 1945;
3. The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

   "WARNING: To be sold on the prescription of medical specialist" which shall be in box with red background;
4. As post marketing surveillance, the applicant shall submit Periodic Safety Update Reports as specified in the Fifth Schedule;
5. All reported serious unexpected adverse reactions related to drug shall be intimated to the Central Licensing Authority and regulatory action resulting from their review shall be complied with;
6. No claims except those mentioned above shall be made for the drug without prior approval of the Central Licensing Authority;
7. **Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the county shall be got approved from the Central Licensing Authority before the drugs is marketed;**
8. **Updated stability study data shall be submitted at periodic interval. If long-term stability data submitted do not cover the proposed shelf-life of the product, the stability study shall be continued to firmly establish the shelf-life and the complete stability data shall be submitted.**
9. **Written informed consent from each patient/ or his representative prior to administration of the drug shall be obtained by the prescriber i.e. Medical Specialist. Informed consent form to be used should contain in a language understandable to the patient/ or his representative the factual detail about the drug, its restricted emergency use approval,**

alternative therapy available etc. The copy of the informed consent form should be submitted to CDSCO before launching the drug product for marketing.

10. The drug is contraindicated in patients with severe renal, hepatic impairment, pregnant and lactating women.

11. The drug should be used with caution in patient with history of abnormalities in metabolism of uric acid or having Gout.

12. Firm is required to conduct Phase IV clinical trial with the drug and accordingly the firm should submit Phase IV clinical trial protocol within one month.

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:27333/TS/2019

Dated:27/07/2019
Valid until:26/07/2020

GOOD MANUFACTURING PRACTICES CERTIFICATE

This is to certify that **M/s OPTIMUS PHARMA PRIVATE LIMITED** situated at address **PLOT NO.73/B,73/B/2 EPIP, PASHAMYLARAM(V), PATANCHERU(M), SANGAREDDY(DIST.),502307** is holding Drug Manufacturing Licence in Form 25 bearing No. **22/SRD/TS/2017/F/G** Date.**21/07/2017** Valid upto **20/07/2022** for manufacture for sale or distribution of drugs approved by this Department.The firm is subjected to periodical inspection by this Department.

The firm is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules, 1945.

The firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

Digitally Signed By
DR BOLLAM VENKATESWARLU
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:27-07-2019 15:05:06 PM

This Document is Digitally Signed. Signature is not required

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:27334/TS/2019

Dated:27/07/2019
Valid until:26/07/2020

GOOD MANUFACTURING PRACTICES CERTIFICATE

This is to certify that **M/s OPTIMUS PHARMA PRIVATE LIMITED** situated at address **PLOT NO 73/B/2,73/B,EPIP, PASHAMYLARAM(V), PATANCHERU(M), SANGAREDDY(DIST.),502307** is holding Drug Manufacturing Licence in Form 28 bearing No. **TS/SGY/2017-26065** Date.**01/09/2017** Valid upto **31/08/2022** for manufacture for sale or distribution of drugs approved by this Department.The firm is subjected to periodical inspection by this Department.

The firm is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules, 1945.

The firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

Digitally Signed By
DR BOLLAM VENKATESWARLU
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:27-07-2019 15:05:37 PM

This Document is Digitally Signed. Signature is not required

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SUMMARY

The Pre-approval and current Good Manufacturing Practice (cGMP) inspection of this drug manufacturer of oral solid dosage forms (i.e., tablets, capsules, and pellets) and topical dosage forms (i.e., ointments and creams) was conducted to provide coverage for ANDA [redacted] under FACTS assignment ID 11943343 and MARCS Operation ID 126860. This inspection was conducted in accordance to Compliance Programs 7346.832, Drug Pre-Approval Inspections, and 7356.002, Drug Manufacturing Inspections. Additionally, this inspection provided GMP coverage to the Quality, Production, Facilities and Equipment, Materials, Packaging and Labeling, and Laboratory Control Systems.

There was no previous inspection of this manufacturing facility.

No Form FDA 483, Inspectional Observations was issued, no samples were collected, and no refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	Optimus Pharma Private Limited
Location:	Plot No. 73/B, 73/B/2, EPIP, PASHAMYLARAM, PATANCHERU, SANGAREDDY Hyderabad, India
Phone:	(+91) 8455-223653
FAX:	(+91) 8455-223657
Mailing address:	Plot No. 73/B, 73/B/2, EPIP, PASHAMYLARAM, PATANCHERU, SANGAREDDY Hyderabad, India
Email address:	srini@optimuspharma.com
Dates of inspection:	09/02/2019 to 09/06/2019
Days in the facility:	5
Participants:	[redacted] **Investigator**

On 09/02/2019, I presented my credentials and explained the purpose of my visit to Dr. Desireddy Srinivasa Reddy, Managing Director who identified himself as the firm's most responsible individual. Also present were Dr. Kanwal Pandita, Technical Advisor, Mr. Vivek Dhar, President-Operations and Group Audit Coordinator, Mr. Dillip Kumar Jena, President – Formulation, R&D, and Operation (Site Head), Mr. Yalaya Raveendra Reddy, GM – Head Quality Assurance and Regulatory Affairs, Mr. Ramesh Nethala, Sr. Manager -QC, and Mr. Anil Sahebrao Shejawal, AGM – Production.

On 09/06/2019, I conducted a closeout meeting with Dr. Desireddy Srinivasa Reddy, Managing Director, who identified himself as the firm's most responsible individual. Also present were Dr. Kanwal Pandita, Technical Advisor, Mr. Vivek Dhar, President-Operations and Group Audit Coordinator, Mr. Dillip Kumar Jena, President – Formulation, R&D, and Operation (Site Head), Mr. Yalaya Raveendra Reddy, GM – Head Quality Assurance and Regulatory Affairs, Mr. Ramesh Nethala, Sr. Manager -QC, and Mr. Anil Sahebrao Shejawal, AGM – Production.

All FDA correspondence, including FMD 145, should be addressed to:

Mr. Dillip Kumar Jena, President – Formulation R&D and Operations
Plot No. 73/B, 73/B/2, EPIP, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (District), Hyderabad-502307, Telangana, India
Tel: +91-8455-223653, e-mail: dillipkumar.J@optimuspharma.com

Name of person most responsible for the company overall (company headquarters)

Dr. Desireddy Srinivasa Reddy, Managing Director
Plot No. 6P, 2nd floor Signature Towers Kothaguda, Kondapur, Hyderabad-500084, Telangana, India. Tel: +91 40 33889898, e-mail: srini@optimuspharma.com

GENERAL DISCUSSION WITH MANAGEMENT

On 09/06/2019, I conducted a closeout meeting with Dr. Desireddy Srinivasa Reddy, Managing Director who identified himself as the firm's most responsible individual. Also present were Dr. Kanwal Pandita, Technical Advisor, Mr. Vivek Dhar, President-Operations and Group Audit Coordinator, Mr. Dillip Kumar Jena, President – Formulation, R&D, and Operation (Site Head), Mr. Yalaya Raveendra Reddy, GM – Head Quality Assurance and Regulatory Affairs, Mr. Ramesh Nethala, Sr. Manager -QC, and Mr. Anil Sahebrao Shejawal, AGM – Production. I discussed the following [redacted] during this meeting and throughout the inspection:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

Dr. Desireddy Srinivasa Reddy acknowledged the [redacted]

ADDITIONAL INFORMATION

N/A

SAMPLES COLLECTED

No samples were collected during the inspection.

VOLUNTARY CORRECTIONS

N/A

EXHIBITS COLLECTED

1 Building's layout, 1 page
2 Organogram, 1 page
3 List of products manufactured by Optimus Pharma Private Limited
4 [redacted] Finished Product Specification

5 [redacted]
10 List of [redacted] exhibit batches and stability studies
11 Manufacturing process for [redacted] tablets

ATTACHMENTS
Initial Field Recommendation (IFR), 2 pages

[redacted] 10/10/2019
[redacted]
Investigator