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DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

L.Dis.No: 2108/A3/2019 Dated: 31- 01-2020

To:
M/s Aurobindo Pharma Limited
Unit – III, Sy.No.313 & 314,
Bachupally,Bachupally Mandal,
Medchal-Malkajgiri District, Telangana State, India.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder- Issue of World Health Organization Good Manufacturing Practice Certificate - Regarding.

Ref: 1. Your application dt: 11-06-2019
2. Joint inspection Dates: 23.10.2019, 24.10.2019 and 25.10.2019.
3. Ref No. 5-6(205 A4)/2019/6613, dt. 06.01.2020 of Deputy Drugs Controller (I),Central Drugs Standard Control Organisation, Zonal Office, CDSCO Bhavan, Hyderabad, Telangana State,India.

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I forward herewith **World Health Organization Good Manufacturing Practice Certificate** for the products recommended by the Joint Inspection Team consisting of Officers of CDSCO, Zonal Office, Hyderabad, and officers from Drugs Control Administration, **Telangana** state, India.

This Certificate is valid for a period of **Three years** from the date of issue and this certificate is meant for Export Purpose only.

Yours faithfully,

DRUGS CONTROL ADMINISTRATION
HYDERABAD
JD(FAC)
GOVERNMENT OF TELANGANA

31/01/20

Dr.B VENKATESWARLU
JOINT DIRECTOR & LICENSING AUTHORITY (FAC)

L.Dis.No: 2108/A3/2019-WHO/GMP Certificate issued to M/s. Aurobindo Pharma Limited, Unit-III, Situated at Sy, no. 313&314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana state,India.

LIST OF PRODUCTS APPROVED UNDER WHO/GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1. **ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600 / 300 mg**
   Each film coated tablet contains:
   Abacavir sulfate USP
   Equivalent to Abacavir ..... 600 mg
   Lamivudine USP ..... 300 mg
   Colour: Titanium dioxide, FD & C yellow # 6 (Sunset yellow aluminum lake)

2. ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600/300 mg
   ABACAVEX - L 600/300
   Each film coated tablet contains:
   Abacavir Sulfate USP
   Equivalent to Abacavir ..... 600 mg
   Lamivudine USP ..... 300 mg
   Colour: Titanium Dioxide, FD&C Yellow # 6 (Sunset yellow Aluminium Lake)

3. **ABACAVIR SULFATE AND LAMIVUDINE TABLETS 60 / 30 mg**
   Each film coated tablet contains:
   Abacavir sulfate USP
   Equivalent to Abacavir ..... 60 mg
   Lamivudine USP ..... 30 mg
   Colour: Titanium dioxide, FD & C yellow # 6 (Sunset yellow aluminum lake)

4. ABACAVIR SULFATE AND LAMIVUDINE TABLETS 60/30 mg
   ABACAVEX - L 60/30
   Each film coated tablet contains:
   Abacavir Sulfate USP
   Equivalent to Abacavir ..... 60 mg
   Lamivudine USP ..... 30 mg
   Colour: Titanium Dioxide, FD&C Yellow # 6 (Sunset yellow Aluminium Lake)

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LIST OF PRODUCTS APPROVED UNDER WHO/GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

238. NEVIRAPINE TABLETS USP 200 mg
NEVIREX-200
Each tablet contains:
Nevirapine USP..... 200 mg

239. NEVIRAPINE TABLETS USP 200 mg
NEBRIPRIM
Each tablet contains:
Nevirapine USP..... 200 mg

240. NEVIRAPINE ORAL SUSPENSION USP 50mg / 5ml
Each 5 ml contains:
Nevirapine as
Nevirapine Hemihydrate USP ..... 50 mg

241. NEVIRAPINE EXTENDED RELEASE TABLETS USP 400 mg
Each extended Release tablet contains:
Nevirapine USP ..... 400 mg

242. ONDANSETRON HCL TABLETS 4 mg
Each film coated tablet contains:
Ondansetron Hydrochloride Dihydrate
Equivalent to Ondansetron Ph.Eur ..... 4 mg
Colour: Titanium dioxide

243. ONDANSETRON HCL TABLETS 4 mg
AURODANZ 4
Each film coated tablet contains:
Ondansetron Hydrochloride Dihydrate
Equivalent to Ondansetron Ph.Eur ..... 4 mg
Colour: Titanium dioxide

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

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LIST OF PRODUCTS APPROVED UNDER WHO/GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

404. ZIDOVUDINE 300 mg, LAMIVUDINE 150 mg AND NEVIRAPINE 200 mg TABLETS
ZIDOVEX-LN
Each film coated tablet contains:
Zidovudine USP..... 300 mg
Lamivudine USP ..... 150 mg
Nevirapine USP..... 200 mg
Colour: Titanium Dioxide

405. ZOLPIDEM TARTRATE TABLETS USP 10 mg
Each film coated tablet contains:
Zolpidem Tartrate USP..... 10 mg
Colour: Titanium dioxide.

406. ZALEPLON CAPSULES 5 mg
Each capsule contains:
Zaleplon ..... 5 mg
Approved colours used in empty capsule shell.

407. ZALEPLON CAPSULES 10 mg
Each capsule contains:
Zaleplon ..... 10 mg
Approved colours used in empty capsule shell.

(407 Products)

Manufacturer : M/s. AUROBINDO PHARMA LIMITED,
Unit-III, Sy. No.313 & 314,
Bachupally,Bachupally Mandal,
Medchal-Malakajgiri District,
Telangana state, India.

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L.Dis.No: 2108/A3/2019-WHO/GMP Certificate issued to M/s. Aurobindo Pharma Limited, Unit-III, Situated at Sy, no. 313&314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana state, India.

LIST OF PRODUCTS APPROVED UNDER WHO/GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

When Applicable : Placing the products on the market as detailed above.

It is certified that these products have been authorized to be placed on the market for use in the country and exporting countries.

Drug License No. : 19/HD/AP/95/F/R, dated: 20-11-1993
In Form –25 & 28.

It is also certified that (a) the manufacturing plant in which the products are produced is subjected to inspection at suitable intervals.

The unit M/s. AUROBINDO PHARMA LIMITED, Unit-III, Sy. No. 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District ,Telangana state, India, was inspected jointly by Mr. Venumadhav, Drugs Inspector, CDSCO, Hyderabad, and Dr.K.Prabhakar, Drugs Inspector, Drugs Control Administration, Hyderabad on: 23.10.2019, 24.10.2019 and 25.10.2019.

The manufacturer confirms to requirement for Good Manufacturing Practices in the manufacturing and quality control (As recommended by the World Health Organization) in respect of 407 (Four hundred and seven only) products mentioned above for export in the international market.

This Certificate is valid for a period of **Three years** from the date of issue and this certificate is meant for Export Purpose only.

DRUGS CONTROL ADMINISTRATION
HYDERABAD
JD(FAC)
GOVERNMENT OF TELANGANA

Dr.B VENKATESWARLU
Joint Director & Licensing Authority (FAC)

To,
M/S. AUROBINDO PHARMA LIMITED,
Unit-III, Sy. No.313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District, Telanganga state, India.