

**DRUGS CONTROL ADMINISTRATION
Government of Telangana**



L.Dis.No: 4284/A3/2017

Dated: 30-06-2017

To:
M/s Aurobindo Pharma Limited
Unit – III, Sy.No.313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District, Telangana, 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: 23-02-2017
2. Inspection Dates: 17.02.2017 and 18.02.2017.

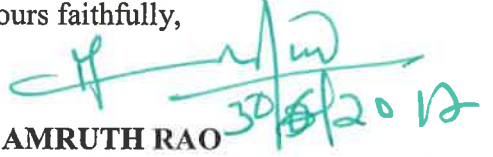
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I forward herewith **World Health Organization Good Manufacturing Practice Certificate** for the products recommended by the Inspection Team consisting of officers of Drugs Control Administration, Telangana, India.

This Certificate is valid for a period of **Two** years from the date of issue, and this certificate is meant for export purpose only.



Yours faithfully,


M. AMRUTH RAO
Joint Director & Licensing authority

DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No: 4284/A3/2017

Dated: 30-06-2017.

**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 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)
3. **ABACAVIR TABLETS USP 60 mg**
Each film coated tablet contains:
Abacavir Sulfate USP
Equivalent to Abacavir 60 mg
Colour: Titanium Dioxide & Iron oxide yellow
4. **AMLODIPINE BESILATE TABLETS 5 mg**
Each un-coated tablet contains:
Amlodipine Besilate Ph. Eur
Equivalent to Amlodipine 5 mg
5. **AMLODIPINE BESILATE TABLETS 5 mg**
KARDAM 5
Each un-coated tablet contains:
Amlodipine Besilate Ph. Eur
Equivalent to Amlodipine 5 mg
6. **AMLODIPINE BESILATE TABLETS 10 mg**
Each un-coated tablet contains:
Amlodipine Besilate Ph. Eur
Equivalent to Amlodipine 10 mg



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30/6/2017

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

333. RIBAVIRIN TABLETS USP 200 mg

Each film coated tablet contains:

Ribavirin USP..... 200 mg

Colour: Titanium Dioxide, Iron oxide red and Yellow Iron oxide.

334. RIBAVIRIN CAPSULES 200 mg

Each capsule contains:

Ribavirin Ph.Eur 200 mg

Approved colours used in empty capsule shell

335. RIBAVIRIN CAPSULES 200 mg

HERIB 200

Each capsule contains:

Ribavirin Ph.Eur 200 mg

Approved colours used in empty capsule shell

336. SERTRALINE TABLETS 50 mg

Each film coated tablet contains:

Sertraline Hydrochloride Ph. Eur

Equivalent to Sertraline 50 mg

Colours: Titanium Dioxide.

337. SERTRALINE TABLETS 50mg

AUROLIFT 50 mg

Each film coated tablet contains:

Sertraline Hydrochloride Ph. Eur

Equivalent to Sertraline..... 50 mg

Colour: Titanium dioxide.

338. SERTRALINE TABLETS 50 mg

AURASERT 50

Each film coated tablet contains:

Sertraline Hydrochloride Ph. Eur

Equivalent to Sertraline 50 mg

Colours: Titanium Dioxide.



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30/6/2017

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

339. SERTRALINE TABLETS 100 mg

Each film coated tablet contains:
Sertraline Hydrochloride Ph. Eur
Equivalent to Sertraline 100 mg
Colours: Titanium Dioxide.

340. SERTRALINE TABLETS 100mg

AUROLIFT 100 mg

Each film coated tablet contains:
Sertraline Hydrochloride Ph. Eur
Equivalent to Sertraline..... 100 mg
Colour: Titanium dioxide.

341. SERTRALINE TABLETS 100 mg

AURASERT 100

Each film coated tablet contains:
Sertraline Hydrochloride Ph. Eur
Equivalent to Sertraline 100 mg
Colours: Titanium Dioxide.

342. SERTRALINE HYDROCHLORIDE ORAL CONCENTRATE 20 mg/ml

Each ml oral concentrate contains:
Sertraline hydrochloride Ph. Eur
Equivalent to Sertraline 20 mg

343. SIMVASTATIN TABLETS BP 5 mg

Each film-coated tablet contains:
Simvastatin Ph. Eur..... 5 mg
Colour: Titanium dioxide and Iron oxide yellow.

344. SIMVASTATIN TABLETS BP 5 mg

KARDAK 5

Each film-coated tablet contains:
Simvastatin Ph. Eur..... 5 mg
Colour: Titanium dioxide and Iron oxide yellow.



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30/6/2017

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Dated: 30-06-2017.

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

420. ZOLPIDEM TARTRATE TABLETS USP 10 mg

Each film coated tablet contains:
Zolpidem Tartrate USP..... 10 mg
Colour: Titanium dioxide.

421. ZALEPLON CAPSULES 5 mg

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

422. ZALEPLON CAPSULES 10 mg

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

(422 Products)

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

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 exporting countries.

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



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

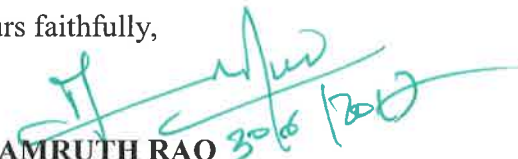
The unit M/s. AUROBINDO PHARMA LIMITED, Unit-III, Sy. No. 313 & 314, Bachupally, Bachupally Mandal, Medchal-Malkajgiri District, Telangana, India, was inspected by Sri.P.Venkateswarlu, Assistant Director, Drugs Control Administration, Vengalrao Nagar, Hyderabad, Telangana, and K. Anvesh, Drugs Inspector, Drugs Control Administration, Vengalrao Nagar, Hyderabad, Telangana, on: 17.02.2017 to 18.02.2017.

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 422 (Four hundred and Twenty Two products only) products mentioned above for export in the international market.

This Certificate is valid for a period of **Two Years** from the date of issue and this certificate is meant for export of drugs only.



Yours faithfully,


M. AMRUTH RAO
Joint Director & Licensing authority

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