



**DRUGS CONTROL ADMINISTRATION**  
**Government of Telangana**



L. Dis. No.:7655/E1/2018

Dated: 29-05-2019

To

M/s. Aurobindo Pharma Limited  
Unit – VII, SEZ, TSIIC, Plot. No.S1,  
Survey No's:411/P, 425/P, 434/P, 435/P & 458/P,  
Green Industrial Park,  
Polepally Village, Jedcherla Mandal,  
Mahaboobnagar District, Telangana.

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: 10.10.2018.  
2. Joint Inspection Dates: 26-06-2018 and 27.06.2018.  
3. Ref No. 5-6(204-A4)/2018/575, dt. 07.05.2019 of Deputy Drugs  
Controller (I), Central Drugs Standard Control Organisation, Zonal Office,  
CDSCO Bhavan, Hyderabad, Telangana.  
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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 Central Drugs Standard Control Organisation and Officer from Drugs Control Administration, Telangana, 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,



*B. Venkateswarlu*  
29/05/19

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

L.Dis.No: 7655/E1/2018- WHO/GMP Certificate issued to M/s. Aurobindo Pharma Limited, unit – VII, SEZ, TSIIC, Plot no. S1, Survey no's. 411/P, 425/P, 434/P, 435/P & 458/P, Green Industrial park, Polepally village, Jedcherla Mandal, Mahaboobnagar District, Telangana, India.

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

**144. VALSARTAN TABLETS 40 mg**

Each film coated tablet contains:

Valsartan Ph.Eur 40 mg

Colour: Titanium dioxide, Iron oxide yellow, Iron oxide red.

**145. VALSARTAN TABLETS 80 mg**

Each film coated tablet contains:

Valsartan Ph.Eur 80 mg

Colour: Titanium dioxide, Iron oxide yellow, Iron oxide red.

**146. DOLUTEGRAVIR TABLETS 50 MG**

Each Film Coated tablet contains

Dolutegravir Sodium Equivalent to 50 mg of Dolutegravir .

**147. ARIPIPRAZOLE TABLETS USP 5 mg**

Each tablet contains:

Aripiprazole USP 5 mg

**148. ARIPIPRAZOLE TABLETS USP 10 mg**

Each tablet contains:

Aripiprazole USP 10 mg

**149. ARIPIPRAZOLE TABLETS USP 15 mg**

Each tablet contains:

Aripiprazole USP 15 mg

**150. ARIPIPRAZOLE TABLETS USP 20 mg**

Each tablet contains:

Aripiprazole USP 20 mg

**151. ARIPIPRAZOLE TABLETS USP 30 mg**

Each tablet contains:

Aripiprazole USP 30 mg

**152. ATAZANAVIR CAPSULES 100 mg**

Each hard gelatin capsule contains:

Atazanavir Sulfate Equivalent to Atazanavir 100 mg

**153. ATAZANAVIR CAPSULES 150 mg**

Each hard gelatin capsule contains:

Atazanavir Sulfate Equivalent to Atazanavir 150 mg



*B. K. 28/05/19*

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

**170. VALGANCICLOVIR TABLETS 450 mg**

Each film coated tablet contains:  
Valganciclovir Hydrochloride 496.36 mg  
Equivalent to Valganciclovir 450 mg

(170 Products)

Manufacturer : M/s. AUROBINDO PHARMA LIMITED,  
Unit – VII, SEZ, TSIIC, Plot. No.S1,  
Sy No's:411/P,425/P,434/P, 435/P & 458/P,  
Green Industrial Park,  
Polepally Village, Jedcherla Mandal,  
Mahaboobnagar 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 Licence No. : 22/MN/AP/2009/F/R, dated: 29-04-2009  
In Form – 25 and 28,

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

The unit M/s. AUROBINDO PHARMA LIMITED, Unit – VII, SEZ, TSIIC, Plot. No.S1, Sy No's:411/P,425/P,434/P, 435/P & 458/P, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar District, Telangana, India was inspected jointly by Dr.B.Laxminarayana, Drugs Inspector, Kothur (Mfg) Drugs Control Administration, Hyderabad, and Mr.G.Narendra Kumar, Drugs Inspector, Central Drugs Standard Control Organisation "CDSCO" Hyderabad, Telangana on: 26-06-2018 and 27.06.2018.

The manufacturer conforms to requirement for Good Manufacturing Practices in the manufacturing and quality control (As recommended by the World Health Organization) in respect of One hundred and seventy (170) products mentioned above for export in the international market.



*B. Venkatesh*  
28/05/19



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**SCHEME FOR EXPORT PURPOSE**

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*B Venkateswarlu*  
29/10/19

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

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