

**GOVERNMENT OF ANDHRA PRADESH  
DRUGS CONTROL ADMINISTRATION**

**From**

M B R Prasad, M.Pharm, M.Phil, A.I.C  
Director& Licensing Authority,  
O/o. The Director General,  
Drugs Control Administration,  
Siddhartha Medical College Campus,  
Gunadala, Vijayawada - 520 008,  
Andhra Pradesh, India.

**To**

M/s. Laurus Labs Limited,  
Unit-II, Plot No.19, 20 & 21,  
Western Sector, APSEZ,  
Gurajapalem Village,  
Rambilli Mandal,  
Anakapalli District – 531011,  
Andhra Pradesh, India.

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Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of WHO- GMP Certificate – Regarding

Ref: 1. Your application dated: 16-03-2024.  
2. Joint Inspection dated:22-11-2023 to 23-11-2023.  
3. This office File No.: HMF07-14051/1667/2023-ADMIN-DCA, Dated: 01-01-2024.

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I, forward here with **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products mention in the Joint Inspection Report of the Officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

The Certificate is valid up to **31-12-2026** from the date of issue and this certificate is meant for Export of Drugs only.

Yours faithfully,

  
Digitally signed by BABU  
RAJENDRA PRASAD  
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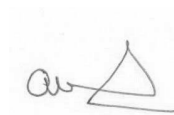
**DIRECTOR & LICENCING AUTHORITY,  
DRUGS CONTROL ADMINISTRATION.**

**GOVERNMENT OF ANDHRA PRADESH  
DRUGS CONTROL ADMINISTRATION**

Office of the Director,  
Licensing & Approving Authority,  
Drugs Control Administration,  
Siddhartha Medical College Campus,  
Gunadala, Vijayawada - 520 008,  
Andhra Pradesh, India.

**LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATE**

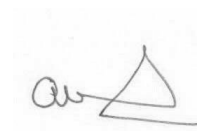
<b>S. No.</b>	<b>Name of the Product</b>
01	<b>Darunavir Tablets 400 mg</b> Each Film Coated Tablet Contains Darunavir IH 400 mg Color: Titanium Dioxide and Sunset Yellow FCF
02	<b>Darunavir Tablets 600 mg</b> Each Film Coated Tablet Contains Darunavir IH 600 mg Color: Titanium Dioxide, Brilliant Blue FCF Aluminum Lake and TartrazineAluminum Lake.
03	<b>Darunavir Tablets 800 mg</b> Each Film Coated Tablet Contains Darunavir IH 800 mg Color: Titanium Dioxide Brilliant Blue FCF Aluminum Lake, Indigo Carmine Aluminum Lake and Allura red AC Aluminum Lake.
04	<b>Metformin Hydrochloride Tablets USP 500 mg</b> Each Film Coated Tablet Contains Metformin Hydrochloride USP 500 mg Color: Titanium Dioxide
05	<b>Metformin Hydrochloride Tablets USP 850 mg</b> Each Film Coated Tablet Contains Metformin Hydrochloride USP 850 mg Color: Titanium Dioxide
06	<b>Metformin Hydrochloride Tablets USP 1000 mg</b> Each Film Coated Tablet Contains: Metformin Hydrochloride USP 1000 mg Color: Titanium Dioxide
07	<b>Metformin Hydrochloride 500 mg Film Coated Tablets</b> Each Film Coated Tablet Contains 500 mg Metformin Hydrochloride corresponding to 390 mg Metformin base.



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S. No.	Name of the Product
08	<b>Metformin Hydrochloride 850 mg Film Coated Tablets</b> Each Film Coated Tablet Contains 850 mg Metformin Hydrochloride corresponding to 662.9 mg Metformin base.
09	<b>Metformin Hydrochloride 1000 mg Film Coated Tablets</b> Each Film Coated Tablet Contains 1000 mg Metformin Hydrochloride corresponding to 780 mg Metformin base.
10	<b>Efavirenz, Emtricitabine and TenofovirDisoproxil Fumarate Tablets 600 mg/200 mg/300 mg</b> Each Film Coated Tablet Contains Efavirenz USP 600 mg Emtricitabine 200 mg TenofovirDisoproxil Fumarate 300 mg Equivalent to TenofovirDisoproxil 245 mg Colors: Titanium Dioxide, Red Oxide of Iron, Ferrosoferric Oxide/ Black Oxide of Iron.
11	<b>Atazanavir Capsules 150 mg</b> Each Capsule Contains AtazanavirSulfate equivalent to Atazanavir 150 mg Colors: Titanium Dioxide, FD &C Blue 2, Yellow Oxide of Iron
12	<b>Atazanavir Capsules 200 mg</b> Each Capsule Contains AtazanavirSulfate equivalent to Atazanavir 200 mg Colors: Titanium Dioxide, FD & C Blue 2, Yellow Oxide of Iron
13	<b>Atazanavir Capsules 300 mg</b> Each Capsule Contains AtazanavirSulfate equivalent to Atazanavir 300 mg Colors: Titanium Dioxide, FD & C Yellow 6, FD& C Blue 2, Yellow Oxide of Iron
14	<b>Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 600 mg/300 mg/300 mg</b> Each Film Coated Tablet Contains Efavirenz USP 600 mg Lamivudine USP 300 mg TenofovirDisoproxil Fumarate 300 mg equivalent to 245 mg of TenofovirDisoproxil. Color: Titanium Dioxide



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S. No.	Name of the Product
15	<b>Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 400 mg/300 mg/300 mg</b> Each Film Coated Tablet Contains Efavirenz USP 400 mg, Lamivudine USP 300 mg, TenofovirDisoproxil Fumarate 300 mg (equivalent to TenofovirDisoproxil 245 mg).
16	<b>TenofovirDisoproxil Fumarate Tablets 300 mg</b> Each Film Coated Tablet Contains TenofovirDisoproxil Fumarate 300mg Equivalent to TenofovirDisoproxil 245 mg Color: Indigo carmine aluminium lake and Titanium Dioxide
17	<b>TENOLAURUS</b> <b>TenofovirDisoproxil Fumarate Tablets 300 mg</b> Each film coated tablet contains: TenofovirDisoproxil fumarate 300 mg (Equivalent to TenofovirDisoproxil 245 mg) Color: Indigo carmine aluminium Lake and Titanium Dioxide

Manufacturer Address : M/sLaurus Labs Limited,  
Unit-II, Plot No.19, 20 & 21, Western Sector, APSEZ,  
Gurajapalem Village, Rambilli Mandal,  
Anakapalli District - 531 011, Andhra Pradesh, India.

Drug License No. : 16/VSP/AP/2015/F&B/CC/R, dated-15-09-2015,  
Valid up to 15-08-2026 in Form-25.

It is also certified that

- The manufacturing plan in which the products are produced is subject to inspection at suitable intervals. The unit M/s.Laurus Labs Limited, Unit-II, Plot No. 19, 20 & 21, Western Sector, APSEZ, Gurajapalem Village, RambilliMandal, Anakapalli District -531011, Andhra Pradesh, India, was jointly inspected by Mr. R VenugopalADC(I), CDSCO Visakhapatnam and Mrs.K. Indira Bharathi, Drug Inspector, DCA, Visakhapatnam on dated: 22.11.2023 to 23-11-2023.
- The Manufacturer confirm to requirement for Good Manufacturing Practices in the manufacture and quality (As recommended by the World Health Organization) in respect of product mentioned above (Seventeen Number) for Export in the International Market.

The Certificate is valid up to **31-12-2026** from the date of issue and this certificate is meant for Export of Drugs only.



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