

**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.

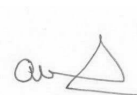
Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of WHO- GMP
Certificate – Regarding
Ref: 1. Your application dated: 28.02.2024.
2. Joint Inspection dated: 22.11.2023 to 23.11.2023.
3. File No.: HMF07-14051/1667/2023-ADMIN-DCA, Dated: 01-01-2024.

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 MEESALA
Date: 2024.05.01
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**DIRECTOR & LICENCING AUTHORITY,
DRUGS CONTROL ADMINISTRATION.**

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DRUGS CONTROL ADMINISTRATION**

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

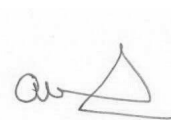
LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATE

S. No.	Name of the Product
01	Tenofovir Alafenamide Tablets 25 mg Each film-coated tablet contains 25 mg of Tenofovir Alafenamide (equivalent to 28 mg of Tenofovir Alafenamide Fumarate)
02	TAFLAURUS Tenofovir Alafenamide Tablets 25 mg Each Film Coated Tablet Contains 25 mg of Tenofovir Alafenamide (equivalent to 28 mg of Tenofovir Alafenamide Fumarate)
03	Emtricitabine and Tenofovir Alafenamide Tablets 200 mg/25 mg Each film coated tablet contains Emtricitabine 200 mg Tenofovir Alafenamide 25 mg equivalent to Tenofovir Alafenamide Fumarate 28 mg
04	VIROTINOMIDE Emtricitabine and Tenofovir Alafenamide Tablets 200 mg/25 mg Each film coated tablet contains Emtricitabine 200 mg Tenofovir Alafenamide 25 mg equivalent to Tenofovir Alafenamide Fumarate 28 mg.
05	Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets 50 mg/200 mg/25 mg Each film coated tablet contains Dolutegravir Sodium equivalent to 50 mg of Dolutegravir Emtricitabine 200 mg Tenofovir Alafenamide 25 mg (equivalent to 28 mg of Tenofovir Alafenamide Fumarate)
06	Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300 mg Each film coated tablet contains Emtricitabine 200 mg Tenofovir Disoproxil Fumarate 300 mg Equivalent to Tenofovir Disoproxil 245 mg

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07	TENOLAURUS-E Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300 mg Each film coated tablet contains Emtricitabine IH 200 mg Tenofovir Disoproxil Fumarate IH 300 mg Equivalent to Tenofovir Disoproxil 245 mg
08	Emtricitabine and Tenofovir Disoproxil 200 mg/245 mg film-coated tablets Each film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300 mg of tenofovir disoproxil fumarate or 136 mg of tenofovir) Colors - Titanium dioxide, FD&C BLUE #2 Indigo Carmine Aluminum Lake
09	Tenovamed Inovamed Emtricitabine and Tenofovir Disoproxil 200 mg/245 mg film-coated tablets Each film-coated tablet contains 200 mg of Emtricitabine and 245 mg of Tenofovir Disoproxil (equivalent to 300 mg of Tenofovir Disoproxil Fumarate or 136 mg of Tenofovir).
10	Hydroxychloroquine Sulfate Tablets USP 200 mg Each tablet contains Hydroxychloroquine sulfate USP 200 mg Color - Titanium dioxide
11	ORTHOKIND - 200 Hydroxychloroquine Sulfate Tablets USP 200 mg Each tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium dioxide
12	Hydroxychloroquine Sulfate Tablets USP 200 mg Each film-coated tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium Dioxide
13	Hydroxychloroquine Sulfate Tablets USP 200 mg RUMAKIND Each film-coated tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium Dioxide
14	Hydroxychloroquine Sulfate Tablets USP 200 mg ORTHOKIND-200 Each film-coated tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium Dioxide



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15	Hydroxychloroquine Sulfate Tablets USP 200 mg HQKIND-200 Each film-coated tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium Dioxide
16	Hydroxychloroquine Sulfate Tablets USP 200 mg HC KIND-200 Each film-coated tablet contains Hydroxychloroquine Sulfate USP 200 mg Color - Titanium Dioxide
17	ABC-Hchloroquine Hydroxychloroquine Sulfate Tablets USP 200 mg Each Film Coated Tablet Contains Hydroxychloroquine Sulfate USP 200 mg Color: Titanium Dioxide

Manufacturer Address: M/s Laurus 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, Rambilli Mandal, Anakapalli District - 531011, Andhra Pradesh, India, was jointly inspected by Mr. R Venugopal ADC(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**.

To
M/s Laurus Labs Limited,
Unit-II, Plot No. 19, 20 & 21,
Western Sector, APSEZ,
Gurajapalem Village, Rambilli Mandal,
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