GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No.894/DCA/AP/2018 Dated: 9 -08-2018

From
M B R Prasad, M.Pharm, M.Phil, A.I.C
Director & Licensing Authority,
O/o.The Director General,
Drugs Control Administration,
Chuttugunta,
Guntur-522 004.

To
M/s Laurus Labs Limited (Unit-2),
Plot No.19, 20 & 21,
Western Sector, APSEZ,
Atchutapuram (M),
Visakhapatnam-531 011.
Andhra Pradesh, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of **World Health Organization G.M.P. Certificate** – Reg.

Ref: 1. Your application Dt: 03.07.2018.
2. Joint Inspection dt.22.03.18 to 23.03.18.

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 **THREE YEARS** from the date of issue and this certificate is meant for Export of Drugs only.

DIRECTORATE OF DRUGS CONTROL A.P. GOVERNMENT OF ANDHRA PRADESH GUNTUR

Yours faithfully,

9/8/18

DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTTATION

Copy to: The Joint Director, Visakhapatnam.

"ANTIBIOTICE" S.A. IAȘI PE ACȚIUNI, REPUBLICA MOLDOVA, mun. CHIȘINĂU "TERAPIA" S.A. CLUJ-NAPOCA "SANFARM-PRIM" S.A. Nr. 1002600039072

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Director,
Licensing & Approving Authority,
Drugs Control Administration,
Chuttugunta,
Guntur–522 004.

L.Dis.No.894/DCA/AP/2018 Dated: 9-08-2018

LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATE

1 . Dolutegravir Tablets 50 mg
Each film-coated tablet contains:
Dolutegravir sodium equivalent to 50 mg of Dolutegravir

2. Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 50 mg /300 mg / 300 mg
Each film-coated tablet contains:
Dolutegravir Sodium Equivalent to Dolutegravir 50mg
Lamivudine USP 300 mg
Tenofovir Disoproxil Fumarate 300 mg Equivalent to 245 mg of Tenofovir Disoproxil

Manufacturer : M/s.Laurus Labs Limited (Unit-2),
Plot No: 19, 20 & 21,
Western Sector, APSEZ,
Atchutapuram (M),
Visakhapatnam-531011.
Andhra Pradesh, India.

Drug Licence No. : 16/VSP/AP/2015/F&B/CC,
Dt.15-09-2015 in Form-25

It is also certified that

a) The manufacturing plan in which the products are produced is subject to inspection at suitable intervals.

The unit M/s.Laurus Labs Limited (Unit-2), Plot No: 19, 20 & 21,Western Sector, APSEZ, Atchutapuram (M), Visakhapatnam-531011, Andhra Pradesh, India was jointly inspected by Smt.D.Suneetha (Mfg), Drugs Inspector, Visakhapatnam (Mfg) and Mr.G.Narednra Kumar, Drugs Inspector, CDSCO, Hyderabad on dated: 22.03.2018 to 23.03.2018.

b) The Manufacturer confirm to requirement for Good Manufacturing Practices in the manufacture and quality (As recommended by the World Health Organisation) in respect of products mentioned above (Four Numbers) for Export in the International Market.

The Certificate is valid **THREE YEARS** from the date of issue and this certificate is meant for Export of Drugs only.

9/8/18

DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTTATION

DIRECTORATE OF DRUGS CONTROL GOVERNMENT OF A.P.

M/s. Laurus Labs Limited (Unit-2),
Plot No.19, 20 & 21,
Western Sector, APSEZ,
Atchutapuram (M),
Visakhapatnam-531011.
Andhra Pradesh, India.

"SANFARM-PRIM" S.A.