7-5/2013/EU/WC-0213
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 27 JUN 2019

To,

M/s Laurus Labs Limited (Unit-1),
Plot No.21,Jawaharlal Nehru Pharma City,
Parwada,Visakhapatnam District -531021,
Andhra Pradesh, India.

Sub: - Written Confirmation of M/s Laurus Labs Limited (Unit-1),Plot No.21, Jawaharlal Nehru Pharma City, Parwada, Visakhapatnam District -531021,Andhra Pradesh, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b (2) (b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zonal office and the recommendation received from DDC (I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the event of non-compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of issue	Valid up to
01.	37	27 JUN 2019	02.07. 2022
02.	10	27 JUN 2019	02.07 .2022

Yours faithfully,

(Dr.S.Eswara Reddy)
Drugs Controller General (India).

w/c EPCL 19/06/19

24-6-19

25/06/19

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

WC-0213

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Laurus Labs Limited (Unit-1),**
Plot No.21,Jawaharlal Nehru Pharma City,
Parwada,Visakhapatnam District -531021,
Andhra Pradesh, India

2. Manufacturer's license number: 05/VP/AP/2008/B/CC

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU(= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: **18/06/2018 and 19/06/2018**

The Written Confirmation remains valid until: **02nd July, 2022.**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India.

Name and function of responsible person: Dr. S. Eswara Reddy.
Drugs Controller General (India).

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

27 JUN 2019

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

WC-0213

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Laurus Labs Limited (Unit-1),
Plot No.21,Jawaharlal Nehru Pharma City,
Parwada,Visakhapatnam District -531021,
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir IH	Manufacturing & Packing
2.	Abacavir Sulfate USP/Ph. Int./IH/Ph.Eur.	Manufacturing & Packing
3.	Atazanavir Sulphate IH	Manufacturing & Packing
4.	Atropine Sulphate USP/Ph. Eur.	Manufacturing & Packing
5.	Bortezomib IH	Manufacturing & Packing
6.	Canagliflozin IH	Manufacturing & Packing
7.	Cabazitaxel IH	Manufacturing & Packing
8.	Capecitabine USP/IP	Manufacturing & Packing
9.	Carfilzomib IH	Manufacturing & Packing
10.	Clopidogrel Hydrogen Sulphate Ph.Eur	Manufacturing & Packing
11.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
12.	Daclatasvir Dihydrochoride IH	Manufacturing & Packing
13.	Darunavir IH	Manufacturing & Packing
14.	Darunavir Ethanolate IH	Manufacturing & Packing
15.	Docetaxel anhydrous IP/IH/Ph.Eur	Manufacturing & Packing
16.	Dolutegravir Sodium IH	Manufacturing & Packing
17.	Efavirenz USP/IH/Ph.Int	Manufacturing & Packing
18.	Emtricitabine Ph. Int./IH	Manufacturing & Packing
19.	Erlotinib Hydrochloride IH	Manufacturing & Packing
20.	Felbamate USP/IH	Manufacturing & Packing
21.	Gemcitabine Hydrochloride USP/Ph. Eur. /BP/IH	Manufacturing & Packing
22.	Hydroxy Chlorquine Sulfate USP	Manufacturing & Packing
23.	Homatropine Methyl Bromide USP/Ph. Eur.	Manufacturing & Packing
24.	Imatinib Mesylate IH	Manufacturing & Packing
25.	Irinotecan HCl Trihydrate USP/IH	Manufacturing & Packing
26.	Lamivudine USP/Ph. Int. /BP/Ph. Eur.	Manufacturing & Packing
27.	Lenalidomide IH	Manufacturing & Packing

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure – 01

CERTIFICATE NO. : WC-0213

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Laurus Labs Limited (Unit-1), Plot No.21,Jawaharlal Nehru Pharma City, Parwada,Visakhapatnam District -531021, Andhra Pradesh, India.**

S. No.	Active substance(s)	Activity(ies)
28.	Metformin HCl IP/USP/Ph.Eur/JP/IH	Manufacturing & Packing
29.	Oseltamivir Phosphate IH	Manufacturing & Packing
30.	Pazopanib Hydrochloride IH	Manufacturing & Packing
31.	Pemetrexed Disodium IH	Manufacturing & Packing
32.	Pregabalin Ph.Eur/IH	Manufacturing & Packing
33.	Ritonavir IH/Ph.Eur.	Manufacturing & Packing
34.	Temozolamide USP	Manufacturing & Packing
35.	Tenofovir Disoproxil Fumarate Ph. Int./IH	Manufacturing & Packing
36.	Thalidomide USP/IH	Manufacturing & Packing
37.	Montelukast Sodium USP/IH/Ph. Eur.	Manufacturing & Packing

ITEM(S) Thirty Seven (37) ONLY

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Government of India

21 JUN 2019

24-6-19

25/06/19

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure – 02

CERTIFICATE NO. : **WC-0213**

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Laurus Labs Limited (Unit-1), Plot No.21,Jawaharlal Nehru Pharma City, Parwada,Visakhapatnam District -531021, Andhra Pradesh, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Azacitidine IH	Manufacturing & Packing
2.	Lenalidomide HCL Monohydrate IH	Manufacturing & Packing
3.	Sofosbuvir IH	Manufacturing & Packing
4.	Tenofovir Disproxil Phosphate IH	Manufacturing & Packing
5.	Tenofovir Disproxil Succinate IH	Manufacturing & Packing
6.	Tenofovir Alafenamide Fumarate IH	Manufacturing & Packing
7.	Enzalutamide IH	Manufacturing & Packing
8.	Rilpivirine HCl IH	Manufacturing & Packing
9.	Velpatasvir IH	Manufacturing & Packing
10.	Sunitinib IH	Manufacturing & Packing

ITEM(S) Ten (10) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

27 JUN 2019