F:No: 7-5/2013/EU/WC-0023
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 26 JUN 2019

To
M/s Aurobindo Pharma Limited, Unit-XI,
Survey No.1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram (Village), Ranasthalam (Mandal),
Srikakulam (District)-532409,
Andhra Pradesh (State),India

SUB: Written Confirmation of M/s Aurobindo Pharma Limited, Unit-XI,Survey No.1/22, 2/1 to 5, 6 to 18, 61 to 69, Pydibhimavaram (Village), Ranasthalam (Mandal), Srikakulam (District) -532409, Andhra Pradesh (State), 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 Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 upto
01	63	26 JUN 2019	Three years from the date of issue
02	02	26 JUN 2019	Three years from the date of issue

Yours faithfully,

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

O/C 20.6.2019

21-6-19

21/06/19

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

CERTIFICATE NO. : **WC-023**

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 Aurobindo Pharma Limited, Unit-XI,
Survey No.1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram (Village), Ranasthalam (Mandal),
Srikakulam (District)-532409,
Andhra Pradesh (State), India

2. Manufacturer's license number: 32/SK/AP/2003/B/R

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 Annexed

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: 02nd &03rd JAN 2019.

The Written Confirmation remains valid until: (03) Three years from the date of issue.

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

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

26 JUN 2019

O/C 20.6.19. 21-6-19

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

Annexure-01
WC-0023

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 Aurobindo Pharma Limited,Unit-XI,
Survey No.1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram (Village),Ranasthalam (Mandal),
Srikakulam (District)-532409,
Andhra Pradesh (State),India

List of APIs:

Sl. No.	Name of the active substances	Activitie(s)
1.	Abacavir Sulfate Ph.Eur	Manufacturing and Packing
2.	Alendronate Sodium Ph.Eur	Manufacturing and Packing
3.	Atomoxetine Hydrochloride Ph.Eur	Manufacturing and Packing
4.	Amoxicillin Trihydrate Ph.Eur	Manufacturing and Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing and Packing
6.	Clindamycin Hydrochloride Ph.Eur	Manufacturing and Packing
7.	Cloxacillin Sodium Ph.Eur	Manufacturing and Packing
8.	Celecoxib Ph.Eur	Manufacturing and Packing
9.	Cefixime Trihydrate Ph.Eur	Manufacturing and Packing
10.	Cefalexin Monohydrate Ph.Eur	Manufacturing and Packing
11.	Clindamycin Palmitate Hydrochloride IH	Manufacturing and Packing
12.	Darifenacin Hydrobromide IH	Manufacturing and Packing
13.	Dextromethorphan Hydrobromide IH	Manufacturing and Packing
14.	Didanosine Ph.Eur	Manufacturing and Packing
15.	Dicloxacillin Sodium Ph.Eur	Manufacturing and Packing
16.	Duloxetine Hydrochloride Ph.Eur	Manufacturing and Packing
17.	Esomeprazole Magnesium Dihydrate Ph.Eur	Manufacturing and Packing
18.	Esomeprazole Sodium IH	Manufacturing and Packing
19.	Emtricitabine IH	Manufacturing and Packing
20.	Efavirenz IH	Manufacturing and Packing
21.	Felodipine Ph.Eur	Manufacturing and Packing
22.	Ibandronate Sodium IH	Manufacturing and Packing
23.	Iron Sucrose IH	Manufacturing and Packing
24.	Lamotrigine Ph. Eur	Manufacturing and Packing
25.	Levetiracetam Ph.Eur	Manufacturing and Packing
26.	Levofloxacin IH	Manufacturing and Packing
27.	Lamivudine Crystalline Polymorph Form-II Ph.Eur	Manufacturing and Packing

O/C
20.6.19

21-6-19

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

Annexure-01
WC-0023

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

Sl.No.	Name of the Active Substances	Activitie(s)
28	Lopinavir Ph.Eur	Manufacturing and Packing
29	Linagliptin IH	Manufacturing and Packing
30	Naproxen Ph Eur	Manufacturing and Packing
31	Naproxen Sodium Ph.Eur	Manufacturing and Packing
32	Nateglinide IH	Manufacturing and Packing
33	Nevirapine Ph.Eur	Manufacturing and Packing
34	Olmesartan Medoxomil Ph.Eur	Manufacturing and Packing
35	Omeprazole Ph.Eur	Manufacturing and Packing
36	Omeprazole Magnesium Ph.Eur	Manufacturing and Packing
37	Pioglitazone Hydrochloride Ph.Eur	Manufacturing and Packing
38	Pitavastatin Calcium IH	Manufacturing and Packing
39	Prasugrel Hydrochloride IH	Manufacturing and Packing
40	Pregabalin Ph.Eur	Manufacturing and Packing
41	Raloxifene Hydrochloride Ph.Eur	Manufacturing and Packing
42	Ranolazine IH	Manufacturing and Packing
43	Repaglinide Ph.Eur	Manufacturing and Packing
44	Rizatriptan Benzoate Ph.Eur	Manufacturing and Packing
45	Rivaroxaban IH	Manufacturing and Packing
46	Rosuvastatin Calcium Ph.Eur	Manufacturing and Packing
47	Tenofovir Disoproxil Fumarate IH	Manufacturing and Packing
48	Tramadol Hydrochloride Ph.Eur	Manufacturing and Packing
49	Valacyclovir Hydrochloride Hydrate Ph.Eur	Manufacturing and Packing
50	Valsartan Ph.Eur	Manufacturing and Packing
51	Voriconazole Ph.Eur	Manufacturing and Packing
52	Valganciclovir Hydrochloride IH.	Manufacturing and Packing
53	Montelukast Sodium Ph.Eur	Manufacturing and Packing
54	Metformin Hydrochloride Ph.Eur	Manufacturing and Packing
55	Quetiapine Fumarate Ph.Eur	Manufacturing and Packing
56	Slidenafil Citrate Ph.Eur	Manufacturing and Packing
57	Solifenacin Succinate Ph.Eur	Manufacturing and Packing
58	Silodosin IH	Manufacturing and Packing

o/c
20.6.19
21-6-19

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

CERTIFICATE NO. :

Annexure-01
WC-0023

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

Sl.No.	Name of the Active Substances	Activitie(s)
59	Sitagliptin Phosphate IH	Manufacturing and Packing
60	Saxagliptin Monohydrate IH	Manufacturing and Packing
61	Sertraline Hydrochloride Ph.Eur	Manufacturing and Packing
62	Zidovudine Ph.Eur	Manufacturing and Packing
63	Ziprasidone Hydrochloride Monohydrate Ph.Eur.	Manufacturing and Packing

ITEM(S) Sixty Three (63) Only

The Written Confirmation remains valid until: (03)Three Years from the date of Issue

Signature

Stamp of the authority and date

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

26 JUN 2019

o/c
20.6.19
20.6.19

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

CERTIFICATE NO. :

Annexure-02
WC-023

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 Aurobindo Pharma Limited,Unit-XI,**
Survey No.1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram (Village),Ranasthalam(Mandal),
Srikakulam (District)-532409,
Andhra Pradesh (State),India

List of APIs:

S. No.	Name of the Active substance(s)	Activitie(s)
1	Darunavir Propylene Glycolate IHS	Manufacturing & Packing
2	Galantamine Hydrobromide Ph.Eur	Manufacturing & Packing

ITEM(S) Two (02) 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: (03)Three years from the date of Issue

Signature

Stamp of the authority and date

26 JUN 2019

o/c 20.6.19

21-6-19