7-5/2013/EU/WC-0017
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

06 JUN 2022

To

M/s Aurobindo Pharma Limited
Unit - VIII, Sy. No. 10 &13, Gaddapotharam Village
I.D.A. Kazipally, Jinnaram Mandal, Sanga Reddy District,
Telangana State

SUB:- Written Confirmation of M/s Aurobindo Pharma Limited, Unit - VIII, Sy. No. 10 &13, Gaddapotharam Village, I.D.A. Kazipally, Jinnaram Mandal, Sanga Reddy District, Telangana State 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 online application no. WC/RE/2022/2739 dated 30.03.2022 submitted to CDSCO, Hyderabad Zone 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	45	06 JUN 2022	10.06.2025
2	01	06 JUN 2022	10.06.2025

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

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

CERTIFICATE NO. : **WC-0017**

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 - VIII, Sy. No. 10 &13, Gaddapotharam Village, I.D.A.
Kazipally, Jinnaram Mandal, Sanga Reddy District,
Telangana State

2. Manufacturer's licence number: 38/MD/AP/2001/B/R

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

List of API(s):

As per Annexure I & Annexure II

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: 07.03.2022 to 09.03.2022

The Written Confirmation remains valid until: 10.06.2025

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. V.G. Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-2323697[illegible]

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt.

06 JUN 2022

Annexure-1

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

CERTIFICATE NO. : WC-0017

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 - VIII, Sy. No. 10 &13, Gaddapotharam Village
I.D.A. Kazipally, Jinnaram Mandal, Sanga Reddy District, Telangana State

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alfuzosin Hydrochloride Ph.Eur	Manufacturing & Packing
2.	Amlodipine Besilate Ph.Eur	Manufacturing & Packing
3.	Atazanavir Sulfate Ph. Eur.	Manufacturing & Packing
4.	Benazepril Hydrochloride Ph.Eur	Manufacturing & Packing
5.	Betahistine Dihydrochloride Ph.Eur	Manufacturing & Packing
6.	Carvedilol Ph. Eur	Manufacturing & Packing
7.	Clopidogrel Hydrogen Sulfate Ph.Eur	Manufacturing & Packing
8.	Bosentan Monohydrate IH	Manufacturing & Packing
9.	Domperidone Ph.Eur	Manufacturing & Packing
10.	Domperidone Maleate Ph. Eur	Manufacturing & Packing
11.	Dutasteride Ph.Eur	Manufacturing & Packing
12.	Efavirenz IH	Manufacturing & Packing
13.	Fexofenadine Hydrochloride Ph. Eur	Manufacturing & Packing
14.	Finasteride Ph.Eur	Manufacturing & Packing
15.	Fluconazole Ph.Eur	Manufacturing & Packing
16.	Fluoxetine Hydrochloride Ph. Eur	Manufacturing & Packing
17.	Fondaparinux Sodium IH	Manufacturing & Packing
18.	Fosinopril Sodium Ph. Eur	Manufacturing & Packing
19.	Gatifloxacin Hemihydrate IH	Manufacturing & Packing
20.	Hydrochlorothiazide Ph. Eur	Manufacturing & Packing
21.	Meloxicam Ph.Eur	Manufacturing & Packing
22.	Moxifloxacin Hydrochloride Ph. Eur	Manufacturing & Packing
23.	Olanzapine Ph.Eur	Manufacturing & Packing
24.	Palonosetron Hydrochloride IH	Manufacturing & Packing
25.	Pramipexole Dihydrochloride Monohydrate Ph.Eur	Manufacturing & Packing
26.	Quinapril Hydrochloride Ph. Eur	Manufacturing & Packing
27.	Ramipril Ph. Eur	Manufacturing & Packing
28.	Rivastigmine Hydrogen Tartrate Ph.Eur	Manufacturing & Packing
29.	Sertraline Hydrochloride Ph.Eur	Manufacturing & Packing
30.	Sumatriptan Succinate Ph.Eur	Manufacturing & Packing
31.	Tadalafil Ph.Eur	Manufacturing & Packing
32.	Tamsulosin Hydrochloride Ph.Eur	Manufacturing & Packing
33.	Tolterodine Tartrate Ph.Eur	Manufacturing & Packing

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt.

Annexure-1

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

CERTIFICATE NO. : WC-0017

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 - VIII, Sy. No. 10 &13, Gaddapotharam Village
I.D.A. Kazipally, Jinnaram Mandal, Sanga Reddy District, Telangana State

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
34.	Torasemide Anhydrous Ph.Eur	Manufacturing & Packing
35.	Trandolapril Ph.Eur	Manufacturing & Packing
36.	Zidovudine Ph.Eur	Manufacturing & Packing
37.	Zolpidem Tartrate Ph.Eur	Manufacturing & Packing
38.	Apixaban IH	Manufacturing & Packing
39.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
40.	Febuxostat IH	Manufacturing & Packing
41.	Neostigmine Metilsulfate Ph.Eur	Manufacturing & Packing
42.	Zaleplon IH	Manufacturing & Packing
43.	Deferasirox Ph. Eur.	Manufacturing & Packing
44.	Entecavir Monohydrate Ph. Eur.	Manufacturing & Packing
45.	Roflumilast IH	Manufacturing & Packing

ITEM(S) FORTY FIVE (45) ONLY

The Written Confirmation remains valid until: 10.06.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

06 JUN 2022

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

Annexure-2

CERTIFICATE NO. : **WC-0017**

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 - VIII, Sy. No. 10 &13, Gaddapotharam Village
I.D.A. Kazipally, Jinnaram Mandal, Sanga Reddy District, Telangana State

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Eletriptan Hydrobromide IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

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

The Written Confirmation remains valid until: 10.06.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. o

06 JUN 2022