7-5/2013/EU/WC-0461
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
15 NOV 2023

To

M/s. Apitoria Pharma Private Limited, Unit-VI,
Plot no.:17, E-Bonangi Village, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli (District), Andhra Pradesh – 531 019, India

SUB:- Written Confirmation of M/s. Apitoria Pharma Private Limited, Unit-VI, Plot no.:17, E-Bonangi Village, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli (District), Andhra Pradesh – 531 019, 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 - Amendment Reg.

Sir,

This is with reference to your application dated 29.09.2023 received in this office vide diary no. P-3343843 dated 03.10.2023, wherein, you had requested for amendment for change in name of the firm in previously issued Written Confirmation Certificate (WC-0461) issued on 15.12.2022 & 18.09.2023. In this regard, an amended Written Confirmation Certificate is enclosed.

Please acknowledge the receipt

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : **Amended**

WC-0461

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. Apitoria Pharma Private Limited, Unit-VI,**
Plot no.:17, E-Bonangi Village,
Jawaharlal Nehru Pharma City, Parawada Mandal,
Anakapalli (District), Andhra Pradesh – 531 019, India

The Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0461) issued on 15.12.2022 & 18.09.2023 is hereby amended as follows.

In place of	*Read as*
M/s Aurobindo Pharma Limited, Unit- XIV	M/s. Apitoria Pharma Private Limited, Unit-VI

All other conditions of Written Confirmation Certificate will remain same

Signature

15 NOV 2023

Stamp of the authority and date

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

7-5/2013/EU/WC-0461
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

To,

M/s. Aurobindo Pharma Limited,
Unit –XIV, Plot No 17 E-Bonangi Village,
JNPC Jawaharlal Nehru Pharma City Parawda Mandal,
Visakhapatnam District-531019, Andhra Pradesh, India.

15 DEC 2022

Subject :- Written Confirmation of M/s. Aurobindo Pharma Limited, Unit –XIV, Plot No 17 E-Bonangi Village, JNPC Jawaharlal Nehru Pharma City Parawda Mandal, Visakhapatnam District-531019, 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 - Regarding.

Sir,

Please refer to your online application submitted vide WC/RE/2022/5543 to the CDSCO, Zone, Hyderabad office and the recommendation received from DDC(I), 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	05	15 DEC 2022	25.12.2025

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-0461

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 –XIV, Plot No 17 E-Bonangi Village,
JNPC Jawaharlal Nehru Pharma City Parawda Mandal,
Visakhapatnam District-531019, Andhra Pradesh, India.

2. Manufacturer's licence number: 02/VP/AP/2014/B/G

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

List of APIs:

As per List enclosed as Annexure -1

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: 26.10.2021 & 27.10.2021

The Written Confirmation remains valid until: 25.12.2025

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.: +91-11-23236973

15 DEC 2022

Signature

Stamp of the authority and date

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

Annexure-01

CERTIFICATE NO. : WC-0461

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 –XIV, Plot No 17 E-Bonangi Village,
JNPC Jawaharlal Nehru Pharma City Parawda Mandal,
Visakhapatnam District-531019, Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clopidogrel Hydrogen Sulphate Ph.Eur	Manufacturing & Packing
2.	Fluconazole Ph.Eur	Manufacturing & Packing
3.	Carvedilol Ph.Eur	Manufacturing & Packing
4.	Amlodipine Besylate Ph.Eur	Manufacturing & Packing
5.	Lamotrigine Ph.Eur	Manufacturing & Packing

ITEM(S) FIVE (05) ONLY

The Written Confirmation remains valid until: 25.12.2025.

Signature

Stamp of the authority and date

15 DEC 2022

7-5/2013/EU/WC-0461
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
18 SEP 2023

To,

M/s. Aurobindo Pharma Limited
Unit-XIV, Plot No.17 E-Bonangi Village
Jawaharlal Nehru Pharma City, Parawada Mandal
Visakhapatnam District-531 019, Andhra Pradesh, India

SUB:- Written Confirmation to M/s.Aurobindo Pharma Limited, Unit-XIV, Plot No.17 E-Bonangi Village, Jawaharlal Nehru Pharma City, Parawada Mandal, Visakhapatnam District-531 019, 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 online application no. WC/ED/2023/6851 dated 14.03.2023 submitted to CDSCO, DDC(I), Zonal Office, Hyderabad, and the recommendation received from DDC(I), Zonal Office, Hyderabad,, 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	05	15.12.2022	25.12.2025
02	04	18 SEP 2023	25.12.2025

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

Annexure-02

CERTIFICATE NO. : WC-0461

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-XIV, Plot No.17 E-Bonangi Village
Jawaharlal Nehru Pharma City, Parawada Mandal
Visakhapatnam District-531 019
Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Clopidogrel Bisulphate (Form-II) Ph.Eur. (Crystalline Polymorph Form-II)	Manufacturing & Packing
2.	Eslicarbazepine Acetate IH	Manufacturing & Packing
3.	Paracetamol Ph.Eur	Manufacturing & Packing
4.	Ezetimibe IH	Manufacturing & Packing

ITEM FOUR (04) ONLY

The Written Confirmation remains valid until: 25.12.2025

Signature 18 SEP 2023

Stamp of the authority and date