7-5/2013/EU/WC-0121
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
07 DEC 2023

To

M/s. Apitoria Pharma Private Limited, Unit-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (village), Patancheru (Mandal),
Sangareddy District, Pincode – 502307, Telangana, India

SUB:- Written Confirmation of M/s. Apitoria Pharma Private Limited, Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261, IDA, Pashamylaram (village), Patancheru (Mandal), Sangareddy District, Pincode – 502307, Telangana, 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 20.11.2023 received in this office vide diary no. E- 5148/23 dated 22.11.2023, wherein, you had requested for amendment with complete address with pincode in previously issued Written Confirmation Certificate (WC-0121) dated 02.08.2022 & 08.08.2022. In this regard, an amended Written Confirmation Certificate is enclosed.

Please acknowledge the receipt.

Yours faithfully,

Rajeev Singh

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

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

Amended

CERTIFICATE NO. : WC-0121

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (village), Patancheru (Mandal),
Sangareddy District, Pincode – 50230, Telangana, India

The Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0121) issued on 07.06.2022 is hereby amended as follows.

In place of	*Read as*
M/s. Apitoria Pharma Private Limited, Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261, IDA, Pashamylaram (village), Patancheru (Mandal), Sangareddy District, Pincode – 50230, Telangana, India	**M/s. Apitoria Pharma Private Limited, Unit-V,** Plot No. 68-70, 73-91, 95, 96, 260, 261, IDA, Pashamylaram (village), Patancheru (Mandal), Sangareddy District, Pincode – 502307, Telangana, India

All other conditions of Written Confirmation Certificate will remain same

Signature

07 DEC 2023

Stamp of the authority and date

7-5/2013/EU/WC-0121
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

02 AUG 2022

To

M/s. Aurobindo Pharma Limited, Unit-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

Subject:- Written Confirmation of M/s. Aurobindo Pharma Limited, Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261, IDA, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (Dist.), Telangana, 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/RE/2022/3138 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	12	02 AUG 2022	02.07.2025
2	04	02 AUG 2022	02.07.2025

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-0121**

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

2. Manufacturer's licence number: 48/MD/AP/98/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 List enclosed as Annexure-1 & 2

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: 07.07.2022 & 08.07.2022

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

02 AUG 2022

Signature

Stamp of the authority and date

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

Annexure-1

CERTIFICATE NO. : WC-0121

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ampicillin Sodium (Sterile) Ph.Eur	Manufacturing & Packing
2.	Amoxicillin Trihydrate Ph.Eur	Manufacturing & Packing
3.	Oxacillin for Injection USP	Manufacturing & Packing
4.	Ampicillin Trihydrate Ph.Eur	Manufacturing & Packing
5.	Cloxacillin Sodium Ph.Eur	Manufacturing & Packing
6.	Dicloxacillin Sodium Ph.Eur	Manufacturing & Packing
7.	Sulbactam Sodium (Sterile) Ph.Eur	Manufacturing & Packing
8.	Amoxicillin Sodium (Sterile) Ph.Eur	Manufacturing & Packing
9.	Oxacillin Sodium Monohydrate (Sterile) Ph.Eur	Manufacturing & Packing
10.	Oxacillin Sodium Monohydrate Ph.Eur	Manufacturing & Packing
11.	Sulbactam Sodium Ph.Eur	Manufacturing & Packing
12.	Piperacillin and Tazobactum for Injection (8:1) (Bulk Drug) USP	Manufacturing & Packing

ITEM(S) Twelve (12) ONLY

The Written Confirmation remains valid until: 02nd July, 2025

Signature Vkc

Stamp of the authority and date

02 AUG 2022

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

Annexure-2

CERTIFICATE NO. : **WC-0121**

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Flucloxacillin Sodium Ph.Eur	Manufacturing & Packing
2.	Flucloxacillin Magnesium Octahydrate Ph.Eur	Manufacturing & Packing
3.	Flucloxacillin Sodium (Sterile) Ph.Eur	Manufacturing & Packing
4.	Pivmecillinam Hydrochloride Ph.Eur	Manufacturing & Packing

ITEM(S) Four (04) 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: 02nd July, 2025

Signature

Stamp of the authority and date

02 AUG 2022

7-5/2013/EU/WC-0121
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:
08 AUG 2022

To

M/s. Aurobindo Pharma Limited, Unit-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

Subject:- Written Confirmation of M/s. Aurobindo Pharma Limited, Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261, IDA, Pashamylaram (Village), Patancheru (Mandal), Sangareddy (Dist.), Telangana, 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/2022/3701 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	12	02.08.2022	02.07.2025
2	04	02.08.2022	02.07.2025
3	02	08 AUG 2022	02.07.2025
4	01	08 AUG 2022	02.07.2025

Yours faithfully,

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

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

Annexure-3

CERTIFICATE NO. : WC-0121

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ampicillin Anhydrous Ph.Eur	Manufacturing & Packing
2.	Cloxacillin sodium (sterile) Ph. Eur	Manufacturing & Packing

ITEM(S) Two (2) ONLY

The Written Confirmation remains valid until: 02nd July, 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

08 AUG 2022

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

Annexure-4

CERTIFICATE NO. : **WC-0121**

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-V,
Plot No. 68-70, 73-91, 95, 96, 260, 261,
IDA, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy (Dist.), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ampicillin and Sulbactum for injection (sterile mixture (2:1) USP/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: 02nd July, 2025

Signature

Stamp of the authority and date

08 AUG 2022