7-5/2013/EU/WC-0120
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-I,
Survey No.: 379, 385, 386, 388 to 396,
Borpatla Village, Hathnoora Mandal,
Sangareddy District – 502 296, Telangana, India

SUB:- Written Confirmation of M/s. Apitoria Pharma Private Limited, Unit-I, Survey No.: 379, 385, 386, 388 to 396, Borpatla Village, Hathnoora Mandal, Sangareddy District – 502 296, 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 - Regarding

Sir,

This is with reference to your application dated 20.11.2023 & 28.11.2023 (vide dairy no.E-5150 & E-5665 dated 22.11.2023 & 29.11.2023) received in this office, wherein, you had requested for amendment for inclusion of survey number with complete address of the firm in previously issued amended Written Confirmation Certificate (WC-0120) issued on 15.11.2023. 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

Amended

CERTIFICATE NO. : **WC-0120**

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-I,**
Survey No.: 379, 385, 386, 388 to 396,
Borpatla Village, Hathnoora Mandal,
Sangareddy District – 502 296, Telangana, India

The Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0120) issued on 15.11.2023 is hereby amended as follows.

In place of	*Read as*
M/s. Apitoria Pharma Private Limited, Unit-I Survey No.: 379, 385, 388 to 396, Borpatla Village, Hathnooram Mandal, Sangareddy District – 502 296, Telangana, India	**M/s. Apitoria Pharma Private Limited, Unit-I** Survey No.: 379, 385, 386, 388 to 396, Borpatla Village, Hathnoora Mandal, Sangareddy District – 502 296, Telangana, India

All other conditions of Written Confirmation Certificate will remain same

Rajeev Singh

Signature

07 DEC 2023

Stamp of the authority and date

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

7-5/2013/EU/WC-0120
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-I,
Survey No.: 379, 385, 388 to 396, Borpatla Village,
Hathnooram Mandal, Sangareddy District – 502 296, Telangana, India

SUB:- Written Confirmation of M/s. Apitoria Pharma Private Limited, Unit-I, Survey No.: 379, 385, 388 to 396, Borpatla Village, Hathnooram Mandal, Sangareddy District – 502 296, 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 29.09.2023 received in this office vide diary no. 9129 dated 03.10.2023, wherein, you had requested for amendment for change in name of the firm in previously issued Written Confirmation Certificate (WC-0120) issued on 15.07.2022 & 15.05.2023 . 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

Amended

CERTIFICATE NO. :

WC-0120

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-I,**
Survey No.: 379, 385, 388 to 396, Borpatla Village,
Hathnooram Mandal, Sangareddy District-502 296,
Telangana, India

The Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0120) issued on 15.07.2022 & 15.05.2023 is hereby amended as follows.

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

All other conditions of Written Confirmation Certificate will remain same

Rajeev Singh
Signature

15 NOV 2023

Central Drugs Standard Control Organization

Stamp of the authority and date

F:No: 7-5/2013/EU/WC-0120
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-I,
Survey No.379, 385, 386, 388 to 396.,
Borpatla(V), Hathnooram (M),Sangareddy(Dist),
Telangana, India.

15 JUL 2022

SUB: Written Confirmation of M/s Aurobindo Pharma Limited, Unit-1,Survey No.379, 385, 386, 388 to 396., Borpatla(V), Hathnooram (M), 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/2022/2526 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	53	15 JUL 2022	02.07.2025
02	02	15 JUL 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-0120**

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-I,
Survey No.379, 385, 386, 388 to 396.,
Borpatla(V),Hathnooram (M), Sangareddy(Dist),
Telangana,India

2. Manufacturer's license number: 47/MD/AP/95/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: 17& 18 December 2020

The Written Confirmation remains valid until: 02.07.2025

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 JUL 2022

Signature

Stamp of the authority and date

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

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

Annexure-01
WC-0120

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-I, Survey No.379, 385, 386, 388 to 396., Borpatla(V), Hathnooram (M), Sangareddy(Dist),Telangana, India.

List of APIs:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Amisulpride Ph.Eur	Manufacturing and Packing
2.	Aripiprazole Ph.Eur	Manufacturing and Packing
3.	Amlodipine Sesilate Ph.Eur	Manufacturing and Packing
4.	Atorvastatin Calcium Trihydrate Ph.Eur	Manufacturing and Packing
5.	Bisoprolol Fumarate Ph.Eur.	Manufacturing and Packing
6.	Canagliflozin IH	Manufacturing and Packing
7.	Carmustine Ph.Eur.	Manufacturing and Packing
8.	Cefadroxil Monohydrate Ph.Eur.	Manufacturing and Packing
9.	Cefalexin Ph.Eur	Manufacturing and Packing
10.	Cefdinir IHS/USP	Manufacturing and Packing
11.	Cefixime Ph.Eur	Manufacturing and Packing
12.	Cefixime Trihydrate Ph.Eur	Manufacturing and Packing
13.	Cefpodoxime Proxetil Ph.Eur	Manufacturing and Packing
14.	Cefprozil Monohydrate Ph.Eur	Manufacturing and Packing
15.	Ceftibuten IHS	Manufacturing and Packing
16.	Ceftiofur Hydrochloride IH	Manufacturing and Packing
17.	Cefuroxime Axetil Ph. Eur.	Manufacturing and Packing
18.	Ciprofloxacin Hydrochloride Ph.Eur	Manufacturing and Packing
19.	Citalopram Hydrobromide Ph.Eur	Manufacturing and Packing
20.	Dapagloflozin IH	Manufacturing and Packing
21.	Donepezil Hydrochloride IHS/USP	Manufacturing and Packing
22.	Doxazosin Mesilate Ph.Eur.	Manufacturing and Packing
23.	Entacapone Ph.Eur.	Manufacturing and Packing
24.	Escitalopram Oxalate Ph.Eur	Manufacturing and Packing
25.	Famciclovir IHS	Manufacturing and Packing
26.	Flecanide Acetate Ph.Eur	Manufacturing and Packing
27.	Fluvastatin Sodium Ph.Eur	Manufacturing and Packing
28.	Gabapentin Ph.Eur	Manufacturing and Packing

15 JUL 2022

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

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

CERTIFICATE NO. : **Annexure-01**
WC-0120

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)
29.	Gemfibrozil Ph.Eur	Manufacturing and Packing
30.	Glibenclamide Ph.Eur	Manufacturing and Packing
31.	Irbesartan Ph.Eur	Manufacturing and Packing
32.	Empagliflozin IH	Manufacturing and Packing
33.	Losartan Potassium Ph.Eur	Manufacturing and Packing
34.	Metformin Hydrochloride Ph.Eur	Manufacturing and Packing
35.	Metoprolol Succinate Ph.Eur	Manufacturing and Packing
36.	Metoprolol Tartrate Ph.Eur	Manufacturing and Packing
37.	Mirtazapine Ph. Eur	Manufacturing and Packing
38.	Modafinil Ph.Eur	Manufacturing and Packing
39.	Nevirapine Ph.Eur	Manufacturing and Packing
40.	Ondansetron Hydrochloride Dihydrate Ph.Eur	Manufacturing and Packing
41.	Pantoprazole Sodium Sesquihydrate Ph. Eur	Manufacturing and Packing
42.	Paroxetine Hydrochoride Hemihydrate Ph. Eur	Manufacturing and Packing
43.	Perindopril tert-Butylamine Ph.Eur	Manufacturing and Packing
44.	Pirfenidone Ph.Eur.	Manufacturing and Packing
45.	Rabeprazole Sodium Hydrate Ph.Eur	Manufacturing and Packing
46.	Ribavirin Ph.Eur	Manufacturing and Packing
47.	Risperidone Ph.Eur	Manufacturing and Packing
48.	Ritonavir Ph.Eur	Manufacturing and Packing
49.	Simvastatin Ph.Eur	Manufacturing and Packing
50.	Telmisartan Ph.Eur	Manufacturing and Packing
51.	Terazosin Hydrochloride Ph.Eur	Manufacturing and Packing
52.	Terbinafine Hydrochloride Ph.Eur	Manufacturing and Packing
53.	Topiramate USP	Manufacturing and Packing

ITEM(S) Fifty Three (53) Only

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

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

15 JUL

Annexure-02
WC-0120

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

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-I, Survey No.379, 385, 386, 388 to 396., Borpatla(V), Hathnooram (M), Sangareddy(Dist),Telangana, India.

List of APIs:

Sl. No.	Name of the Active substance(s)	Activitie(s)
1.	Tiopronin IHS	Manufacturing & Packing
2.	Cefuroxime Axetil Povidone Mixture IH	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: 02.07.2025

Signature

Stamp of the authority and date

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

15 JUL 2022

7-5/2020/EU/WC-0120
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

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

To,

M/s. Aurobindo Pharma Limited,
Unit -I, Sy.No. 379, 385, 386 388 to 396,
Borpatla, Hathnooram (M), Sangareddy (Dist),
Telangana, India.

15 MAY 2023

Subject :- Written Confirmation M/s. Aurobindo Pharma Limited, Unit -I, Sy.No. 379, 385, 386 388 to 396,Borpatla, Hathnooram (M), 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-Regarding.

Sir,

Please refer to your online application no. WC/ED/2023/6839 submitted to CDSCO, Hyderabad zone 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 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	53	15.07.2022	02.07.2025
02	02	15.07.2022	02.07.2025
03	01	15 MAY 2023	02.07.2025
04	01	15 MAY 2023	02.07.2025

Yours faithfully,

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

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

Annexure-03

CERTIFICATE NO. :

WC-0120

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 -I, Sy.No. 379, 385, 386 388 to 396,
Borpatla, Hathnooram (M), Sangareddy (Dist),
Telangana, India.**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Paclitaxel Ph.Eur	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02/07/2025.

Signature

Stamp of the authority and date

15 MAY 2023

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

Annexure-04

CERTIFICATE NO. :

WC-0120

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 -I, Sy.No. 379, 385, 386 388 to 396,
Borpatla, Hathnooram (M), Sangareddy (Dist),
Telangana, India.

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Docosanol 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: **02/07/2025**

Signature

15 MAY 2023

Stamp of the authority and date

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