7-5/2013/EU/WC/0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDABhawan,Kotla Road,
New Delhi-110002
Dated: 19 SEP 2022

To

M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

Subject:- Written Confirmation of M/s. Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, , Jeedimetla, Medchal- Malkajgiri District, Telangana 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 online application No. WC/FR/2022/5055 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	22	19 SEP 2022	02.07.2025
2	02	19 SEP 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-0119**

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. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

2. Manufacturer's licence number: 99/RR/AP/B/CC

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 enclosed Annexures

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: 17.01.2022 to 19.01.2022

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

19 SEP 2022

Signature

Stamp of the authority and date

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

CERTIFICATE NO. : **Annexure-1**
WC-0119

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

Name and address of site: **M/s. Aurore Pharmaceutical Private Limited,**
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Acyclovir USP	Manufacturing & Packing.
2.	Aciclovir Ph.Eur	Manufacturing & Packing
3.	Amlodipine Besylate USP	Manufacturing & Packing
4.	Amlodipine Besilate Ph.Eur/BP	Manufacturing & Packing
5.	Celecoxib USP/ Ph.Eur	Manufacturing & Packing
6.	Desvenlafaxine Succinate IH	Manufacturing & Packing
7.	Dolutegravir sodium IH	Manufacturing & Packing
8.	Dronedarone Hydrochloride Ph.Eur /USP	Manufacturing & Packing
9.	Erdosteine IH	Manufacturing & Packing
10.	Etoricoxib IH	Manufacturing & Packing
11.	Levetiracetam USP/Ph.Eur/BP	Manufacturing & Packing
12.	Levothyroxine sodium USP/Ph.Eur	Manufacturing & Packing
13.	Oxcarbazepine USP/Ph.Eur	Manufacturing & Packing
14.	Pinaverium Bromide IH	Manufacturing & Packing
15.	Prazosin Hydrochloride USP	Manufacturing & Packing
16.	Tofacitinib Citrate IH	Manufacturing & Packing
17.	Tolvaptan IH	Manufacturing & Packing
18.	Valaciclovir Hydrochloride Ph.Eur/BP	Manufacturing & Packing
19.	Valacyclovir Hydrochloride USP	Manufacturing & Packing
20.	Valaciclovir HydrochlorideHydrated Ph.Eur	Manufacturing & Packing
21.	Valganciclovir Hydrochloride USP	Manufacturing & Packing
22.	Verapamil Hydrochloride USP/Ph.Eur	Manufacturing & Packing

ITEM(S) TWENTY TWO (22) ONLY

The Written Confirmation remains valid until: 02.07.2025

19 SEP 2022

Signature

Stamp of the authority and date

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

CERTIFICATE NO. :

Annexure-2
WC-0119

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

Name and address of site: **M/s. Aurore Pharmaceutical Private Limited,**
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Desvenlafaxine Oxalate IH	Manufacturing & Packing
2.	Salsalate USP	Manufacturing & Packing

ITEM(S) TWO (02) 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

Stamp of the authority and date

19 SEP 2022

7-5/2013/EU/WC/0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDABhawan,Kotla Road,
New Delhi-110002
Dated:
02 NOV 2022

To

M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

Subject:- Written Confirmation of M/s. Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, , Jeedimetla, Medchal- Malkajgiri District, Telangana 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 online application No. WC/FR/2022/2905 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02 NOV 2022	02.07.2025
4	02	02 NOV 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. :

Annexure-3
WC-0119

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

Name and address of site: M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Desvenlafaxine Succinate USP	Manufacturing & Packing
2.	Fluphenazine Hydrochloride USP	Manufacturing & Packing
3.	Raloxefene hydrochloride Ph.Eur /USP	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

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

02 NOV 2022

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

Annexure-4

CERTIFICATE NO. : WC-0119

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

Name and address of site: M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Camostat Mesilate JP	Manufacturing & Packing
2.	Molnupiravir IH	Manufacturing & Packing

ITEM(S) TWO (02) 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

Stamp of the authority and date

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

02 NOV 2022

AMENDED

7-5/2013/EU/WC-0119

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
25 OCT 2023

To,

M/s.Aurore Pharmaceuticals Private Limited
Plot No. 35,36,38,39,40,49,50 51,
Phase-IV, IDA, Jeedimetla,
Medchal–Malkajgiri-500055,Telangana State, India

SUB:- Written Confirmation to M/s.Aurore Pharmaceuticals Private Limited, Plot No. 35,36,38,39,40,49,50 51, Phase-IV, IDA, Jeedimetla, Medchal–Malkajgiri-500055,Telangana 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 online application no. WC/RE/2023/6483 dated 06.02.2023 submitted to CDSCO, DDC(I), Hyderabad Zone, Telangana State, 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5	11	25 OCT 2023	02.07.2025

Yours faithfully,

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

AMENDED
Annexure-05

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

CERTIFICATE NO. :

WC-0119

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.Aurore Pharmaceuticals Private Limited**
Plot No. 35,36,38,39,40,49,50 51,
Phase-IV, IDA, Jeedimetla,
Medchal–Malkajgiri-500055,Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Armodafinil IH	Manufacturing & Packing
2.	Candesartan Cilexetil Ph.Eur	Manufacturing & Packing
3.	Carvedilol Ph.Eur	Manufacturing & Packing
4.	Citalopram Hydrobromide Ph.Eur	Manufacturing & Packing
5.	Citalopram Hydrochloride Ph.Eur	Manufacturing & Packing
6.	Emtricitabine IH	Manufacturing & Packing
7.	Escitalopram Oxalate USP/IH	Manufacturing & Packing
8.	Itraconazole Ph.Eur	Manufacturing & Packing
9.	Mitrazapine Ph.Eur	Manufacturing & Packing
10.	Tadalafil Ph.Eur	Manufacturing & Packing
11.	Telmisartan Ph.Eur	Manufacturing & Packing

ITEM(S) ELEVEN (11) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

25 OCT 2023

Stamp of the authority and date

7-5/2013/EU/WC-0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 25 SEP 2023

To,

M/s.Aurore Pharmaceuticals Private Limited
Plot No. 35,36,38,39,40,49,50 51,
Phase-IV, IDA, Jeedimetla,
Medchal–Malkajgiri-500055,Telangana State, India

SUB:- Written Confirmation to M/s.Aurore Pharmaceuticals Private Limited, Plot No. 35,36,38,39,40,49,50 51, Phase-IV, IDA, Jeedimetla, Medchal–Malkajgiri-500055,Telangana 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 online application no. WC/RE/2023/7066 dated 11-MAY-2023 submitted to CDSCO, DDC(I), Hyderabad Zone, Telangana State, 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5	11	15.09.2023	02.07.2025
6	03	25 SEP 2023	02.07.2025

Yours faithfully,

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

Annexure-06

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

CERTIFICATE NO. : WC-0119

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.Aurore Pharmaceuticals Private Limited**
Plot No. 35,36,38,39,40,49,50 51,
Phase-IV, IDA, Jeedimetla,
Medchal–Malkajgiri-500055,Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Sulindac IHS*	Manufacturing & Packing
2.	Losartan Potassium USP	Manufacturing & Packing
3.	Clozapine Ph.Eur	Manufacturing & Packing

***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 in the serial no. 1 for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India**

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 02.07.2025

Rajeev Singh
Signature

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India
Stamp of the authority and date

25 SEP 2023

7-5/2013/EU/WC/0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

03 NOV 2023

To

M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

Subject:- Written Confirmation of M/s. Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, , Jeedimetla, Medchal- Malkajgiri District, Telangana 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 online application No. WC/FR/2023/6430 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5-A	11	25.10.2023	02.07.2025
6	03	25.09.2023	02.07.2025
7	04	03 NOV 2023	02.07.2025

Yours faithfully,

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

Annexure-7

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

CERTIFICATE NO. : **WC-0119**

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

Name and address of site: **M/s. Aurore Pharmaceutical Private Limited,**
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aripiprazole Ph.Eur/USP	Manufacturing & Packing.
2.	Eszopiclone IH	Manufacturing & Packing
3.	Esomeprazole Magnesium Trihydrate Ph.Eur	Manufacturing & Packing
4.	Esomeprazole Magnesium USP	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 02.07.2025

Rajeev Singh
Signature

Stamp of the authority and date

03 NOV 2023

7-5/2013/EU/WC/0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

15 JAN 2024

To

M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri -500055,
Telangana State, India

Subject:- Written Confirmation of M/s. Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, , Jeedimetla, Medchal- Malkajgiri District, Telangana 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 online application No. WC/RE/2023/7260 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5-A	11	25.10.2023	02.07.2025
6	03	25.09.2023	02.07.2025
7	04	03.11.2023	02.07.2025
8	01	15 JAN 2024	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

CERTIFICATE NO. :

Annexure-8

WC-0119

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

Name and address of site: **M/s. Aurore Pharmaceutical Private Limited,**
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri-500055,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Favipiravir IH	Manufacturing & Packing.

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

15 JAN 2024

7-5/2013/EU/WC/0119
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
23 JAN 2024

To

M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

Subject:- Written Confirmation of M/s. Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, , Jeedimetla, Medchal- Malkajgiri District, Telangana 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 online application No. WC/FR/2023/7259 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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5-A	11	25.10.2023	02.07.2025
6	03	25.09.2023	02.07.2025
7	04	03.11.2023	02.07.2025
8	01	15.01.2024	02.07.2025
9	01	23 JAN 2024	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-9

CERTIFICATE NO. : WC-0119

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

Name and address of site: M/s. Aurore Pharmaceutical Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal- Malkajgiri District,
Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bilastine IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

23 JAN 2024

7-5/2013/EU/WC-0119

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 10 JUN 2024

To

M/s Aurore Pharmaceuticals Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal-Malkajgiri District,
Telangana State, India

SUB:- Written Confirmation M/s Aurore Pharmaceutical Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal-Malkajgiri District, Telangana State, India, 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/FR/2024/8031 dated 31-JAN-2024 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.

9. The manufacturer is required to comply with the provisions of GSR 20(E) dated 18.01.2022

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	22	19.09.2022	02.07.2025
2	02	19.09.2022	02.07.2025
3	03	02.11.2022	02.07.2025
4	02	02.11.2022	02.07.2025
5-A	11	25.10.2023	02.07.2025
6	03	25.09.2023	02.07.2025
7	04	03.11.2023	02.07.2025
8	01	15.01.2024	02.07.2025
9	01	23.01.2024	02.07.2025
10	05	10 JUN 2024	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-10

CERTIFICATE NO. :

WC-0119

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 Aurore Pharmaceuticals Private Limited,**
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51,
Phase-IV, IDA, Jeedimetla,
Medchal-Malkajgiri District, Telangana State, India

List of API(s):

S.No.	Active Substance(s)	Activity(ies)
1	Calcium Gluconate USP/Ph.Eur	Manufacturing & Packing
2	Trabectedin IH	Manufacturing & Packing
3	Eltrombopag Olamine IH	Manufacturing & Packing
4	Marbofloxacin BP/IP/Ph.Eur	Manufacturing & Packing
5	Flecainide Acetate USP/Ph.Eur	Manufacturing & Packing

Items (05) Five Only

Written Confirmation Valid till- 02.07.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization

10 JUN 2024

7-5/2013/EU/WC-0119

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 20 FEB 2025

To,

M/s. Aurore Pharmaceuticals Private Limited,
Plot No. 35,36,38, 39, 40, 49, 50 & 51, Phase-IV, IDA,
Jeedimetla, Medchal - Malkajgiri District, Telangana State, India

SUB: - Written Confirmation of **M/s. Aurore Pharmaceuticals Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal - Malkajgiri District, Telangana 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 online application no. WC/FR/2024/8329 dated 07-May-2024 submitted to CDSCO, DDC(I), 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.
9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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	22	19.09.2022	**02.07.2025**
2	02	19.09.2022	**02.07.2025**
3	03	02.11.2022	**02.07.2025**
4	02	02.11.2022	**02.07.2025**
5-A	11	25.10.2023	**02.07.2025**
6	03	25.09.2023	**02.07.2025**
7	04	03.11.2023	**02.07.2025**
8	01	15.01.2024	**02.07.2025**
9	01	23.01.2024	**02.07.2025**
10	05	10.06.2024	**02.07.2025**
11	05	20 FEB 2025	**02.07.2025**
12	01	20 FEB 2025	**02.07.2025**

Yours faithfully,

Chandrashekar
20/02/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)

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

CERTIFICATE NO. : **WC-0119**

Annexure-11

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. Aurore Pharmaceuticals Private Limited, Plot No. 35,36,38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal - Malkajgiri District, Telangana State, India**

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Indomethacin IP/USP/IH	Manufacturing & Packing
2.	Indometacin Ph.Eur	Manufacturing & Packing
3.	Olanzapine IP/USP/IH/Ph.Eur	Manufacturing & Packing
4.	Risperidone USP/BP/Ph.Eur/IP	Manufacturing & Packing
5.	Dabigatran Etexilate Mesilate IH	Manufacturing & Packing

ITEM(S) FIVE (05) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

चन्द्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

20 FEB 2025

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

Annexure-12

CERTIFICATE NO. : **WC-0119**

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. Aurore Pharmaceuticals Private Limited, Plot No. 35,36,38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal - Malkajgiri District, Telangana State, India**

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Nafamostat Mesilate IH/JP	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

Chandrashekar

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

20 FEB 2025

7-5/2013/EU/WC-0119

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 24 APR 2025

To

M/s. Aurore Pharmaceuticals Private Limited,
Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV,
IDA, Jeedimetla, Medchal – Malkajgiri District,
Telangana State, India

SUB: - Written Confirmation of **M/s. Aurore Pharmaceuticals Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal – Malkajgiri District, Telangana 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 online application no. WC/FR/2024/9443 submitted to DDC (I), CDSCO Hyderabad Zone office, and the recommendation received from DDC (I), CDSCO 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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/New drug category in India.

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
--	--	19.09.2022	**02.07.2025**
01	22	19.09.2022	**02.07.2025**
02	02	19.09.2022	**02.07.2025**
03	03	02.11.2022	**02.07.2025**
04	02	02.11.2022	**02.07.2025**
05-A	11	25.10.2023	**02.07.2025**
06	03	25.09.2023	**02.07.2025**
07	04	03.11.2023	**02.07.2025**
08	01	15.01.2024	**02.07.2025**
09	01	23.01.2024	**02.07.2025**
10	05	10.06.2024	**02.07.2025**
11	05	20.02.2025	**02.07.2025**
12	01	20.02.2025	**02.07.2025**
13	01	24 APR 2025	**02.07.2025**

Yours faithfully,

Chandrashekar
24/04/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

Annexure-13
WC-0119

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. Aurore Pharmaceuticals Private Limited, Plot No. 35, 36, 38, 39, 40, 49, 50 & 51, Phase-IV, IDA, Jeedimetla, Medchal – Malkajgiri District, Telangana State, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Valganciclovir Hydrochloride Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

24 APR 2025