7-5/2013/EU/WC-0041
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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

16 SEP 2022

SUB: - Written Confirmation of M/s Hetero Labs Limited, Unit –I, Sy. No. 10, I.D.A, Gaddapotharam (V) Jinnaram (M), Sangareddy 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/2022/3613 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 | 86 | 16 SEP 2019 | 08.08.2025 |
| 2 | 08 | 16 SEP 2022 | 08.08.2025 |

**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. :** **Amended** **WC-0041**

**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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

**2. Manufacturer's licence number**: 25/MD/AP/97/B/R

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

List of API(s):

**As per Annexure 1 & Annexure 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**: 23.06.2021 to 25.06.2021

**The Written Confirmation remains valid until**: 08.08.2025

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

*Signature*

16 SEP 2022

*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

**CERTIFICATE NO. :**

**Amended**
**Annexure-1**
**WC-0041**

**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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Abacavir IH | Manufacturing & Packing |
| 2. | Abacavir Sulfate Ph.Eur | Manufacturing & Packing |
| 3. | Abacavir Sulphate IH/USP | Manufacturing & Packing |
| 4. | Abiraterone Acetate IH/USP | Manufacturing & Packing |
| 5. | Anastrozole IH/USP/Ph.Eur | Manufacturing & Packing |
| 6. | Aripiprazole USP/Ph. Eur/IH | Manufacturing & Packing |
| 7. | Atazanavir Sulphate IH | Manufacturing & Packing |
| 8. | Atomoxetine Hydrochloride USP/Ph. Eur/IH | Manufacturing & Packing |
| 9. | Afatinib Dimaleate IH | Manufacturing & Packing |
| 10. | Axitinib IH | Manufacturing & Packing |
| 11. | Busulfan USP/EP | Manufacturing & Packing |
| 12. | Bendamustine Hydrochloride IH | Manufacturing & Packing |
| 13. | Bicalutamide IH/ USP/Ph Eur | Manufacturing & Packing |
| 14. | Bortezomib IH | Manufacturing & Packing |
| 15. | Cabazitaxel IH | Manufacturing & Packing |
| 16. | Candesartan Cilexetil BP/Ph.Eur/USP/IH | Manufacturing & Packing |
| 17. | Capecitabine Ph. Eur/USP/IH | Manufacturing & Packing |
| 18. | Carboplatin BP/USP/Ph.Eur | Manufacturing & Packing |
| 19. | Cisplatin BP/USP/Ph.Eur | Manufacturing & Packing |
| 20. | Crizotinib IH | Manufacturing & Packing |
| 21. | Darunavir Amorphous IH | Manufacturing & Packing |
| 22. | Darunavir Ethanolate IH | Manufacturing & Packing |
| 23. | Dasatinib IH | Manufacturing & Packing |
| 24. | Desloratadine IH/Ph Eur | Manufacturing & Packing |
| 25. | Dutasteride IH/USP/Ph.Eur | Manufacturing & Packing |
| 26. | Efavirenz USP/IH | Manufacturing & Packing |
| 27. | Emtricitabine IH/USP | Manufacturing & Packing |
| 28. | Entecapone BP/IH/USP/Ph.Eur | Manufacturing & Packing |
| 29. | Erlotinib Hydrochloride IH | Manufacturing & Packing |
| 30. | Escitalopram Oxalate IH/USP/Ph.Eur | Manufacturing & Packing |

16 SEP 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. :**

**Amended**
**Annexure-1**
**WC-0041**

**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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 31. | Etoricoxib IH | Manufacturing & Packing |
| 32. | Ezetimibe IH/USP | Manufacturing & Packing |
| 33. | Finasteride IH/USP/Ph.Eur | Manufacturing & Packing |
| 34. | Gefitinib IH/BP/ Ph.Eur | Manufacturing & Packing |
| 35. | Gemcitabine Hydrochloride USP/Ph.Eur | Manufacturing & Packing |
| 36. | Hydralazine Hydrochloride BP/USP/Ph.Eur | Manufacturing & Packing |
| 37. | Imatinib Mesilate Ph.Eur | Manufacturing & Packing |
| 38. | Imatinib Mesylate IH | Manufacturing & Packing |
| 39. | Irbesartan BP/USP/Ph.Eur | Manufacturing & Packing |
| 40. | Irinotecan Hydrochlroide USP | Manufacturing & Packing |
| 41. | Lamivudine BP/USP/Ph.Eur | Manufacturing & Packing |
| 42. | Lapatinib Ditosylate Monohydrate IH | Manufacturing & Packing |
| 43. | Letrozole USP/Ph.Eur | Manufacturing & Packing |
| 44. | Levetiracetam IH/BP/USP/Ph.Eur | Manufacturing & Packing |
| 45. | Lopinavir USP/IH/Ph.Eur | Manufacturing & Packing |
| 46. | Lenalidomide IH | Manufacturing & Packing |
| 47. | Maraviroc IH | Manufacturing & Packing |
| 48. | Melphalan Hydrochloride IH | Manufacturing & Packing |
| 49. | Milnacipran Hydrochloride IH | Manufacturing & Packing |
| 50. | Nevirapine Anhydrous BP/USP/Ph. Eur | Manufacturing & Packing |
| 51. | Nilotinib Hydrochloride IH | Manufacturing & Packing |
| 52. | Oxaliplatin USP/Ph.Eur | Manufacturing & Packing |
| 53. | Olmesartan Medoxomil USP/Ph.Eur/IH | Manufacturing & Packing |
| 54. | Oseltamivir Phosphate USP/Ph.Eur/BP | Manufacturing & Packing |
| 55. | Paclitaxel USP/Ph.Eur | Manufacturing & Packing |
| 56. | Pazopanib Hydrochloride IH | Manufacturing & Packing |
| 57. | Eplerenone IH/Ph.Eur | Manufacturing & Packing |
| 58. | Cyclophosphamide Monohydrate USP/Ph.Eur | Manufacturing & Packing |
| 59. | Daclatasvir Dihydrochloride IH | Manufacturing & Packing |
| 60. | Dolutegravir sodium IH | Manufacturing & Packing |

16 SEP 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. :**

**Amended**
**Annexure-1**
**WC-0041**

**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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 61. | Irinotecan Hydrochloride Trihydrate Ph.Eur | Manufacturing & Packing |
| 62. | Pemetrexed Disodium IH | Manufacturing & Packing |
| 63. | Pioglitazone Hydrochloride IH/USP/Ph.Eur | Manufacturing & Packing |
| 64. | Quetiapine Fumarate USP/Ph.Eur/IH | Manufacturing & Packing |
| 65. | Ramipril BP/USP/Ph.Eur | Manufacturing & Packing |
| 66. | Saquinavir Mesylate USP | Manufacturing & Packing |
| 67. | Saquinavir Mesilate BP/Ph.Eur | Manufacturing & Packing |
| 68. | Simvastatin Ph.Eur/USP | Manufacturing & Packing |
| 69. | Sorafenib Tosylate IH | Manufacturing & Packing |
| 70. | Sunitinib Malate IH | Manufacturing & Packing |
| 71. | Telmisartan BP/USP/Ph.Eur | Manufacturing & Packing |
| 72. | Temozolomide USP | Manufacturing & Packing |
| 73. | Tenofovir Disoproxil IH | Manufacturing & Packing |
| 74. | Tenofovir Disoproxil Fumarate IH | Manufacturing & Packing |
| 75. | Terbinafine Hydrochloride BP/USP/Ph.Eur | Manufacturing & Packing |
| 76. | Thalidomide USP | Manufacturing & Packing |
| 77. | Torsemide Anhydrous Ph.Eur | Manufacturing & Packing |
| 78. | Torsemide USP | Manufacturing & Packing |
| 79. | Valsartan BP/USP/Ph.Eur | Manufacturing & Packing |
| 80. | Velpatasvir IH | Manufacturing & Packing |
| 81. | Voriconazole IH/USP/BP/Ph.Eur | Manufacturing & Packing |
| 82. | Zidovudine USP/Ph.Eur/BP | Manufacturing & Packing |
| 83. | Zoledronic Acid Monohydrate IH | Manufacturing & Packing |
| 84. | Zonisamide IH/USP | Manufacturing & Packing |
| 85. | Tenofovir Alafenamide Hemifumarate IH | Manufacturing & Packing |
| 86. | Losartan Potassium Ph.Eur/USP | Manufacturing & Packing |

**ITEM(S) EIGHTY-SIX (86) ONLY**

**The Written Confirmation remains valid until: 08.08.2025**

*Signature* VL

16 SEP 2022

*Stamp of the authority and date*

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

**CERTIFICATE NO. :**

**Amended**
**Annexure-2**
**WC-0041**

**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 Hetero Labs Limited, Unit –I**
**Sy. No. 10, I.D.A, Gaddapotharam (V)**
**Jinnaram (M), Sangareddy District**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Bexarotene IH | Manufacturing & Packing |
| 2. | Cilazapril Ph.Eur | Manufacturing & Packing |
| 3. | Etravirine IH | Manufacturing & Packing |
| 4. | Enzalutamide IH | Manufacturing & Packing |
| 5. | Plerixafor IH | Manufacturing & Packing |
| 6. | Pomalidomide IH | Manufacturing & Packing |
| 7. | Pralatrexate IH | Manufacturing & Packing |
| 8. | Regorafenib IH | Manufacturing & Packing |

**ITEM(S) EIGHT (08) 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: 08.08.2025**

*Signature*

*Stamp of the authority and date*

16 SEP 2022

**7-5/2013/EU/WC-0041**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**(International Cell)**

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

25 NOV 2022

To

**M/s Hetero Labs Limited,**
**Unit –I,SY. No. 10, I.D.A., Gaddapotharam (V),**
**Jinnaram (M), Sangareddy District,**
**Telangana State, India**

**Subject:- Written Confirmation of M/s Hetero Labs Limited, Unit –I, SY. No. 10, I.D.A., Gaddapotharam (V), Jinnaram (M), Sangareddy 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/ED/2022/4559 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. | 86 | 16/09/2022 | 08/08/2022 |
| 2. | 08 | 16/09/2022 | 08/08/2022 |
| 3. | 06 | 25 NOV 2022 | 08/08/2022 |
| 4. | 01 | 25 NOV 2022 | 08/08/2022 |

**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-0041**

**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 Hetero Labs Limited, Unit –I,**
**SY. No. 10, I.D.A., Gaddapotharam (V), Jinnaram (M),**
**Sangareddy District, Telangana State India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Azacitidine IH | Manufacturing & Packing |
| 2. | Docetaxel USP | Manufacturing & Packing |
| 3. | Docetaxel Trihydrate IP/EP/BP | Manufacturing & Packing |
| 4. | Ibrutinib IH | Manufacturing & Packing |
| 5. | Nintedanib Esylate IH | Manufacturing & Packing |
| 6. | Palbociclib IH | Manufacturing & Packing |
| 7. | Trifluridine IH/USP | Manufacturing & Packing |

**ITEM(S) Six (06) ONLY**

**The Written Confirmation remains valid until: 08/08/2025**

*Signature*

*Stamp of the authority and date*

25 NOV 2022

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

**CERTIFICATE NO. :**

**Annexure-4**
**WC-0041**

**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 Hetero Labs Limited, Unit –I, SY. No. 10, I.D.A., Gaddapotharam (V), Jinnaram (M), Sangareddy District, Telangana State India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Nintedanib Esylate 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: 08/08/2025**

*Signature*

Stamp of the authority and date

25 NOV 2022

**7-5/2020/EU/WC-0041**
**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.Hetero Labs Limited,**
**Unit-I, Sy.No.10, I.D.A. Gaddapotharam (V),**
**Jinnaram (M), Sangareddy District, Telangana, India.**

15 MAY 2023

**Subject :-** Written Confirmation M/s. Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A. Gaddapotharam (V), Jinnaram (M), Sangareddy District, 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/2023/6120 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 | 86 | 16.09.2022 | 08.08.2025 |
| 02 | 08 | 16.09.2022 | 08.08.2025 |
| 03 | 07 | 25.11.2022 | 08.08.2025 |
| 04 | 01 | 25.11.2022 | 08.08.2025 |
| 05 | 02 | 15 MAY 2023 | 08.08.2025 |

**Yours faithfully,**

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

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

**Annexure-05**

**CERTIFICATE NO. :**

**WC-0041**

**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.Hetero Labs Limited,
Unit-I, Sy.No.10, I.D.A. Gaddapotharam (V),
Jinnaram (M), Sangareddy District, Telangana,
India.**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Levomilnacipran Hydrochloride IH | Manufacturing & Packing |
| 2. | Vortioxetine Hydrobromide 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:** **08/08/2025**

*Signature*

*Stamp of the authority and date*

15 MAY 2023