7-5/2013/EU/WC-0471

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, Innovare Labs Private Limited,
Plot no. 23A & 23B, Atchutapuram,
Lalam Koduru (Village), Rambilli (Mandal),
Visakhapatnam – 531 011, Andhra Pradesh, India

SUB:- Written Confirmation M/s, Innovare Labs Private Limited, Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village), Rambilli (Mandal), Visakhapatnam – 531 011, Andhra Pradesh, India, as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/RE/2023/7171 dated 02-JUN-2023 and WC/RE/2023/7179 dated 02-JUN-2023 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	05	25 OCT 2023	01.07.2026

Yours faithfully,

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

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

Annexure 1
WC-0471

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, Innovare Labs Private Limited,**
Plot no. 23A & 23B, Atchutapuram,
Lalam Koduru (Village), Rambilli (Mandal),
Visakhapatnam – 531 011, Andhra Pradesh, India

2. Manufacturer's licence number:14/VSP/AP/2018/B/G

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

S.No.	Active Substance(s)	Activity(ies)
1.	Metaxalone USP	Manufacturing & Packing
2.	Cinacalcet Hydrochloride IP	Manufacturing & Packing
3.	Ticagrelor Ph.Eur	Manufacturing & Packing
4.	Moxifloxacin Hydrochloride IP/USP/Ph.Eur	Manufacturing & Packing
5.	Vildagliptin IH	Manufacturing & Packing

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: **08.08.2023 & 09.08.2023**

The Written Confirmation remains valid until: **01.07.2026**

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Rajeev Singh 25 OCT 2023

Signature

Stamp of the authority and date

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

7-5/2020/EU/WC-0471
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 20 NOV 2023

To,

M/s. Innovare Labs Private Limited,
Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village),
Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India,

SUB:- Written Confirmation of M/s.Innovare Labs Private Limited, Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village), Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India, as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/RE/2023/7175 & WC/RE/2023/7176 & WC/RE/2023/7177 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.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	05	25.10.2023	01.07.2026
02	04	20 NOV 2023	01.07.2026

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-02**

WC-0471

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. Innovare Labs Private Limited**
Plot no. 23A & 23B, Atchutapuram,
Lalam Koduru (Village), Rambilli (Mandal),
Visakhapatnam – 531011, Andhra Pradesh, India,

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clopidogrel Bisulfate UPS	Manufacturing & Packing
2.	Clopidogrel Hydrogen Sulfate Ph.Eur	Manufacturing & Packing
3.	Levetiracetam USP/Ph.Eur	Manufacturing & Packing
4.	Oseltamivir Phosphate USP/Ph.Eur	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 01.07.2026

Signature

Stamp of the authority and date

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

20 NOV 2023

7-5/2020/EU/WC-0471
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To,

M/s. Innovare Labs Private Limited,
Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village),
Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India,

SUB:- Written Confirmation of M/s.Innovare Labs Private Limited, Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village), Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India, as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/RE/2023/7169 & WC/RE/2023/7173 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.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	05	25.10.2023	01.07.2026
02	04	20.11.2023	01.07.2026
03	04	18 DEC 2023	01.07.2026

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-0471

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. Innovare Labs Private Limited**
Plot no. 23A & 23B, Atchutapuram,
Lalam Koduru (Village), Rambilli (Mandal),
Visakhapatnam – 531011, Andhra Pradesh, India,

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Rosuvastatin Calcium IP/USP/ Ph.Eur	Manufacturing & Packing
2.	Rivaroxaban Ph.Eur	Manufacturing & Packing
3.	Pregabalin IP/USP/Ph.Eur	Manufacturing & Packing
4.	Voriconazole IP/USP/Ph.Eur	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 01.07.2026

Signature

Stamp of the authority and date

18 DEC 2023

7-5/2020/EU/WC-0471
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. Innovare Labs Private Limited,
Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village),
Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India,

SUB:- Written Confirmation of M/s.Innovare Labs Private Limited, Plot no. 23A & 23B, Atchutapuram, Lalam Koduru (Village), Rambilli (Mandal), Visakhapatnam – 531011, Andhra Pradesh, India, as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/FR/2023/6262 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.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	05	25.10.2023	01.07.2026
02	04	20.11.2023	01.07.2026
03	04	18.12.2023	01.07.2026
04	01	15 JAN 2024	01.07.2026

Yours faithfully,

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

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

Annexure-04

CERTIFICATE NO. :

WC-0471

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. Innovare Labs Private Limited**
Plot no. 23A & 23B, Atchutapuram,
Lalam Koduru (Village), Rambilli (Mandal),
Visakhapatnam – 531011, Andhra Pradesh, India,

List of APIs:

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

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 01.07.2026

Signature

15 JAN 2024

Stamp of the authority and date