7-5/2016/EU/WC-0392
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

22 MAY 2023

To

M/s. Emmennar Pharma Private Limited
(Unit – II), Plot No. 15, Jawaharlal Nehru Pharma City (P)
Tadi (V), Parawada (M), Visakhapatnam Dist – 531 019
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Emmennar Pharma Private Limited, Unit – II, Plot No. 15, Jawaharlal Nehru Pharma City (P), Tadi (V), Parawada (M), Visakhapatnam Dist – 531 019, 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/2023/6046 dated 09.01.2023 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	08	22 MAY 2023	01.02.2026

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. : **WC-0392**

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. Emmennar Pharma Private Limited**
(Unit – II), Plot No. 15, Jawaharlal Nehru Pharma City (P)
Tadi (V), Parawada (M), Visakhapatnam Dist – 531 019
Andhra Pradesh, India

2. Manufacturer's licence number: 48/VP/AP/2011/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

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: 22/02/2023 & 23/02/2023

The Written Confirmation remains valid until: **01/02/2026**

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

Signature

Stamp of the authority and date

22 MAY 2023

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

Annexure-01

CERTIFICATE NO. : WC-0392

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. Emmennar Pharma Private Limited (Unit – II), Plot No. 15, Jawaharlal Nehru Pharma City (P) Tadi (V), Parawada (M), Visakhapatnam Dist – 531 019 Andhra Pradesh, India

List of APIs:

S.No	Active Substance(s)	Activity(ies)
1	Tramadol Hydrochloride IP/BP/Ph.Eur/USP	Manufacturing & Packing
2	Sodium Bicarbonate USP/Ph.Eur	Manufacturing & Packing
3	Zinc Pyrithione IH	Manufacturing & Packing
4	Levetiracetam BP/USP/Ph.Eur	Manufacturing & Packing
5	Acotiamide Hydrochloride Hydrate-IH	Manufacturing & Packing
7	Empagliflozin IH	Manufacturing & Packing
8	Gabapentin IP/BP/Ph.Eur/USP	Manufacturing & Packing
9	Lacosamide Ph.Eur/USP	Manufacturing & Packing

ITEM(S) EIGHT (08) ONLY

The Written Confirmation remains valid until: 01.02.2026

Rajan Singh

Signature

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

Stamp of the authority and date

22 MAY 2023

7-5/2016/EU/WC-0392
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. Emmennar Pharma Private Limited,
(Unit-II), Plot No. 15, Jawaharlal Nehru Pharma City (P)
Tadi (V), Parawada (M), Visakhapatnam Dist -531019,
Andhra Pradesh, India,

SUB:- Written Confirmation of M/s. Emmennar Pharma Private Limited, (Unit-II), Plot No. 15, Jawaharlal Nehru Pharma City (P) Tadi (V), Parawada (M), Visakhapatnam Dist -531019, 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/ED/2023/7224 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	08	22.05.2023	01.02.2026
02	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-02

CERTIFICATE NO. :

WC-0392

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. Emmennar Pharma Private Limited,
(Unit-II), Plot No.15, Jawaharlal Nehru Pharma City (P)
Tadi (V), Parawada (M), Visakhapatnam Dist -531019,
Andhra Pradesh, India,

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Dapagliflozin Propanediol Monohydrate IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 01.02.2026

Rajeev Singh

Signature

15 JAN 2024

Central Drugs Standard Control Organization
Govt. of India

Stamp of the authority and date