7-5/2024/EU/WC-0589

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
02 AUG 2024

To,

M/s.Sionc Pharmaceuticals Pvt. Ltd.,
Unit-II, Plot No. 25 & 25A, J N Pharma City,
Parawada (M), Anakapalli -District -531021,
Andhra Pradesh, India

SUB:-Written Confirmation of **M/s.Sionc Pharmaceuticals Pvt. Ltd., Unit-II, Plot No. 25 & 25A, J N Pharma City, Parawada (M), Anakapalli -District -531021, 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/2023/7490 dated 01.09.2023 submitted to CDSCO, Hyderabad Zone, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 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
--	--	02 AUG 2024	Three Year from the Date of Issue
01	10	02 AUG 2024	Three Year from the Date of Issue
02	04	02 AUG 2024	Three Year from the Date of Issue

Yours faithfully,

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

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

WC-0589

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.Sionc Pharmaceuticals Pvt. Ltd.,**
Unit-II, Plot No. 25 & 25A, J N Pharma City,
Parawada (M), Anakapalli -District -531021,
Andhra Pradesh, India

2. Manufacturer's licence number: **13/VSP/AP/2018/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 list enclosed as 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: 28.11.2023 & 29.11.2023

The Written Confirmation remains valid until: **Three year from the date of issue**

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

02 AUG 2024

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

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

CERTIFICATE NO. :

Annexure-01
WC-0589

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.Sionc Pharmaceuticals Pvt. Ltd., Unit-II, Plot No. 25 & 25A, J N Pharma City, Parawada (M), Anakapalli -District -531021, Andhra Pradesh, India**

List of API(s):

S. No.	Active substance(s)	Activity(ies)
01	Duloxetine Hydrochloride USP	Manufacturing & Packing
02	Eltrombopag Olamine IH	Manufacturing & Packing
03	Gadobutro Monohydrate IH/USP	Manufacturing & Packing
04	Gadoterate Meglumine IH	Manufacturing & Packing
05	Iron Sucrose USP	Manufacturing & Packing
06	Metoprolol Succinate USP	Manufacturing & Packing
07	Ranolazine IH	Manufacturing & Packing
08	Tretinoin IH/USP	Manufacturing & Packing
09	Valsartan IH/USP	Manufacturing & Packing
10	Voriconazole IH/USP	Manufacturing & Packing

ITEM(S) TEN (10) ONLY

The Written Confirmation remains valid until: Three years from the date of Issue

Signature

Stamp of the authority and date

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

02 AUG 2024

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

Annexure-02
WC-0589

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.Sionc Pharmaceuticals Pvt. Ltd.,**
Unit-II, Plot No. 25 & 25A, J N Pharma City,
Parawada (M), Anakapalli -District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Levocarnitine IH	Manufacturing & Packing
02	L-Glutamine IH	Manufacturing & Packing
03	Sodium Phosphate Dibasic Hepta Hydrate IH/USP	Manufacturing & Packing
04	Sodium Phosphate Monobasic IH/USP	Manufacturing & Packing

ITEM(S) FOUR (04) 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: Three years from the date of Issue

Signature

02 AUG 2024

Stamp of the authority and date