7-5/2014/EU/WC-0273
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated
23 JUL 2020

To

M/s. Sionc Pharmaceuticals Pvt Ltd,
Plot No. 34A, Road No. 1 Jawaharlal Nehru Pharma City,
Thanam (V), Parawada Mandal, Visakhapatnam District,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Sionc Pharmaceuticals Pvt Ltd, Plot No. 34A, Road No. 1 Jawaharlal Nehru Pharma City, Thanam (V), Parawada Mandal, Visakhapatnam District 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 application submitted to CDSCO, Zonal Office , Hyderabad and the recommendation received from DDC(I), Hyderabad Zonal office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	23 JUL 2020	11.05.2023
2	18	23 JUL 2020	11.05.2023

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

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

WC-0273

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,
Plot No. 34A, Road No. 1 Jawaharlal Nehru Pharma City,
Thanam (V), Parawada Mandal, Visakhapatnam District
Andhra Pradesh, India

2. Manufacturer's licence number: 52/VP/AP/2010/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 in 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: 29th & 30th November, 2018

The Written Confirmation remains valid until: **11th May, 2023**

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

16/07/20

13.7.2020

Stamp of the authority and date

23 JUL 2020

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

Annexure-1

CERTIFICATE NO. : WC-0273

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,
Plot No. 34A, Road No. 1 Jawaharlal Nehru Pharma City,
Thanam (V), Parawada Mandal, Visakhapatnam District
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Acitretin USP	Manufacturing & Packing
2.	Agomelatine IH	Manufacturing & Packing
3.	Aminocaproic Acid IH	Manufacturing & Packing
4.	Bendamustine Hydrochloride IH	Manufacturing & Packing
5.	Bortezomib IH	Manufacturing & Packing
6.	Chlorambucil IH/Ph.Eur	Manufacturing & Packing
7.	Chlorzoxazone IH	Manufacturing & Packing
8.	Decitabine IH	Manufacturing & Packing
9.	Dimethyl Fumarate IH	Manufacturing & Packing
10.	D-Pencillamine IH/USP	Manufacturing & Packing
11.	Ethacrynic Acid IH	Manufacturing & Packing
12.	Fluphenazine Hydrochloride IH	Manufacturing & Packing
13.	Gadobutrol Monohydrate IH	Manufacturing & Packing
14.	Melphalan Ph.Eur	Manufacturing & Packing
15.	Nilutamide Ph.Eur	Manufacturing & Packing
16.	Nimodipine IH	Manufacturing & Packing
17.	Plerixafor IH	Manufacturing & Packing
18.	Temozolomide IH	Manufacturing & Packing
19.	Thiamine Hydrochloride USP	Manufacturing & Packing
20.	Tretinoin USP	Manufacturing & Packing
21.	Trifluridine IH	Manufacturing & Packing
22.	Zileuton USP	Manufacturing & Packing

ITEM(S) Twenty Two (22) Only

The Written Confirmation remains valid until: 11.05.2023

Signature

10/07/20

13.7.2020

Stamp of the authority and date

23 JUL 2020

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

Annexure-2

CERTIFICATE NO. : WC-0273

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,
Plot No. 34A, Road No. 1 Jawaharlal Nehru Pharma City,
Thanam (V), Parawada Mandal, Visakhapatnam District
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alosetron Hydrochloride IH	Manufacturing & Packing
2.	Belinostat IH	Manufacturing & Packing
3.	Brexpiprazole IH	Manufacturing & Packing
4.	Carfilzomib IH	Manufacturing & Packing
5.	Cariprazine Hydrochloride IH	Manufacturing & Packing
6.	Clofarabine IH	Manufacturing & Packing
7.	Dofetilide IH	Manufacturing & Packing
8.	Ethacrynate Sodium IH	Manufacturing & Packing
9.	Ferric Citrate IH	Manufacturing & Packing
10.	Frovatriptan Succinate IH	Manufacturing & Packing
11.	Melphalan Hydrochloride IH	Manufacturing & Packing
12.	Nitisinone IH	Manufacturing & Packing
13.	Palbociclib IH	Manufacturing & Packing
14.	Phytonadione USP	Manufacturing & Packing
15.	Regadenoson IH	Manufacturing & Packing
16.	Sucroferric Oxyhyroxide IH	Manufacturing & Packing
17.	Vigabatrin Ph.Eur/USP	Manufacturing & Packing
18.	Zofenopril Calcium IH	Manufacturing & Packing

ITEM(S) Eighteen (18) 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: 11th May, 2023

Signature

10/6/20

13.7.20

Stamp of the authority and date

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

23 JUL 2020