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

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

To

M/s Sionc Pharmaceuticals Pvt. Ltd
Plot No. 34A, Road No: 1, J.N. Pharma City,
Thanam Village, Parawada (M),
Visakhapatnam District- 531 021, Andhra Pradesh

Subject: - Written Confirmation of M/s Sionc Pharmaceuticals Pvt. Ltd., Plot No. 34A, Road No: 1, J.N. Pharma City, Thanam Village, Parawada (M), Visakhapatnam District- 531 021, 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/2023/6919 & WC/FR/2023/7050 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 Up to
1	24	15 NOV 2023	11.05.2026
2	22	15 NOV 2023	11.05.2026

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-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, J.N. Pharma City,
Thanam Village, Parawada (M),
Visakhapatnam District- 531 021, Andhra Pradesh

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 APIs: - As per list attached 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: 30.12.2021 & 31.12.2021

The Written Confirmation remains valid until: **11.05.2026**

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

15 NOV 2023

Signature

Stamp of the authority and date

Annexure-1

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

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, J.N. Pharma City,
Thanam Village, Parawada (M),
Visakhapatnam District- 531 021, Andhra Pradesh

List of API(s):

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

ITEM(S) Twenty Four (24) Only

The Written Confirmation remains valid until: 11.05.2026

15 NOV 2023

Signature

Stamp of the authority and date

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.	Agomelatine IH	Manufacturing & Packing
2.	Alosetron Hydrochloride IH	Manufacturing & Packing
3.	Belinostat IH	Manufacturing & Packing
4.	Brexpiprazole IH	Manufacturing & Packing
5.	Carfilzomib IH	Manufacturing & Packing
6.	Cariprazine Hydrochloride IH	Manufacturing & Packing
7.	Cladribine HPBCD Complex IH	Manufacturing & Packing
8.	Clofarabine IH	Manufacturing & Packing
9.	Dofetilide IH	Manufacturing & Packing
10.	Ethacrynate Sodium IH	Manufacturing & Packing
11.	Ferric Citrate IH	Manufacturing & Packing
12.	Fluphenazine Hydrochloride IH	Manufacturing & Packing
13.	Frovatriptan Succinate IH	Manufacturing & Packing
14.	Melphalan Hydrochloride IH	Manufacturing & Packing
15.	Nelarabine IH	Manufacturing & Packing
16.	Nitisinone IH	Manufacturing & Packing
17.	Palbociclib IH	Manufacturing & Packing
18.	Phytonadione USP	Manufacturing & Packing
19.	Regadenoson IH	Manufacturing & Packing
20.	Selexipag IH	Manufacturing & Packing
21.	Sucroferric Oxyhyroxide IH	Manufacturing & Packing
22.	Zofenopril Calcium IH	Manufacturing & Packing

ITEM(S) Twenty Two (22) 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 active substances for the purpose of export only, those are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 11.05.2026

Signature

15 NOV 2023

Stamp of the authority and date

7-5/2014/EU/WC-0273

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 10 JUN 2024

To,

M/s.Sionc Pharmaceuticals Pvt.Ltd,
Plot No: 34A, Road No: 1, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada (M), Visakhapatnam District -531021,
Andhra Pradesh, India

SUB:- Grant of Written Confirmation of M/s. Sionc Pharmaceuticals Pvt.Ltd, Plot No:34A, Road No:1, Jawaharlal Nehru Pharma City, Thanam Village, Parawada (M), Visakhapatnam 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/ED/2023/7774 dated 29.11.2023 submitted to ADC(I), CDSCO Sub-Zone, Visakhapatnam and the recommendation received from ADC(I), CDSCO Sub-Zone, Visakhapatnam 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
--	--	15.11.2023	11.05.2026
01	24	15.11.2023	11.05.2026
02	22	15.11.2023	11.05.2026
03	02	10 JUN 2024	11.05.2026

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-03**

WC-00273

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 Village,
Parawada (M), Visakhapatnam District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	**DOTA/TETRAXETAN IH**	Manufacturing & Packing
2.	**Pentetic Acid 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 above active substance 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: 11.05.2026

Signature

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

10 JUN 2024

7-5/2014/EU/WC-0273

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

17 DEC 2025

To

M/s. Sionc Pharmaceuticals Pvt. Ltd.,
Plot No. 34A, Road no: 1, Jawaharlal Nehru Pharma City,
Thanam Village, IDA, Parawada (M),
Visakhapatnam District -531021,
Andhra Pradesh, India

Subject: Written Confirmation of **M/s. Sionc Pharmaceuticals Pvt. Ltd., Plot No. 34A, Road no: 1, Jawaharlal Nehru Pharma City, Thanam Village, Parawada (M), Visakhapatnam 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/ED/2025/10599 submitted to CDSCO, Visakhapatnam Sub-Zone office, and the recommendation received from ADC (I), Visakhapatnam Sub-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 with the provisions 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
--	--	15.11.2023	**11.05.2026**
1	24	15.11.2023	**11.05.2026**
2	22	15.11.2023	**11.05.2026**
3	02	10.06.2024	**11.05.2026**
4	01	17 DEC 2025	**11.05.2026**
5	02	17 DEC 2025	**11.05.2026**

Yours faithfully,

Chandrashekar
4/12/25

Dr. Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. : Annexure-4 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 Village, IDA, Parawada (M), Visakhapatnam District -531021, Andhra Pradesh, India**

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Pazopanib Hydrochloride IH	Manufacturing & Packing

ITEM(s) ONE (01) ONLY

The Written Confirmation remains valid until: **11.05.2026**

Chandrashekar 16/12/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषध मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation Ministry of Health & Family Welfare, Govt. of India सत्यमेव जयते

17 DEC 2025

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

CERTIFICATE NO. :

Annexure-5
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 Village, IDA, Parawada (M), Visakhapatnam District -531021, Andhra Pradesh, India**

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Ruxolitinib Phosphate IH	Manufacturing & Packing
2.	Ruxolitinib Hemifumarate 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: **11.05.2026**

Chandrashekar 16/12/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

17 DEC 2025