

7-5/2013/EU/WC-0226
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 30 SEP 2022

To

**M/s. Emcure Pharmaceuticals Limited,
D-24 & D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District. Pune-413 802.
Maharashtra, India**

Subject:- Written Confirmation of M/s. Emcure Pharmaceuticals Limited, D-24 & D-24/1, M.I.D.C., Kurkumbh, Taluka: Daund, District. Pune-413 802. Maharashtra, 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/2022/3352 submitted to CDSCO, West Zone office and the recommendation received from DDC(I), West Zone Mumbai 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 conform 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	25	13 0 SEP 2022	02.07.2025
2	07	13 2 SEP 2022	02.07.2025

Yours faithfully,



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



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. Emcure Pharmaceuticals Limited,
D-24 & D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District. Pune-413 802.
Maharashtra, India**

2. Manufacturer's licence number: 25/PD/164

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

As per List enclosed as Annexure-1 & 2

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: 06.07.2022 & 07.07.2022

The Written Confirmation remains valid until: 02.07.2025

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

30 SEP 2022

Signature

Stamp of the authority and date





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

Name and address of site: **M/s. Emcure Pharmaceuticals Limited,
D-24 & D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District. Pune-413 802.
Maharashtra, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Acetazolamide Ph. Eur.	Manufacturing & Packing
2.	Atosiban Acetate (IH)	Manufacturing & Packing
3.	Bendamustine Hydrochloride (IH)	Manufacturing & Packing
4.	Cyclophosphamide Ph. Eur.	Manufacturing & Packing
5.	Carmustine Ph. Eur.	Manufacturing & Packing
6.	Dexketoprofen Trometamol (IH)	Manufacturing & Packing
7.	Decitabine Monohydrate (IH)	Manufacturing & Packing
8.	Docetaxel Trihydrate Ph. Eur.	Manufacturing & Packing
9.	Esomeprazole Sodium (IH)	Manufacturing & Packing
10.	Febuxostat (IH)	Manufacturing & Packing
11.	Flecainide Acetate Ph. Eur.	Manufacturing & Packing
12.	Iron Sucrose Complex Solution (IH)	Manufacturing & Packing
13.	Leflunomide Ph. Eur.	Manufacturing & Packing
14.	Mycophenolate Mofetil Ph. Eur.	Manufacturing & Packing
15.	Melphalan Hydrochloride (IH)	Manufacturing & Packing
16.	Propofol Ph. Eur.	Manufacturing & Packing
17.	Palonosetron Hydrochloride USP	Manufacturing & Packing
18.	Rizatriptan Benzoate Ph. Eur.	Manufacturing & Packing
19.	Sevelamer Carbonate (IH)	Manufacturing & Packing
20.	Sevelamer Hydrochloride (IH)	Manufacturing & Packing
21.	Treosulfan (IH)	Manufacturing & Packing
22.	Zoledronic Acid Monohydrate Ph. Eur.	Manufacturing & Packing
23.	Eribulin Mesylate (IH)	Manufacturing & Packing
24.	Ferric Carboxymaltose (IH)	Manufacturing & Packing
25.	Teriflunomide (IH)	Manufacturing & Packing

ITEM(S) TWENTY FIVE (25) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

30 SEP 2022

Stamp of the authority and date





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

Name and address of site: M/s. Emcure Pharmaceuticals Limited,
D-24 & D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District. Pune-413 802.
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bexarotene (IH)	Manufacturing & Packing
2.	Foscarnet Sodium Hexahydrate Ph. Eur.	Manufacturing & Packing
3.	Trientine Dihydrochloride (IH)	Manufacturing & Packing
4.	Fingolimod Hydrochloride Ph. Eur.	Manufacturing & Packing
5.	Isoprenaline Hydrochloride Ph. Eur.	Manufacturing & Packing
6.	Treprostinil (IH)	Manufacturing & Packing
7.	Levosimendan (IH)	Manufacturing & Packing

ITEM(S) SEVEN (07) 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: 02.07.2025

Signature

Stamp of the authority and date



30 SEP 2022

7-5/2013/EU/WC-0226
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

To,

**M/s. Emcure Pharmaceuticals Limited,
D-24, D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District- Pune- 413802**

25 NOV 2022

Subject :- Written Confirmation of M/s. Emcure Pharmaceuticals Limited, D-24, D-24/1, M.I.D.C., Kurkumbh, Taluka: Daund, District: Pune- 413802 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 – Regarding.

Sir,

Please refer to your online application submitted vide WC/ED/2022/5701 to the CDSCO, Zone, Mumbai office and the recommendation received from DDC(I), 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:-

9. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
10. 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.
11. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
12. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
13. The Written Confirmation will be withdrawn in the events of non compliance of Standards.
14. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

15. 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.


16. 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	25	30.09.2022	02.07.2025
02	07	30.09.2022	02.07.2025
03	01	25 NOV 2022	02.07.2025
04	01	25 NOV 2022	02.07.2025

Yours faithfully,


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



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

Annexure-03

CERTIFICATE NO. : WC-0226

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. Emcure Pharmaceuticals Limited,
 D-24, D-24/1, M.I.D.C., Kurkumbh,
 Taluka: Daund, District: Pune- 413802, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ropivacaine Hydrochloride Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: **02.07.2025.**

Signature

Stamp of the authority and date



25 NOV 2022



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

Annexure-04

CERTIFICATE NO. : WC-0226

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. Emcure Pharmaceuticals Limited,
 D-24, D-24/1, M.I.D.C., Kurkumbh,
 Taluka: Daund, District: Pune- 413802, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Diflunisal USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 02.07.2025

Vik
Signature

Stamp of the authority and date

25 NOV 2022

7-5/2013/EU/WC-0226
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated 05 NOV 2024

To

M/s. Emcure Pharmaceuticals Limited,
D-24, D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District: Pune -413802, India

SUB:- Written Confirmation of **M/s. Emcure Pharmaceuticals Limited, D-24, D-24/1, M.I.D.C., Kurkumbh, Taluka: Daund, District: Pune -413802, 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/2024/8710 submitted to CDSCO, West Zone Mumbai office, and the recommendation received from DDC(I), West Zone Mumbai 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
--	--	30.09.2022	02.07.2025
01	25	30.09.2022	02.07.2025
02	07	30.09.2022	02.07.2025
03	01	25.11.2022	02.07.2025
04	01	25.11.2022	02.07.2025
05	01	05 NOV 2024	02.07.2025

Yours faithfully,

Chandrashekar
05/11/24
(Ranga Chandrashekar)
Joint Drugs Controller (India)

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



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

CERTIFICATE NO. : **Annexure-05**
WC-0226

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. Emcure Pharmaceuticals Limited,**
D-24, D-24/1, M.I.D.C., Kurkumbh,
Taluka: Daund, District: Pune -413802, India

List of API(s):

S.No.	Active Substance(s)	Activity(ies)
01	Adenosine Ph. Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written confirmation remains valid until: **02.07.2025**

Chandrashekar Ranga

Signature

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



05 NOV 2024