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 07 OCT 2019

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

SUB: Written Confirmation of M/s. Emcure Pharmaceuticals Limited, D-24, D-24/1, M.I.D.C., Kurkumbh, Taluka: Daund, District.Pune-413 802 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, West Zone, Mumbai 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

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	Validity
01	56	07 OCT 2019	02/07/2022
02	14	07 OCT 2019	02/07/2022

Yours faithfully,

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

D/c of

4-10-19

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

WC-0226

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

2. Manufacturer's license 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 at Annexure- 01 & 02

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: 24th & 25st June 2019

The Written Confirmation remains valid until: 02nd July, 2022

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

Stamp of the authority and date

07 OCT 2019

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

Annexure- 01

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

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.

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Acetazolamide USP/ Ph. Eur.	Manufacturing & Packing
2.	Bendamustine Hydrochloride IH	Manufacturing & Packing
3.	Busulfan USP	Manufacturing & Packing
4.	Cyclophosphamide USP	Manufacturing & Packing
5.	Dexketoprofen Trometamol IH	Manufacturing & Packing
6.	Esomeprazole Sodium IH	Manufacturing & Packing
7.	Eszopiclone IH	Manufacturing & Packing
8.	Gemcitabine Hydrochloride USP	Manufacturing & Packing
9.	Irinotecan Hydrochloride USP	Manufacturing & Packing
10.	Oxaliplatin USP	Manufacturing & Packing
11.	Palonosetron Hydrochloride IH	Manufacturing & Packing
12.	Ritonavir USP	Manufacturing & Packing
13.	Rizatriptan Benzoate USP	Manufacturing & Packing
14.	Sevelamer Carbonate IH	Manufacturing & Packing
15.	Sevelamer Hydrochloride IH	Manufacturing & Packing
16.	Topotecan Hydrochloride Trihydrate IH	Manufacturing & Packing
17.	Zoledronic Acid IH	Manufacturing & Packing
18.	Zolmitriptan IH	Manufacturing & Packing
19.	Acamprosate Calcium IH	Manufacturing & Packing
20.	Atazanavir Sulfate IH	Manufacturing & Packing
21.	Busulfan Ph. Eur.	Manufacturing & Packing
22.	Carmustine USP / Ph. Eur,	Manufacturing & Packing
23.	Colesevelam Hydrochloride IH	Manufacturing & Packing
24.	Cyclophosphamide Ph. Eur.	Manufacturing & Packing
25.	Dapoxetine Hydrochloride IH	Manufacturing & Packing
26.	Decitabine Monohydrate IH	Manufacturing & Packing
27.	Dexmedetomidine Hydrochloride USP	Manufacturing & Packing
28.	Docetaxel Trihydrate USP / Ph. Eur.	Manufacturing & Packing
29.	Etodolac USP	Manufacturing & Packing
30.	Ethacrynic Acid USP	Manufacturing & Packing
31.	Febuxostat IH	Manufacturing & Packing
32.	Flecainide Acetate USP / Ph. Eur.	Manufacturing & Packing

4-10-19

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

CERTIFICATE NO. :Annexure- 01

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

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.

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
33.	Gemcitabine Hydrochloride Ph. Eur.	Manufacturing & Packing
34.	Iron Sucrose Complex IH	Manufacturing & Packing
35.	Iron Sucrose Complex Solution IH	Manufacturing & Packing
36.	Ketorolac Tromethamine USP	Manufacturing & Packing
37.	Leflunomide USP / Ph.Eur.	Manufacturing & Packing
38.	Melphalan Hydrochloride IH	Manufacturing & Packing
39.	Memantine Hydrochloride USP	Manufacturing & Packing
40.	Metoclopramide Hydrochloride USP	Manufacturing & Packing
41.	Mycophenolate Mofetil USP / Ph. Eur.	Manufacturing & Packing
42.	Neostigmine Methylsulfate USP	Manufacturing & Packing
43.	Oxaliplatin Ph.Eur.	Manufacturing & Packing
44.	Pantoprazole Sodium USP	Manufacturing & Packing
45.	Pemetrexed Disodium Hemipentahydrate IH	Manufacturing & Packing
46.	Perphenazine USP	Manufacturing & Packing
47.	Promethazine Hydrochloride USP	Manufacturing & Packing
48.	Propafenone Hydrochloride USP	Manufacturing & Packing
49.	Propofol USP / Ph. Eur.	Manufacturing & Packing
50.	Rizatriptan Benzoate Ph. Eur.	Manufacturing & Packing
51.	Ropivacaine Hydrochloride USP	Manufacturing & Packing
52.	Rivastigmine Tartrate USP	Manufacturing & Packing
53.	Sulfamethoxazole USP	Manufacturing & Packing
54.	Thiotepa USP	Manufacturing & Packing
55.	Tolterodine Tartrate IH	Manufacturing & Packing
56.	Zileuton USP	Manufacturing & Packing

ITEM(S) Fifty Six (56) Only

The Written Confirmation remains valid until: 02nd July, 2022

Signature

4-10-19

Stamp of the authority and date

07 OCT 2019

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

CERTIFICATE NO. : **WC-0226**

Annexure – 02

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.

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1.	Argatroban USP	Manufacturing & Packing
2.	Bexarotene IH	Manufacturing & Packing
3.	Cidofovir USP	Manufacturing & Packing
4.	Clofarabine IH	Manufacturing & Packing
5.	Fingolimod Hydrochloride IH	Manufacturing & Packing
6.	Foscarnet Sodium USP	Manufacturing & Packing
7.	Ibandronate Sodium Monohydrate IH	Manufacturing & Packing
8.	Midodrine Hydrochloride USP	Manufacturing & Packing
9.	Olsalazine Sodium Ph. Eur.	Manufacturing & Packing
10.	Prochlorperazine Edisylate USP	Manufacturing & Packing
11.	Trimethobenzamide Hydrochloride USP	Manufacturing & Packing
12.	Treosulfan IH	Manufacturing & Packing
13.	Trientine Hydrochloride USP	Manufacturing & Packing
14.	Tenofovir Alafamide Fumarate IH	Manufacturing & Packing

ITEM(S) Fourteen (14) 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 or sale in India.

The Written Confirmation remains valid until: 02nd July, 2022

Signature

Stamp of the authority and date

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

07 OCT 2019