7-5/2013/EU/WC-0082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
17 JUN 2022

To

M/s Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No. 842-843, At – Karakhdi,
Tal. – Padra, Dist – Vadodara, Gujarat

SUB:- Written Confirmation of M/s Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At – Karakhdi, Tal. – Padra, Dist – Vadodara 391 450, Gujarat 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/2022/3220 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 Upto
01	55	17 JUN 2022	02.07.2025
02	26	17 JUN 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

CERTIFICATE NO. : WC-0082

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 Alembic Pharmaceuticals Limited
API Division, Karakhadi
Plot No. 842-843, At – Karakhdi, Tal. – Padra,
Dist – Vadodara 391 450, Gujarat

2. Manufacturer's licence number: G/25/1826 & G/28/1283

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 Annexure 1 & Annexure 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: 12.07.2021 & 13.07.2021

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

Signature

17 JUN 2022

Stamp of the authority and date

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

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

Annexure-01

CERTIFICATE NO. : WC-0082

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 Alembic Pharmaceuticals Limited, API Division Karakhadi, Plot No. 842-843, At – Karakhdi, Tal. – Padra, Dist – Vadodara, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Afatinib Dimaleate IH	Manufacturing & Packing
2.	Agomelatine IH	Manufacturing & Packing
3.	Apixaban	Manufacturing & Packing
4.	Aripiprazole Ph. Eur.	Manufacturing & Packing
5.	Asenapine Maleate IH	Manufacturing & Packing
6.	Axitinib IH	Manufacturing & Packing
7.	Azilsartan Medoxomil Monopotassium IH	Manufacturing & Packing
8.	Bosentan	Manufacturing & Packing
9.	Canagliflozin IH	Manufacturing & Packing
10.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
11.	Dapagliflozin IH	Manufacturing & Packing
12.	Darifenacin Hydrobromide	Manufacturing & Packing
13.	Dasatinib IH	Manufacturing & Packing
14.	Deferasirox	Manufacturing & Packing
15.	Deferasirox Ph.Eur.	Manufacturing & Packing
16.	Donepezil Hydrochloride	Manufacturing & Packing
17.	Dronedarone Hydrochloride U.S.P.	Manufacturing & Packing
18.	Duloxetine Hydrochloride Ph.Eur	Manufacturing & Packing
19.	Empagliflozin IH	Manufacturing & Packing
20.	Erlotinib Hydrochloride IH	Manufacturing & Packing
21.	Etoricoxib IH	Manufacturing & Packing
22.	Febuxostat	Manufacturing & Packing
23.	Felodipine Ph.Eur	Manufacturing & Packing
24.	Fenofibrate PH. Eur.	Manufacturing & Packing
25.	Gefitinib Ph. Eur	Manufacturing & Packing
26.	Ibrutinib IH	Manufacturing & Packing
27.	Iloperidone	Manufacturing & Packing
28.	Lacosamide Ph. Eur.	Manufacturing & Packing
29.	Lenalidomide IH	Manufacturing & Packing
30.	Linagliptin IH	Manufacturing & Packing

17 JUN 2022

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

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

CERTIFICATE NO. : **WC-0082**

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

31.	Solifenacin Succinate Ph.Eur.	Manufacturing & Packing
32.	Modafinil Ph.Eur	Manufacturing & Packing
33.	Pirfenidone IH	Manufacturing & Packing
34.	Pirfenidone Ph. Eur.	Manufacturing & Packing
35.	Pramipexole Dihydrochloride Monohydrate EP	Manufacturing & Packing
36.	Prasugrel IH	Manufacturing & Packing
37.	Prasugrel Hydrochloride	Manufacturing & Packing
38.	Prasugrel Hydrochloride EP	Manufacturing & Packing
39.	Pregabalin Ph.Eur	Manufacturing & Packing
40.	Rivaroxaban	Manufacturing & Packing
41.	Rivaroxaban Ph. Eur.	Manufacturing & Packing
42.	Ropinirole Hydrochloride USP	Manufacturing & Packing
43.	Sofosbuvir IH	Manufacturing & Packing
44.	Solifenacin Succinate IH	Manufacturing & Packing
45.	Sorafenib Tosylate IH	Manufacturing & Packing
46.	Tadalafil Ph. Eur.	Manufacturing & Packing
47.	Telmisartan Ph. Eur.	Manufacturing & Packing
48.	Ticagrelor IH	Manufacturing & Packing
49.	Ticagrelor Ph. Eur.	Manufacturing & Packing
50.	Venlafaxine Hydrochloride Ph. Eur.	Manufacturing & Packing
51.	Vilazodone Hydrochloride IH	Manufacturing & Packing
52.	Vildagliptin IH	Manufacturing & Packing
53.	Warfarin Sodium Ph. Eur	Manufacturing & Packing
54.	Zolmitriptan	Manufacturing & Packing
55.	Zolmitriptan Ph. Eur.	Manufacturing & Packing

ITEM(S) FIFTY FIVE (55) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

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

17 JUN 2022

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

Annexure-02

CERTIFICATE NO. :

WC-0082

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 Alembic Pharmaceuticals Limited, API Division Karakhadi, Plot No. 842-843, At – Karakhdi, Tal. – Padra, Dist – Vadodara, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alogliptin Benzoate	Manufacturing & Packing
2.	Vortioxetine Hydrobromide	Manufacturing & Packing
3.	Warfarin Sodium Clathrate Ph. Eur.	Manufacturing & Packing
4.	Vardenafil Hydrochloride Trihydrate EP	Manufacturing & Packing
5.	Tenofovir Alafenamide Hemifumarate IH	Manufacturing & Packing
6.	Sacubitril Valsartan Trisodium Hemipentahydrate IH	Manufacturing & Packing
7.	Selexipag IH	Manufacturing & Packing
8.	Ribociclib Succinate IH	Manufacturing & Packing
9.	Riociguat IH	Manufacturing & Packing
10.	Nisoldipine	Manufacturing & Packing
11.	Obeticholic Acid IH	Manufacturing & Packing
12.	Olaparib IH	Manufacturing & Packing
13.	Osimertinib Mesylate IH	Manufacturing & Packing
14.	Palbociclib IH	Manufacturing & Packing
15.	Minodronic Acid Hydrate IH	Manufacturing & Packing
16.	Lurasidone Hydrochloride	Manufacturing & Packing
17.	Macitentan IH	Manufacturing & Packing
18.	Ivacaftor IH	Manufacturing & Packing
19.	Fingolimod Hydrochloride IH	Manufacturing & Packing
20.	Fingolimod Hydrochloride Ph. Eur.	Manufacturing & Packing
21.	Fesoterodine Fumarate	Manufacturing & Packing
22.	Elvitegravir IH	Manufacturing & Packing
23.	Bosutinib	Manufacturing & Packing
24.	Brexpiprazole IH	Manufacturing & Packing
25.	Bazedoxifene Acetate IH	Manufacturing & Packing
26.	Apremilast IH	Manufacturing & Packing

ITEM(S) Twenty Six (26) 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

17 JUN 2022

Stamp of the authority and date

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