F:No: 7-5/2013/EU/WC-0081
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s. Alembic Pharmaceuticals Limited,
(API Division Panelav) at-Panelav,
Tal-Halol, Dist-Panchmahal,
Gujarat, India

SUB: Written Confirmation of M/s. Alembic Pharmaceuticals Limited, (API Division Panelav) at-Panelav, Tal-Halol, Dist-Panchmahal, Gujarat, 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/2022/3298 submitted to CDSCO, Ahmedabad Zone and the recommendation received from DDC (I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	43	30 JUN 2022	02.07.2025
02	06	30 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

WC-0081

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. Alembic Pharmaceuticals Limited,**
(API Division Panelav), at-Panelav,
Tal-Halol, Dist-Panchmahal,
Gujarat, India

2. Manufacturer's license Number: G/1411 & G/1050

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 Annexed

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: 17.06.2021 & 18.06.2021

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

30 JUN 2022

Stamp of the authority and date

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

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

CERTIFICATE NO. : **Annexure- 01**
WC 0081

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 Panelav) at -Panelav,
Tal-Halol, Dist-Panchmahal,
Gujarat, INDIA.

List of APIs:-

Sl.No	Name of the Active substances	Activitie(s)
1.	Azithromycin Dihydrate Ph. Eur.	Manufacturing & Packing
2.	Azithromycin Monohydrate Ph. Eur.	Manufacturing & Packing
3.	Celecoxib Ph. Eur.	Manufacturing & Packing
4.	Clarithromycin EP	Manufacturing & Packing
5.	Clonidine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
6.	Clonidine USP	Manufacturing & Packing
7.	Deferasirox IH	Manufacturing & Packing
8.	Erythromycin EP	Manufacturing & Packing
9.	Etoricoxib IH	Manufacturing & Packing
10.	Famotidine EP	Manufacturing & Packing
11.	Fenofibrate Ph. Eur.	Manufacturing & Packing
12.	Fluoxetine Hydrochloride EP	Manufacturing & Packing
13.	Hydrochlorothiazide EP	Manufacturing & Packing
14.	Irbesartan Ph.Eur	Manufacturing & Packing
15.	Ivabradine Hydrochloride IH	Manufacturing & Packing
16.	Lacosamide IH	Manufacturing & Packing
17.	Lamotrigine EP	Manufacturing & Packing
18.	Leflunomide EP	Manufacturing & Packing
19.	Lercanidipine Hydrochloride IH	Manufacturing & Packing
20.	Linezolid IH	Manufacturing & Packing
21.	Memantine Hydrochloride IH	Manufacturing & Packing
22.	Metoprolol Succinate USP	Manufacturing & Packing
23.	Metoprolol Tartrate USP	Manufacturing & Packing
24.	Mexiletine Hydrochloride EP	Manufacturing & Packing
25.	Modafinil USP	Manufacturing & Packing
26.	Olmesartan Medoxomil Ph.Eur	Manufacturing & Packing

30 JUN 2022

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

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

Annexure- 01

CERTIFICATE NO. : WC 0081

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

Sl.No	Name of the Active substances	Activitie(S)
27.	Rivastigmine Base IH	Manufacturing & Packing
28.	Rivastigmine Hydrogen Tartrate Ph.Eur	Manufacturing & Packing
29.	Rivastigmine Tartrate USP	Manufacturing & Packing
30.	Ropinirole Hydrochloride USP	Manufacturing & Packing
31.	Roxithromycin EP	Manufacturing & Packing
32.	Telmisartan EP	Manufacturing & Packing
33.	Valsartan EP	Manufacturing & Packing
34.	Venlafaxine Hydrochloride Ph.Eur	Manufacturing & Packing
35.	Vildagliptin IH	Manufacturing & Packing
36.	Pramipexole Dihydrochloride USP (As Monohydrate)	Manufacturing & Packing
37.	Deferasirox Ph.Eur	Manufacturing & Packing
38.	Lacosamide Ph.Eur	Manufacturing & Packing
39.	Linezolid USP	Manufacturing & Packing
40.	Desvenlafaxine USP	Manufacturing & Packing
41.	Desvenlafaxine Succinate USP	Manufacturing & Packing
42.	Pramipexole Dihydrochloride Monohydrate EP	Manufacturing & Packing
43.	Quetiapine Fumarate Ph.Eur.	Manufacturing & Packing

ITEM(S) Forty Three (43) 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

20 JUN 2022

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

Annexure – 02
WC-0081

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. Alembic Pharmaceuticals Limited,
(API Division Panelav), at-Panelav,
Tal-Halol, Dist-Panchmahal,
Gujarat, India

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Fenofibric Acid Choline Salt IH	Manufacturing & Packing.
2	Fenofibric Acid IH	Manufacturing & Packing.
3	O-Desmethyl Venlafaxine Succinate Monohydrate IH	Manufacturing & Packing.
4	Meprobamate USP	Manufacturing & Packing.
5	Ivabradine Adipate IH	Manufacturing & Packing.
6	Teriflunomide IH/Ph.Eur	Manufacturing & Packing.

ITEM(S) Six (06) 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: 02.07.2025

Signature

Stamp of the authority and date

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

30 JUN 2022