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: 05 JUL 2019

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 application submitted to CDSCO, Ahmedabad Zone and the recommendation received from DDC (I), Ahmedabd 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	39	05 JUL 2019	02.07.2022
02	06	05 JUL 2019	02.072022

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

O/C

27.06.2019

28-6-19

01/07/19

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

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: 20th & 21st JUN 2018 &12 JUL 2018

The Written Confirmation remains valid until: 02.07.2022

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.S.Eswara Reddy.
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

05 JUL 2019

O/C 27.06.2019 28-6-19 01/07/19

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

Annexure- 01
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

Sl.No	Name of the Active substances	Activitie(S)
28	Pramipexole Dihydrochloride Monohydrate EP	Manufacturing & Packing
29	Pregabalin Ph.Eur	Manufacturing & Packing
30	Quetiapine Fumarate Ph.Eur	Manufacturing & Packing
31	Rivastigmine Base Ph.Eur	Manufacturing & Packing
32	Rivastigmine Hydrogen Tartrate EP	Manufacturing & Packing
33	Rivastigmine Tartrate USP	Manufacturing & Packing
34	Ropinirole Hydrochloride USP	Manufacturing & Packing
35	Roxithromycin Ph.Eur	Manufacturing & Packing
36	Telmisartan EP	Manufacturing & Packing
37	Valsartan Ph.Eur	Manufacturing & Packing
38	Venlafaxine Hydrochloride Ph.Eur	Manufacturing & Packing
39	Vildagliptin	Manufacturing & Packing

ITEM(S) Thirty Nine (39) Only

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

05 JUL 2019

O/C 27.06.2019

28-6-19

01/07/19

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 EP	Manufacturing & Packing
2.	Azithromycin Monohydrate EP	Manufacturing & Packing
3.	Bupropion Hydrochloride USP	Manufacturing & Packing
4.	Celecoxib EP	Manufacturing & Packing
5.	Clarithromycin EP	Manufacturing & Packing
6.	Clonidine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
7.	Clonidine USP	Manufacturing & Packing
8.	Deferasirox IH	Manufacturing & Packing
9.	Erythromycin EP	Manufacturing & Packing
10.	Etoricoxib IH	Manufacturing & Packing
11.	Famotidine Ph.Eur	Manufacturing & Packing
12.	Fenofibrate EP	Manufacturing & Packing
13.	Fluoxetine Hydrochloride EP	Manufacturing & Packing
14.	Hydrochlorothiazide Ph. Eur.	Manufacturing & Packing
15.	Irbesartan Ph.Eur	Manufacturing & Packing
16.	Ivabradine Hydrochloride IH	Manufacturing & Packing
17.	Lacosamide IH	Manufacturing & Packing
18.	Lamotrigine Ph.Eur	Manufacturing & Packing
19.	Leflunomide EP	Manufacturing & Packing
20.	Lercanidipine Hydrochloride IH	Manufacturing & Packing
21.	Linezolid IH	Manufacturing & Packing
22.	Memantine Hydrochloride IH	Manufacturing & Packing
23.	Metoprolol Succinate USP	Manufacturing & Packing
24.	Metoprolol Tartrate USP	Manufacturing & Packing
25.	Mexiletine Hydrochloride EP	Manufacturing & Packing
26.	Modafinil Ph.Eur	Manufacturing & Packing
27.	Olmesartan Medoxomil Ph.Eur	Manufacturing & Packing

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

Annexure – 02
WC-081

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	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: 02.07.2022

Signature

Stamp of the authority and date

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

05 JUL 2019

27.06.2019

28-6-19

01/07/19