

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

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:

To

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

05 OCT 2021

Sub: Written Confirmation M/s Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No 842-843, At -Karakhdi, Tal-Padra, Dist-Vadodara, 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 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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	27	26.06.2019	02.07.2022
02	13	26.06.2019	02.07.2022
03	05	05.07.2019	02.07.2022
04	03	05.07.2019	02.07.2022
05	08	22.10.2019	02.07.2022
06	01	18.02.2020	02.07.2022
07	02	20.03.2020	02.07.2022
08	04	20.04.2021	02.07.2022
09	01	18.09.2021	02.07.2022
10	03	05 OCT 2021	02.07.2022
11	08	05 OCT 2021	02.07.2022

Yours faithfully,



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





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

Annexure-10

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, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Pirfenidone Ph.Eur.	Manufacturing & Packing
2.	Dasatinib IH	Manufacturing & Packing
3.	Lenalidomide IH	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 02.07.2022

Signature

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Stamp of the authority and date



05 JUL 2021



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

Annexure-11

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, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Brexpiprazole IH	Manufacturing & Packing
2.	Elvitegravir IH	Manufacturing & Packing
3.	Obeticholic Acid IH	Manufacturing & Packing
4.	Osimertinib Mesylate IH	Manufacturing & Packing
5.	Palbociclib IH	Manufacturing & Packing
6.	Ribociclib Succinate IH	Manufacturing & Packing
7.	Selexipag IH	Manufacturing & Packing
8.	Tenofovir Alafenamide Hemifumarate IH	Manufacturing & Packing

ITEM(S) EIGHT (08) 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: 02.07.2022

Signature

Stamp of the authority and date



05 OCT 2021