

**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: 22 OCT 2019

To  
**M/s. Alembic Pharmaceuticals Limited, API Division,**  
**Karakhadi, Plot No. 842-843, At- Karakhadi, Tal- Padra,**  
**Dist.Vadodara-391450, Gujarat.**

**SUB: Written Confirmation of M/s. Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At- Karakhadi, Tal- Padra, Dist. Vadodara-391450, 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 application submitted to CDSCO, Ahmedabad Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	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 OCT 2019	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- 05

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

Name and Address of site: M/s. Alembic Pharmaceuticals Limited, API Division,  
Karakhadi, Plot No. 842-843, At- Karakhadi, Tal-  
Padra, Dist. Vadodara-391450, Gujarat.

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Agomelatin IH	Manufacturing & Packing
2.	Dronedarone Hydrochloride U.S.P.	Manufacturing & Packing
3.	Etoricoxib IH	Manufacturing & Packing
4.	Fenofibrate Ph.Eur.	Manufacturing & Packing
5.	Ibrutinib IH	Manufacturing & Packing
6.	Pirfenidone IH	Manufacturing & Packing
7.	Sofosbuvir IH	Manufacturing & Packing
8.	Telmisartan Ph.Eur.	Manufacturing & Packing

**ITEM(S) Eight (8) Only**

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2022

Signature

*[Handwritten Signature]*

*[Handwritten Signature]*

Stamp of the authority and date



22 OCT 2019