7-5/2013/EU/WC-0111
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

06 JAN 2020

To,

M/s. Corcord Biotech Limited,
Survey No.- 1482-86, Trasad Road, Dholka,
Dist. - Ahmedabad-382 225, Gujarat, India

SUB:- Application for amendment of the Written Confirmation of favour M/s. Corcord Biotech Limited, Survey No.- 1482-86, Trasad Road, Dholka, Dist.- Ahmedabad-382 225, 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 this office vide letter number QA-TKS/2019-CDSCO-1201 dated 18/12/2019 for addition of manufacturing license number i.e. G/28/1282 in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

02/01/2020

03/01/2020

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

CERTIFICATE NO. : (Amended) WC-0111

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. Corcord Biotech Limited,**
Survey No.- 1482-86, Trasad Road, Dholka,
Dist. - Ahmedabad-382 225, Gujarat, India

2. Manufacturer's licence number: G/1641 & G/28/1282

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 enclosed as Annexure-1 & 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: 18.07.2019 and 19.07.2019

The Written Confirmation remains valid until: **02nd July, 2022**

The authenticity of this written confirmation may be verified with the issuing regulatory authority. Inclusion

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

Stamp of the authority and date

06 JAN 2020

Signature

03/01/2020

3/01/2020