7-5/2013/EU/WC-0097

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

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

To

M/s CTX Lifesciences Pvt. Ltd.,
Block No 251/P, 252/P, 253 to 255, 256P,
258/P, 276/P, 277, 278/P, 279 to 282, 283/P,
284/P, GIDC, Sachin -394230, Dist Surat,
Gujarat, India

Sub: Written Confirmation M/sCTX Lifesciences Pvt. Ltd., Block No 251/P, 252/P, 253 to 255, 256P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin - 394230, Dist Surat, 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 W/RE/2022/4172 submitted to CDSCO, Ahemdabad zone office and the recommendation received from DDC (I), Ahemdabad 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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	Valid Upto
1	34	24 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

CERTIFICATE NO. : **WC-0097**

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 CTX Lifesciences Pvt. Ltd.,**
Block No 251/P, 252/P, 253 to 255, 256P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin -394230, Dist. Surat, Gujarat, India

2. Manufacturer's licence number: G/25/1723

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

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: 06.04.2022 & 07.04.2022

The Written Confirmation remains valid until: 02nd July, 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 24 JUN 2022

Stamp of the authority and date

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

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

Annexure-1

CERTIFICATE NO. :

WC-0097

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 CTX Lifesciences Pvt. Ltd.,
Block No 251/P, 252/P, 253 to 255, 256P,
258/P, 276/P, 277, 278/P, 279 to 282, 283/P,
284/P, GIDC, Sachin -394230, Dist. Surat,
Gujarat, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Acetazolamide	Manufacturing & Packing
2.	Alogliptin Benzoate IH	Manufacturing & Packing
3.	Amiodarone Hydrochloride EP	Manufacturing & Packing
4.	Amisulpride EP/BP	Manufacturing & Packing
5.	Apixaban IH	Manufacturing & Packing
6.	Azilsartan Medoxomil Potassium IH	Manufacturing & Packing
7.	Carbamazepine EP	Manufacturing & Packing
8.	Carvedilol EP/BP/USP	Manufacturing & Packing
9.	Chlorothiazide EP/USP	Manufacturing & Packing
10.	Chlorthalidone EP/USP	Manufacturing & Packing
11.	Deferasirox IH	Manufacturing & Packing
12.	Duloxetine Hydrochloride EP/USP	Manufacturing & Packing
13.	Eslicarbazpine Acetate IH	Manufacturing & Packing
14.	Hydrochlorothiazide EP	Manufacturing & Packing
15.	Irbesartan EP/USP	Manufacturing & Packing
16.	Lamotrigine EP	Manufacturing & Packing
17.	Lercanidipine Hydrochloride IH	Manufacturing & Packing
18.	Mesalazine EP	Manufacturing & Packing
19.	Mesalamine USP	Manufacturing & Packing
20.	Metoprolol Succinate EP	Manufacturing & Packing
21.	Metoprolol Tartrate EP	Manufacturing & Packing
22.	Olmesartan Medoxomil EP	Manufacturing & Packing
23.	Ordansetron Hydrochloride Dihydrate USP/EP/BP	Manufacturing & Packing
24.	Oxcarbazepine IH/EP/USP	Manufacturing & Packing
25.	Oxymetazoline Hydrochloride EP	Manufacturing & Packing
26.	Pregabalin IH/EP/USP	Manufacturing & Packing
27.	Propranolol Hydrochloride EP/USP	Manufacturing & Packing
28.	Rosuvastatin Calcium IH/IP/EP	Manufacturing & Packing
29.	Sevelamer Carbonate IH	Manufacturing & Packing
30.	Sevelamer Hydrochloride IH	Manufacturing & Packing
31.	Sexagliptin Hydrochloride Dihydrate IH	Manufacturing & Packing
32.	Terazosin Hydrochloride Dihydrate EP/USP	Manufacturing & Packing
33.	Ticagrelor IH	Manufacturing & Packing
34.	Xylometazoline Hydrochloride EP	Manufacturing & Packing

ITEM(S) Five (34) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

24 JUN 2022

Stamp of the authority and date

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