7-5/2014/EU/WC-0310
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

28 NOV 2023

To

M/s Glenmark Life Sciences Limited
Plot No. Z-103/I, Dahej SEZ, Phase II,.
Dahej, Dist-Bharuch, Gujarat, India

SUB:- Written Confirmation of M/s Glenmark Life Sciences Limited Plot No. Z-103/I, Dahej SEZ, Phase II,. Dahej, Dist-Bharuch, 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. **WC/RE/2023/7557** 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
1	53	28 NOV 2023	Three years from Date of Issue

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : WC-0310

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 Glenmark Life Sciences Limited**
Plot No. Z-103/I, Dahej SEZ, Phase II,.
Dahej, Dist-Bharuch, Gujarat, India,

2. Manufacturer's licence number: G/25/2005 & G/28/1513

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per Annexure

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: 17.10.2023

The Written Confirmation remains valid until: **Three years from date of issue**

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

28 NOV 2023

Stamp of the authority and date

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

CERTIFICATE NO. : Annexure-1 WC-0310

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 Glenmark Life Sciences Limited
Plot No. Z-103/I, Dahej SEZ, Phase II,.
Dahej, Dist-Bharuch, Gujarat, India

List of API(s):

Sr. No.	Active Substance (s)	Activity(ies)
01.	Deferasirox (IH)	Manufacturing & Packing
02.	Azelaic Acid (IH)	Manufacturing & Packing
03.	Ticagrelor (IH)	Manufacturing & Packing
04.	Tadalafil (USP/ Ph.Eur.)	Manufacturing & Packing
05.	Colistimethate Sodium (IP/BP/Ph. Eur./ USP)	Manufacturing & Packing
06.	Potassium Chloride (IP/BP/Ph. Eur./ USP)	Manufacturing & Packing
07.	Rivaroxaban (IH)	Manufacturing & Packing
08.	Amiodarone Hydrochloride (IP/BP/Ph. Eur./ USP)	Manufacturing & Packing
09.	Dabigatran Etexilate Mesylate (IH)	Manufacturing & Packing
10.	Fluconazole (IP/BP/Ph. Eur./ USP)	Manufacturing & Packing
11.	Etoricoxib (IH)	Manufacturing & Packing
12.	Desloratadine (Ph.Eur)	Manufacturing & Packing
13.	Bisoprolol Fumarate (BP/Ph. Eur.)	Manufacturing & Packing
14.	Lornoxicam (IH)	Manufacturing & Packing
15.	Daclatasvir Dihydrochloride (IH)	Manufacturing & Packing
16.	Zonisamide (USP)	Manufacturing & Packing
17.	Riluzole (USP)	Manufacturing & Packing
18.	Lithium Carbonate (USP)	Manufacturing & Packing
19.	Sucralfate (USP)	Manufacturing & Packing
20.	Ezetimibe (IH)	Manufacturing & Packing
21.	Glimepiride (USP)	Manufacturing & Packing
22.	Imiquimod (USP)	Manufacturing & Packing
23.	Rosuvastatin Calcium (IH)	Manufacturing & Packing
24.	Esomeprazole Magnesium Trihydrate (USP)	Manufacturing & Packing
25.	Olmesartan Medoxomil (BP/Ph. Eur.)	Manufacturing & Packing

Signature

Stamp of the authority and date

28 NOV 2023

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

CERTIFICATE NO. : WC-0310

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

Sr. No.	Active Substance (s)	Activity(ies)
26.	Pirfenidone (Ph.Eur.)	Manufacturing & Packing
27.	Pregabalin (Ph. Eur.)	Manufacturing & Packing
28.	Teneligliptin Hydrobromide Hydrate (IH)	Manufacturing & Packing
29.	Dapagliflozin Amorphous (IH)	Manufacturing & Packing
30.	Perindopril Tert-Butylamine (Ph.Eur.)	Manufacturing & Packing
31.	Teriflunomide (IH)	Manufacturing & Packing
32.	Mirabegron (IH)	Manufacturing & Packing
33.	Dimethyl Fumarate (IH)	Manufacturing & Packing
34.	Efinaconazole (IH)	Manufacturing & Packing
35.	Lomitapide Mesylate (IH)	Manufacturing & Packing
36.	Ospemifene (IH)	Manufacturing & Packing
37.	Tavaborole (IH)	Manufacturing & Packing
38.	Deoxycholic Acid (USP)	Manufacturing & Packing
39.	Nintedanib Esylate (IH)	Manufacturing & Packing
40.	Gabapentin Enacarbil (IH)	Manufacturing & Packing
41.	Voriconazole (Ph. Eur./ USP)	Manufacturing & Packing
42.	Alogliptin Benzoate (IH)	Manufacturing & Packing
43.	Dipyridamole USP/Ph.Eur.	Manufacturing & Packing
44.	Sertaconazole Nitrate B.P./Ph.Eur.	Manufacturing & Packing
45.	Telmisartan JP	Manufacturing & Packing
46.	Omeprazole USP	Manufacturing & Packing
47.	Tofacitinib Citrate (IH)	Manufacturing & Packing
48.	Apremilast (IH)	Manufacturing & Packing
49.	Solriamfetol Hydrochloride (IH)	Manufacturing & Packing
50.	Ursodiol USP	Manufacturing & Packing
51.	Bilastine (IH)	Manufacturing & Packing
52.	Lifitegrast (IH)	Manufacturing & Packing
53.	Lithium Carbonate (Ph.Eur.)	Manufacturing & Packing

ITEM(S) FiftyThree (53) Only

The Written Confirmation remains valid until: **Three years from date of issue**

28 NOV 2023

Signature

Stamp of the authority and date