7-5/2013/EU/WC-0057
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

07 JUN 2022

To

M/s Glenmark Life Sciences Limited
Plot No 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

SUB:- Written Confirmation of M/s Glenmark Life Sciences Limited, Plot No 3109, GIDC, Industrial Estate, Ankleshwar, Dist – Bharuch -393 002 Gujarat Sate 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/2022/2950 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	64	07 JUN 2022	25.06.2025
2	10	07 JUN 2022	25.06.2025

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-0057**

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 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

2. Manufacturer's licence number: G/25/1629 & G/28/1170

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 1 & Annexure 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: 10.05.2022 & 11.05.2022

The Written Confirmation remains valid until: 25.06.2025

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

07 JUN 2022

Stamp of the authority and date

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

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

Annexure-1

CERTIFICATE NO. : WC-0057

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 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amiodarone Hydrochloride Ph. Eur./USP/BP	Manufacturing & Packing
2.	Cilostazol USP	Manufacturing & Packing
3.	Glimepiride Ph. Eur./USP/BP	Manufacturing & Packing
4.	Perindopril tert-butylamine Ph. Eur.	Manufacturing & Packing
5.	Perindopril Erbumine Ph. Eur./BP	Manufacturing & Packing
6.	Topiramate USP	Manufacturing & Packing
7.	Trandolapril Ph. Eur./USP/BP	Manufacturing & Packing
8.	Terbinafine Hydrochloride Ph. Eur./USP/BP	Manufacturing & Packing
9.	Zolpidem Tartrate Ph. Eur./USP/BP	Manufacturing & Packing
10.	Adapalene Ph. Eur./BP	Manufacturing & Packing
11.	Lercanidipine Hydrochloride Amorphous	Manufacturing & Packing
12.	Lercanidipine Hydrochloride Crystalline	Manufacturing & Packing
13.	Olmesartan Medoxomil Ph. Eur.	Manufacturing & Packing
14.	Desloratadine Ph.Eur.	Manufacturing & Packing
15.	Ezetimibe IH	Manufacturing & Packing
16.	Imiquimod IH	Manufacturing & Packing
17.	Esomeprazole base IH	Manufacturing & Packing
18.	Aprepitant IH	Manufacturing & Packing
19.	Telmisartan Ph. Eur./USP/BP	Manufacturing & Packing
20.	Rosuvastatin Calcium IH / Ph. Eur.	Manufacturing & Packing
21.	Ropinirole Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
22.	Fluconazole Ph. Eur./USP/BP	Manufacturing & Packing
23.	Tazarotene IH	Manufacturing & Packing
24.	Riluzole USP	Manufacturing & Packing
25.	Zolmitriptan IH	Manufacturing & Packing
26.	Solifenacin succinate IH/Ph.Eur	Manufacturing & Packing
27.	Tadalafil Ph. Eur.	Manufacturing & Packing
28.	Trospium Chloride Ph. Eur./BP	Manufacturing & Packing
29.	Rizatriptan Benzoate Ph. Eur.	Manufacturing & Packing
30.	Levocetirizine Dihydrochloride IH	Manufacturing & Packing
31.	Bosentan Monohydrate IH	Manufacturing & Packing

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

07 JUN 2022

Annexure-1

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

CERTIFICATE NO. : WC-0057

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 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
32.	Deferasirox IH	Manufacturing & Packing
33.	Darifenacin Hydrobromide IH	Manufacturing & Packing
34.	Dronedarone Hydrochloride IH	Manufacturing & Packing
35.	Eszopiclone IH	Manufacturing & Packing
36.	Esomeprazole Magnesium Dihydrate Ph.Eur.	Manufacturing & Packing
37.	Etoricoxib IH	Manufacturing & Packing
38.	Esomeprazole Sodium IH	Manufacturing & Packing
39.	Linezolid IH	Manufacturing & Packing
40.	Loratadine Ph. Eur./USP/BP	Manufacturing & Packing
41.	Lacosamide IH	Manufacturing & Packing
42.	Milnacipran Hydrochloride IH	Manufacturing & Packing
43.	Oxcarbazepine USP	Manufacturing & Packing
44.	Palonosetron Hydrochloride IH	Manufacturing & Packing
45.	Paliperidone IH	Manufacturing & Packing
46.	Prasugrel Hydrochloride IH	Manufacturing & Packing
47.	Rasagiline Mesylate IH	Manufacturing & Packing
48.	Strontium Ranelate IH	Manufacturing & Packing
49.	Sitagliptin Phosphate IH	Manufacturing & Packing
50.	Sitagliptin Phosphate Monohydrate IH	Manufacturing & Packing
51.	Sitagliptin Phosphate Anhydrous IH	Manufacturing & Packing
52.	Saxagliptin Monohydrate IH	Manufacturing & Packing
53.	Zonisamide USP	Manufacturing & Packing
54.	Voriconazole Ph. Eur.	Manufacturing & Packing
55.	Perindopril Arginine IH	Manufacturing & Packing
56.	Lurasidone Hydrochloride IH	Manufacturing & Packing
57.	Vilazodone Hydrochloride IH	Manufacturing & Packing
58.	Linagliptin IH	Manufacturing & Packing
59.	Vildagliptin IH	Manufacturing & Packing
60.	Arformoterol Tartrate IH	Manufacturing & Packing

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

07 JUN 2022

Annexure-1

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

CERTIFICATE NO. : WC-0057

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 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
61.	Tofacitinib Citrate IH	Manufacturing & Packing
62.	Apixaban IH	Manufacturing & Packing
63.	Luliconazole IH	Manufacturing & Packing
64.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing

ITEM(S) SIXTY FOUR (64) ONLY

The Written Confirmation remains valid until: 25.06.2025

Signature

Stamp of the authority and date

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

07 JUN 2022

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

Annexure-2

CERTIFICATE NO. : **WC-0057**

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 3109, GIDC, Industrial Estate
Ankleshwar, Dist – Bharuch -393 002 Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ivacaftor IH	Manufacturing & Packing
2.	Atovaquone USP/Ph.Eur.	Manufacturing & Packing
3.	Cilazapril Ph. Eur.	Manufacturing & Packing
4.	Frovatriptan Succinate IH	Manufacturing & Packing
5.	Fingolimod Hydrochloride IH	Manufacturing & Packing
6.	Moexipril Hydrochloride IH	Manufacturing & Packing
7.	Rufinamide USP	Manufacturing & Packing
8.	Prasugrel Base IH	Manufacturing & Packing
9.	Rasagiline Tartrate IH	Manufacturing & Packing
10.	Paliperidone Palmitate IH	Manufacturing & Packing

ITEM(S) TEN (10) 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: 25.06.2025

Signature

Stamp of the authority and date

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

07 JUN 2022