



No: WHO-GMP/19061427/ /B 60314
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date : 19 JUN 2019

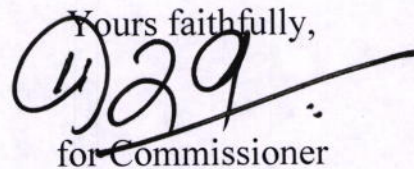
To,
✓ M/s. GLENMARK LIFE SCIENCES LTD.,
PLOT NO 3109, GIDC, INDUSTRIAL ESTATE,
ANKLESHWAR - 393 002,
DIST- BHARUCH.

Sub :- Drugs & Cosmetics Act, 1940 & Rules there under.
Issue of WHO-GMP Certificate

Sir,

Ref:- Your letter Dated : 29/04/2019

I send herewith World Health Organisation – Good Manufacturing Practices Certificate (WHO-GMP) in ONE copy as desired by you.

Yours faithfully,

for Commissioner

Food & Drugs Control Administration

No: WHO-GMP/19061427/2019/

/B Gandhinagar Date: - -2019

Copy forwarded to :-

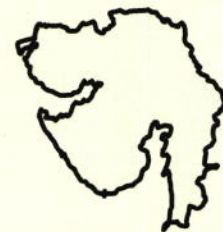
1. Assistant Commissioner, BHARUCH
2. Copy to Dy. Drugs Controller , CDSCO, Air Cargo Complex, Ahmedabad
3. G-Branch.

for Commissioner
Food & Drugs Control Administration



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : **19061427**

On the basis of the inspection carried out on **13-14/05/2019 & 15/06/2019** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

- 1 Name & Address of site : **GLENMARK LIFE SCIENCES LTD.**
PLOT NO 3109, GIDC, INDUSTRIAL ESTATE, ANKLESHWAR,
City : ANKLESHWAR - 393 002, Dist. BHARUCH
GUJARAT STATE, INDIA

- 2 Manufacturer's Licence number : **G/25/1629** **G/28/1170**

- 3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **17/06/2022**. It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. – Pin : 382010

Name & function of : **(Dr. H.G. KOSHIA)**
responsible Person **Commissioner**

Email : **comfdca@gujarat.gov.in**

Phone : **91-79-23253417, Fax : 91-79-232-53400**

Date : **18/06/2019**



LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES (FOR EXPORT ONLY)
Licence in Form No. 25 Bearing No. G/25/1629

Sr. No.	PRODUCT NAME
1.	ADAPALENE Ph. Eur., B.P., USP
2.	ADAPALENE MICROSPHERE 10% W/W
3.	AMIODARONE HYDROCHLORIDE I.P., BP, Ph. Eur., USP
4.	APIXABAN
5.	APREPITANT Ph. Eur., USP
6.	ARFORMOTEROL TARTRATE
7.	ATOVAQUONE USP
8.	BOSENTAN MONOHYDRATE
9.	BUPROPION HYDROCHLORIDE USP
10.	BUTENAFINE HYDROCHLORIDE
11.	CANAGLIFLOZIN HEMIHYDRATE
12.	CILAZAPRIL Ph. Eur.,
13.	CILOSTAZOL I.P., USP
14.	DARIFENACIN HYDROBROMIDE
15.	DESLORATADINE Ph. Eur., USP


For Glenmark Life Sciences Limited

(Vinay Agarwal)
Authorised Signatory

For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar
18 JUN 2019 to 17 JUN 2022
Glenmark Life Sciences Limited

(Formerly known as Zorg Laboratories Private Limited)

Plot No, 3109, GIDC Industrial Estate, Ankleshwar - 393 002, India.

Registered Office: Plot No 170-172, Chandramouli Industrial Estate, Mohol Bazarpath, Solapur - 413 213, India.

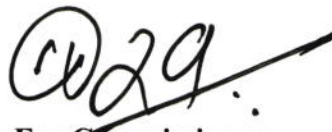
T : 91 2646 222265/69 CIN: U74900PN2011PLC139963 E: complianceofficer@glenmarklifesciences.com

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Sr. No.	PRODUCT NAME
16.	DEFERASIROX
17.	DRONEDARONE HYDROCHLORIDE USP
18.	ESOMEPRAZOLE BASE
19.	ESOMEPRAZOLE MAGNESIUM DIHYDRATE Ph. Eur., USP
20.	ESOMEPRAZOLE SODIUM
21.	ESZOPICLONE USP
22.	ETORICOXIB
23.	EZETIMIBE USP
24.	FINGOLIMOD HYDROCHLORIDE
25.	FLUCONAZOLE IP, BP, Ph. Eur., USP
26.	FOSAPREPITANT DIMEGLUMINE
27.	FROVATRIPTAN SUCCINATE
28.	GLATIRAMER ACETATE
29.	GLIMEPIRIDE IP, BP, Ph. Eur., USP
30.	IMIQUIMOD USP


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Sr. No.	PRODUCT NAME
31.	IVACAFTOR
32.	LACOSAMIDE
33.	LERCANIDIPINE HYDROCHLORIDE
34.	LEVOCETIRIZINE DIHYDROCHLORIDE
35.	LINAGLIPTIN
36.	LINEZOLID
37.	LORATADINE Ph. Eur., BP, USP
38.	LORNOXICAM
39.	LULICONAZOLE
40.	LURASIDONE HYDROCHLORIDE
41.	MILNACIPRAN HYDROCHLORIDE
42.	MOEXIPRIL HYDROCHLORIDE
43.	OLMESARTAN MEDOXOMIL Ph. Eur., B.P., USP
44.	OLOPATADINE HYDROCHLORIDE USP
45.	OXCARBAZEPINE I.P., B.P., USP


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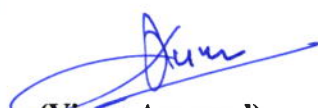
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Sr. No.	PRODUCT NAME
46.	PALIPERIDONE
47.	PALIPERIDONE PALMITATE
48.	PALONOSETRON HYDROCHLORIDE
49.	PERINDOPRIL ARGININE
50.	PERINDOPRIL ERBUMINE Ph. Eur., B.P., USP
51.	PERINDOPRIL TERT-BUTYLAMINE PH. EUR.
52.	PRASUGREL HYDROCHLORIDE
53.	RASAGILINE MESYLATE
54.	RASAGILINE TARTRATE
55.	RILUZOLE USP
56.	RIZATRIPTAN BENZOATE IP, Ph. Eur., USP
57.	ROPINIROLE HYDROCHLORIDE Ph. Eur., USP
58.	ROSUVASTATIN CALCIUM Ph. Eur.,
59.	RUFINAMIDE
60.	SITAGLIPTIN PHOSPHATE


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Sr. No.	PRODUCT NAME
61.	SITAGLIPTIN PHOSPHATE ANHYDROUS
62.	SITAGLIPTIN PHOSPHATE MONOHYDRATE Ph. Eur.,
63.	SAXAGLIPTIN MONOHYDRATE
64.	SOLIFENACIN SUCCINATE Ph. Eur.,
65.	STRONTIUM RANELATE
66.	TADALAFIL Ph. Eur., B.P. USP
67.	TAZAROTENE
68.	TELAPREVIR
69.	TELMISARTAN I.P., BP, Ph. Eur., USP
70.	TERBINAFINE HYDROCHLORIDE Ph. Eur., B.P., USP
71.	TOFACITINIB CITRATE
72.	TOPIRAMATE USP
73.	TRANDOLAPRIL I.P., B.P., Ph. Eur., USP
74.	TROSPIMUM CHLORIDE Ph. Eur., B.P., USP
75.	VILAZODONE HYDROCHLORIDE



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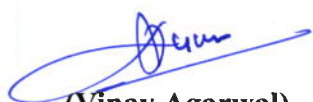
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Sr. No.	PRODUCT NAME
76.	VILDAGLIPTIN
77.	VORICONAZOLE Ph. Eur., USP
78.	ZOLMITRIPTAN USP
79.	ZOLPIDEM TARTRATE IP, BP, Ph. Eur., USP
80.	ZONISAMIDE USP

**For Glenmark Life Sciences Limited****(Vinay Agarwal)
Authorised Signatory****For Commissioner
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Gujarat State, Gandhinagar****18 JUN 2019 to 17 JUN 2022**

LIST OF PRODUCT

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Licence in Form No. 28 Bearing No. G/28/1170

Sr. No.	PRODUCT NAME
1.	COLISTIMETHATE SODIUM I.P.
	COLISTIMETHATE SODIUM B.P.
	COLISTIMETHATE SODIUM Ph.Eur.
	COLISTIMETHATE SODIUM USP



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1 of 1

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