



Food & Drugs Control Administration

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



Certificate No. : **1708289**

On the basis of the inspection carried out on **19-20/06/2017 & 08/08/2017** 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 PHARMACEUTICALS 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 **18/08/2019**. 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 : **19/08/2017**



LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES (FOR EXPORT ONLY)

Licence in Form No. 25 Bearing No. G/25/1629

Valid Form 19/08/2017 to 18/08/2019

Sr. No.	PRODUCT NAME
1.	Adapalene Ph.Eur., BP, USP
2.	Adapalene Microsphere 10% w/w
3.	Alfuzosin Hydrochloride I.P., B.P., Ph.Eur., USP
4.	Amiodarone Hydrochloride I.P., BP, Ph.Eur., USP
5.	Apixaban
6.	Aprepitant Ph.Eur., USP
7.	Arformoterol Tartrate
8.	Atovaquone USP
9.	Bosentan Monohydrate
10.	Bupropion Hydrochloride USP
11.	Butenafine Hydrochloride
12.	Choline Fenofibrate
13.	Cilazapril Ph.Eur.
14.	Cilostazol I.P., USP
15.	Darifenacin Hydrobromide
16.	Desloratadine Ph.Eur., USP
17.	Deferasirox



For Glenmark Pharmaceuticals Limited


(Vinay Agarwal)
Authorised Signatory


For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

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Valid Form 19/08/2017 to 18/08/2019

Sr. No.	PRODUCT NAME
18.	Dronedarone Hydrochloride USP
19.	Esomeprazole Base
20.	Esomeprazole Magnesium Dihydrate Ph.Eur., USP
21.	Esomeprazole Potassium
22.	Esomeprazole Sodium
23.	Eszopiclone USP
24.	Etoricoxib
25.	Ezetimibe USP
26.	Fingolimod Hydrochloride
27.	Fluconazole IP, BP, Ph.Eur., USP
28.	Fosaprepitant Dimeglumine
29.	Frovatriptan Succinate
30.	Glatiramer Acetate
31.	Glimepiride IP, BP, Ph.Eur., USP
32.	Imiquimod USP
33.	Itraconazole Ph.Eur., BP, USP
34.	Ivacaftor



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Sr. No.	PRODUCT NAME
35.	Lacosamide
36.	Lercanidipine Hydrochloride
37.	Levocetirizine Dihydrochloride Ph.Eur.
38.	Linagliptin
39.	Linczolid
40.	Loratadine Ph.Eur., BP, USP
41.	Lornoxicam
42.	Luliconazole
43.	Lurasidone Hydrochloride
44.	Milnacipran Hydrochloride
45.	Moexipril Hydrochloride
46.	Olmesartan Medoxomil Ph.Eur., B.P., USP
47.	Oxcarbazepine I.P., B.P., USP
48.	Paliperidone
49.	Paliperidone Palmitate
50.	Palonosetron Hydrochloride



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Valid Form 19/08/2017 to 18/08/2019

Sr. No.	PRODUCT NAME
51.	Perindopril Arginine
52.	Perindopril Erbumine Ph.Eur., B.P., USP
53.	Perindopril Tert-Butylamine Ph.Eur.
54.	Prasugrel Hydrochloride
55.	Rasagiline Mesylate
56.	Rasagiline Tartrate
57.	Riluzole USP
58.	Rizatriptan Benzoate IP, Ph.Eur., USP
59.	Ropinirole Hydrochloride Ph.Eur., USP
60.	Rosuvastatin Calcium Ph.Eur.
61.	Rufinamide
62.	Sitagliptin Phosphate
63.	Sitagliptin Phosphate Anhydrous
64.	Sitagliptin Phosphate Monohydrate Ph.Eur.
65.	Saxagliptin Monohydrate
66.	Solifenacin Succinate Ph.Eur.
67.	Strontium Ranelate



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Valid Form 19/08/2017 to 18/08/2019

Sr. No.	PRODUCT NAME
68.	Tadalafil Ph.Eur., B.P. USP
69.	Tazarotene
70.	Telaprevir
71.	Telmisartan I.P., BP, Ph.Eur., USP
72.	Terbinafine Hydrochloride Ph.Eur., B.P., USP
73.	Tofacitinib Citrate
74.	Topiramate USP
75.	Trandolapril I.P., B.P., Ph.Eur., USP
76.	Tropium Chloride Ph.Eur., B.P., USP
77.	Vilazodone Hydrochloride
78.	Vildagliptin
79.	Voriconazole Ph.Eur., USP
80.	Zolmitriptan USP
81.	Zolpidem Tartrate IP, BP, Ph.Eur., USP
82.	Zonisamide USP



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