

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No:501/P&B/2020

Dated: 02-02-2020

From:

M.B.R.Prasad, M.Pharm, M.Phil, AIC,
Director & Licensing Authority,
O/o the Director General,
Drugs and Copyright,
Drugs Control Administration,
Chuttgutta, Guntur - 522004.Andhra Pradesh (State),India-532 409.

To

M/s.Aurobindo Pharma Limited (Unit-XI),
Survey Nos. 1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram (Village),
Ranasthalam (Mandal),
Srikakulam (District),
India-532 409.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and rules made there under -Application of M/s Aurobindo Pharma Limited (Unit-XI),Survey Nos. 1/22, 2/1 to 5, 6 to 18, 61 to 69,Pydibhimavaram (Village),Ranasthalam (Mandal),Srikakulam (District),Andhra Pradesh (State),India- 532 409 for issue of **World Health Organization G.M.P Certificate-Reg.**

Ref: 1.Your application dated: 12.10.2019 and 28.12.2019
2.Joint Inspection Report Dt:07.01.2020 and 08.01.2020.

I, forward herewith **WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

This Certificate is valid for a period of **Three Years** from the date of issue and this certificate is meant for Export of Drugs only.

Yours faithfully,



**DIRECTOR AND LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION**

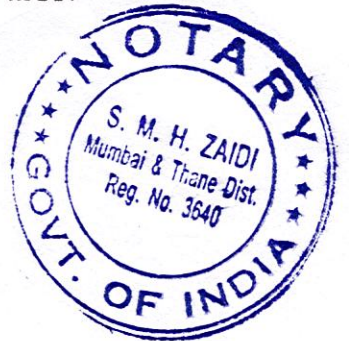
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ATTESTED

Chetan A. Naik
Secretary

The Memon Chamber of Commerce



Page 1 of 6



BEFORE ME

S. M. H. ZAIDI
NOTARY
Government of India
Mumbai & Thane Dist

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भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by DIRECTOR
acting in the capacity of DIRECTOR
bears the seal/stamp of SECRETARY, THE MEMON CHAMBER
OF COMMERCE

Certified
at NEW DELHI, INDIA the 14-Aug-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0000743920

Seal / Stamp
is issued to AUROBINDO PHARMA LIMITED

Signature



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. D.vie
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

O/o the Director General,
Drugs and Copyright,
Drugs Control Administration,
Chuttugunta, Guntur-522004.

L.Dis.No: 501/P&B/2020

Dated: 13-02-2020

LIST OF PRODUCTS APPROVED
UNDER WHO GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1. Abacavir Sulfate	USP/Ph.Eur
2. Alendronate Sodium	USP/Ph.Eur
3. Atomoxetine Hydrochloride	USP/Ph.Eur
4. Carisoprodol	USP
5. Celecoxib	USP/Ph.Eur
6. Cilastatin Sodium	IH
7. Cinacalcet Hydrochloride	IH
8. Clopidogrel Bisulfate	USP
9. Clindamycin Hydrochloride	USP/Ph.Eur
10. Clindamycin Palmitate Hydrochloride	IH/USP
11. Colesevelam Hydrochloride	IH
12. Dabigatran Etexilate Mesylate	IH
13. Darifenacin Hydrobromide	IH
14. Darunavir Propylene Glycolate	IH
15. Dextromethorphan Hydrobromide	USP/Ph.Eur.
16. Didanosine	USP/Ph.Eur
17. Divalproex Sodium	USP
18. Dolutegravir Sodium	IH
19. Dronedarone Hydrochloride	USP
20. Duloxetine Hydrochloride	USP/Ph.Eur
21. Efavirenz	USP
22. Emtricitabine	IH
23. Esomeprazole Magnesium Dihydrate	USP/Ph.Eur
24. Esomeprazole Sodium	IH
25. Ezetimibe	IH/USP
26. Felodipine	USP/Ph.Eur
27. Galantamine Hydrobromide	USP/Ph.Eur.
28. Ibandronate Sodium	IH



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29.	Iron Sucrose	IH
30.	Lacosamide	IH
31.	Lamivudine	USP/Ph.Eur
32.	Lamivudine (Crystalline Polymorph Form I)	USP
33.	Lamivudine (Crystalline Polymorph Form II)	Ph.Eur
34.	Lamotrigine	USP/ Ph.Eur
35.	Levetiracetam	USP/ Ph.Eur
36.	Levofloxacin	USP
37.	Linagliptin	IH
38.	Lopinavir	USP/ Ph.Eur
39.	Metformin Hydrochloride	USP/Ph.Eur
40.	Montelukast Sodium	USP/Ph.Eur.
41.	Naftopidil	IH
42.	Naproxen	USP/ Ph.Eur
43.	Naproxen Sodium	USP/Ph.Eur
44.	Nateglinide	IH
45.	Nevirapine	USP/Ph.Eur
46.	Nevirapine Hemi Hydrate	USP/Ph.Eur
47.	Olmesartan Medoxomil	USP/Ph.Eur
48.	Omeprazole	USP/Ph.Eur
49.	Omeprazole Magnesium	USP/Ph.Eur
50.	Pioglitazone Hydrochloride	USP/Ph.Eur.
51.	Pitavastatin Calcium	IH
52.	Prasugrel Hydrochloride	IH
53.	Pregabalin	USP /Ph.Eur
54.	Quetiapine Fumarate	USP/Ph.Eur
55.	Raloxifene Hydrochloride	USP/Ph.Eur
56.	Ranolazine	IH
57.	Repaglinide	USP/Ph.Eur
58.	Risedronate Sodium	USP
	Risedronate Sodium Hemi Pentahydrate	Ph.Eur
59.	Rivaroxaban	IH
60.	Rizatriptan Benzoate	USP/Ph.Eur
61.	Rosuvastatin Calcium	IH/USP/Ph.Eur
62.	Saxagliptin Monohydrate	IH
63.	Sertraline Hydrochloride	USP/Ph.Eur
64.	Sevelamer Carbonate	IH
65.	Sevelamer Hydrochloride	IH



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66. Sildenafil Citrate	USP/Ph.Eur.
67. Sitagliptin Phosphate	IH
68. Solifenacin Succinate	IH/Ph.Eur
69. Stavudine	USP
70. Tenofovir Disoproxil Fumarate	IH
71. Tramadol Hydrochloride	USP/Ph.Eur
72. Valacyclovir Hydrochloride	USP
Valacyclovir Hydrochloride Hydrate	Ph.Eur
73. Valganciclovir Hydrochloride	IH/USP
74. Valsartan	USP/Ph.Eur
75. Voriconazole	USP/Ph.Eur.
76. Zidovudine	USP/Ph.Eur
77. Ziprasidone Hydrochloride Monohydrate	USP/Ph.Eur
78. Zolmitriptan	IH/ USP
79. Amoxicillin Trihydrate	BP/Ph. Eur.
Amoxicillin	USP
80. Ampicillin	BP/USP/Ph. Eur.
81. Ampicillin Trihydrate	BP/USP/Ph. Eur.
82. Cefadroxil Monohydrate	BP/Ph.Eur
83. Cefadroxil	USP
84. Cefalexin Monohydrate	BP/Ph.Eur
85. Cephalexin	USP
86. Cefixime	BP /USP/Ph.Eur
87. Cefpodoxime Proxetil	IH/USP
88. Cephadrine	BP/USP/Ph.Eur.
89. Cloxacillin Sodium	BP/USP/Ph.Eur.
90. Cloxacillin Benzathine	BP/USP
91. Dicloxacillin Sodium	BP/USP/Ph.Eur.
92. Flucloxacillin Magnesium Octahydrate	BP/Ph.Eur.
93. Flucloxacillin Sodium	BP/Ph.Eur.
94. Oxacillin Sodium	BP/ USP/Ph.Eur.
95. Sultamicillin	BP/Ph.Eur.
96. Sultamicillin Tosilate Dihydrate	BP/Ph.Eur.
97. Carbimazole	Ph.Eur
98. Dichlorphenamide	USP
99. Dimethyl Fumarate	IH
100. Esomeprazole Magnesium Trihydrate	IH
101. Ganciclovir	USP



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102. Hydralazine Hydrochloride	USP/Ph.Eur
103. Mesalamine	IH/USP
104. Silodosin	IH
105. Methohexital	USP
106. Cefdinir	USP
107. Apremilast	IH
108. Dalfampridine	IH
109. Lurasidone Hydrochloride	IH
110. Macitentan	IH
111. Mirabegron	IH
112. Teriflunomide	IH
113. Azilsartan Kamedoxomil	IH
114. Atovaquone	USP
115. Cariprazine Hydrochloride	IH
116. Fudosteine	IH
117. Lorcaserin Hydrochloride Hemihydrate	IH
118. Lumacaftor	IH
119. Methenamine Hippurate	USP
120. Omeprazole Sodium	Ph.Eur.
121. Phenoxybenzamine Hydrochloride	USP
122. Pivmecillinam Hydrochloride	BP/Ph.Eur

Manufacturer : M/s.Aurobindo Pharma Limited (Unit-XI),
Survey Nos. 1/22, 2/1 to 5, 6 to 18, 61 to 69,
Pydibhimavaram Village,Ranasthalam Mandal,
Srikakulam District,Andhra Pradesh State,India- 532 409.

Drug Licence No. : 32/SK/AP/2003/B/R,dated 17.06.2003 inForm-25&28.

It is also certified that

- a) The manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The unit of M/s. Aurobindo Pharma Limited. Unit-XI, Survey Nos. 1/22, 2/1 to 5, 6 to 18, 61 to 69,Pydibhimavaram Village,Ranasthalam Mandal,Srikakulam District,Andhra Pradesh State,India- 532 409 was jointly inspected by Mrs. A.Lavanya, Drugs Inspector,DCA, Srikakulamand Sri. R. Srinivasan, ADC(I), CDSCO, Visakhapatnamon07.01.2020 to 08.01.2020.



Handwritten signature and date 10/8/2020

L.Dis.No:501/P&B/2020 - WHO GMP Certificate (122 Products) issued to M/s. Aurobindo Pharma Limited (Unit- XI), Sy.No.1/22,2/1 to5, 6 to18, 61 to 69, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh State, India - 532 409.



- b) The Manufacturer conforms to requirement for Good Manufacturing Practices in the manufacture and quality control (As recommended by the World Health Organization) in respect of products mentioned above (**One Hundred and Twenty Two**) for Export in the International Market.

This Certificate is valid for a period of **Three Years** from the date of issue and this certificate is meant for Export of Drugs only.



a-2/2/2020
**DIRECTOR AND LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION**

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No 0 8 4 6 0

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Chetan A. Naik
Secretary
The Memon Chamber of Commerce

