

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

From:

M.B.R.Prasad, M.Pharm, M.Phil, AIC,
Director & Licensing Authority,
O/o the Director General,
Drugs and Copyright,
Drugs Control Administration,
Siddhartha Medical College Campus,
Gunadala, Vijayawada - 520 008

To

M/s. AUROBINDO PHARMA LIMITED (Unit-XI),
Sy No's. 52, 53, 58, 59, 61 to 78, 127 & 128,
Pydibhimavaram Village &
Sy No's. 1, 2, 4 to 9, 11, 29, 30, 31 & 32,
Chittivalasa Village, Ranasthalam Mandal,
Srikakulam District, Andhra Pradesh State,
India, PIN: 532 409

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and rules made there under – Issue of World Health Organization G.M.P. Certificate – Reg.

Ref: 1. Your application dated: 12.12.2022
2. Joint Inspection Report Dt: 28.12.2022, 29.12.2022 and 30.12.2022.
3. Ref:5 – 6 (409 – A7) 2022 – 23 / 5200, Dated: 10.01.2023 of Central Drugs Standard Control Organization, Zonal office, CDSCO Bhavan, Hyderabad.

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,

Digitally signed by BABU
RAJENDRA PRASAD MEESALA
Date: 2023.03.12 08:45:05
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**DIRECTOR AND LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION**



GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

O/o The Director General,
Drugs and Copyright,
Drugs Control Administration,
Siddhartha Medical College Campus,
Gunadala, Vijayawada - 520 008

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.	APREMILAST	IH
4.	ATOMOXETINE HYDROCHLORIDE	USP/Ph.Eur
5.	ATOVAQUONE	USP
6.	CARBIMAZOLE	Ph.Eur
7.	CARIPRAZINE HYDROCHLORIDE	IH
8.	CARISOPRODOL	USP
9.	CELECOXIB	USP/Ph.Eur
10.	CINACALCET HYDROCHLORIDE	IH
11.	CLOPIDOGREL BISULFATE	USP
12.	CLINDAMYCIN PALMITATE HYDROCHLORIDE	IH/USP
13.	DABIGATRAN ETEXILATE MESYLATE	IH
14.	DALFAMPRIDINE	IH
15.	DARIFENACIN HYDROBROMIDE	IH
16.	DARUNAVIR PROPYLENE GLYCOLATE	IH
17.	DEXTROMETHORPHAN HYDROBROMIDE	USP/Ph.Eur
18.	DICHLORPHENAMIDE	USP
19.	DIDANOSINE	USP/Ph.Eur
20.	DIMETHYL FUMARATE	IH
21.	DIVALPROEX SODIUM	USP
22.	DOLUTEGRAVIR SODIUM	IH
23.	DRONEDARONE HYDROCHLORIDE	USP
24.	DULOXETINE HYDROCHLORIDE	USP/Ph.Eur
25.	EFAVIRENZ	USP
26.	EMTRICITABINE	IH
27.	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	USP/Ph.Eur

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DIRECTOR AND LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION



WHO GMP Certificate (133 Products) issued to M/s. Aurobindo Pharma Limited (Unit-XI), Sy No's. 52, 53, 58, 59, 61 to 78, 127 & 128, Pydibhimavaram Village & Sy No's. 1, 2, 4 to 9, 11, 29, 30, 31 & 32, Chittivalasa Village, Ranasthalam Mandal, Srikakulam District. Andhra Pradesh State, India, PIN: 532 409.

28. ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	IH
29. ESOMEPRAZOLE SODIUM	IH
30. EZETIMIBE	IH/USP
31. FELODIPINE	USP/Ph.Eur
32. GALANTAMINE HYDROBROMIDE	USP/Ph.Eur
33. GANCICLOVIR	USP
34. HYDRALAZINE HYDROCHLORIDE	USP/Ph.Eur
35. IBANDRONATE SODIUM	IH
36. LACOSAMIDE	IH
37. LAMIVUDINE	USP/Ph.Eur
38. LAMIVUDINE (Crystalline Polymorph Form I)	USP
39. LAMIVUDINE (Crystalline Polymorph Form II)	Ph.Eur
40. LAMOTRIGINE	USP/Ph.Eur
41. LEVETIRACETAM	USP/Ph.Eur
42. LEVOFLOXACIN	USP
43. LINAGLIPTIN	IH
44. LOPINAVIR	USP/Ph.Eur
45. LORCASERIN HYDROCHLORIDE HEMIHYDRATE	IH
46. LUMACAFTOR	IH
47. LURASIDONE HYDROCHLORIDE	IH
48. MACITENTAN	IH
49. MESALAMINE	IH/USP
50. METFORMIN HYDROCHLORIDE	USP/Ph.Eur
51. METHENAMINE HIPPURATE	USP
52. METHOHEXITAL	USP
53. MIRABEGRON	IH
54. MONTELUKAST SODIUM	USP/Ph.Eur
55. NAPROXEN	USP/Ph.Eur
56. NAPROXEN SODIUM	USP/Ph.Eur
57. NATEGLINIDE	IH
58. NEVIRAPINE	USP/Ph.Eur
59. NEVIRAPINE HEMI HYDRATE	USP/Ph.Eur
60. OLMESARTAN MEDOXOMIL	USP/Ph.Eur
61. OMEPRAZOLE	USP/Ph.Eur
62. OMEPRAZOLE MAGNESIUM	USP/Ph.Eur

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63. OMEPRAZOLE SODIUM	Ph.Eur
64. PHENOXYBENZAMINE HYDROCHLORIDE	USP
65. PIOGLITAZONE HYDROCHLORIDE	USP/Ph.Eur
66. PITAVASTATIN CALCIUM	IH
67. PRASUGREL HYDROCHLORIDE	IH
68. PREGABALIN	USP/Ph.Eur
69. QUETIAPINE FUMARATE	USP/Ph.Eur
70. RALOXIFENE HYDROCHLORIDE	USP/Ph.Eur
71. RANOLAZINE	IH
72. REPAGLINIDE	USP/Ph.Eur
73. RISEDRONATE SODIUM	USP
RISEDRONATE SODIUM HEMI PENTAHYDRATE	Ph.Eur
74. RIVAROXABAN	IH
75. RIZATRIPTAN BENZOATE	USP/Ph.Eur
76. ROSUVASTATIN CALCIUM	IH/USP/Ph.Eur
77. SAXAGLIPTIN MONOHYDRATE	IH
78. SERTRALINE HYDROCHLORIDE	USP/Ph.Eur
79. SEVELAMER CARBONATE	IH
80. SEVELAMER HYDROCHLORIDE	IH
81. SILDENAFIL CITRATE	USP/Ph.Eur
82. SILODOSIN	IH
83. SITAGLIPTIN PHOSPHATE	IH
84. SOLIFENACIN SUCCINATE	IH/Ph.Eur
85. STAVUDINE	USP
86. TENOFOVIR DISOPROXIL FUMARATE	IH
87. TERIFLUNOMIDE	IH
88. TRAMADOL HYDROCHLORIDE	USP/Ph.Eur
89. VALACYCLOVIR HYDROCHLORIDE	USP
VALACYCLOVIR HYDROCHLORIDE HYDRATE	Ph.Eur
90. VALGANCICLOVIR HYDROCHLORIDE	IH/USP
91. VALSARTAN	USP/Ph.Eur
92. VORICONAZOLE	USP/Ph.Eur
93. ZIDOVUDINE	USP/Ph.Eur
94. ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE	USP/Ph.Eur
95. ZOLMITRIPTAN	IH/USP

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96. AMOXICILLIN TRIHYDRATE	BP/Ph.Eur
AMOXICILLIN	USP
97. AMPICILLIN	BP/USP/Ph.Eur
98. AMPICILLIN TRIHYDRATE	BP/USP/Ph.Eur
99. CEFADROXIL MONOHYDRATE	BP/Ph.Eur
100. CEFADROXIL	USP
101. CEFALEXIN MONOHYDRATE	BP/Ph.Eur
102. CEPHALEXIN	USP
103. CEFDINIR	USP
104. CEFIXIME	BP/USP/Ph.Eur
105. CEFPODOXIME PROXETIL	IH/USP
106. CEPHRADINE	BP/USP/Ph.Eur
107. CLOXACILLIN SODIUM	BP/USP/Ph.Eur
108. CLOXACILLIN BENZATHINE	BP/USP
109. DICLOXACILLIN SODIUM	BP/USP/Ph.Eur
110. FLUCLOXACILLIN MAGNESIUM OCTAHYDRATE	BP/Ph.Eur
111. FLUCLOXACILLIN SODIUM	BP/Ph.Eur
112. OXACILLIN SODIUM	BP/USP/Ph.Eur
113. PIVMECILLINAM HYDROCHLORIDE	BP/Ph.Eur
114. SULTAMICILLIN	BP/Ph.Eur
115. SULTAMICILLIN TOSILATE DIHYDRATE	BP/Ph.Eur
116. DALFAMPRIDINE	USP
117. DRONEDARONE HYDROCHLORIDE	Ph.Eur
118. ESOMEPRAZOLE SODIUM	Ph.Eur
119. LACOSAMIDE	USP/Ph.Eur
120. METHOHEXITAL	IH
121. PRASUGREL HYDROCHLORIDE	USP
122. RIVAROXABAN	Ph.Eur
123. TERIFLUNOMIDE	Ph.Eur
124. ZOLMITRIPTAN	Ph.Eur
125. BILASTINE	IH
126. DEXTROMETHORPHAN POLISTIREX	IH
127. FAMPRIDINE	IH
128. NIRMATRELVIR	IH
129. SAFINAMIDE MESYLATE	IH
130. SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	IH

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DIRECTOR AND LICENCING AUTHORITY
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131. SITAGLIPTIN PHOSPHATE ANHYDROUS	USP
132. TENOFOVIR ALAFENAMIDE FUMARATE	IH
133. LEVOFLOXACIN HEMIHYDRATE	Ph.Eur

Manufacturer : M/s. AUROBINDO PHARMA LIMITED (Unit-XI),
Sy No's. 52, 53, 58, 59, 61 to 78, 127 & 128,
Pydibhimavaram Village &
Sy No's. 1, 2, 4 to 9, 11, 29, 30, 31 & 32,
Chittivalasa Village, Ranasthalam Mandal,
Srikakulam District, Andhra Pradesh State, India, PIN: 532 409

Drug Licence No. : 32/SK/AP/2003/B/R, dated 17.06.2003 in Form-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), Sy No's. 52, 53, 58, 59, 61 to 78, 127 & 128, Pydibhimavaram Village & Sy No's. 1, 2, 4 to 9, 11, 29, 30, 31 & 32, Chittivalasa Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh State, India, PIN: 532 409 was jointly inspected by Mrs. A. Lavanya, Drugs Inspector, DCA, Srikakulam and Sri. G. Nishanth, Drugs Inspector, CDSCO Zonal Office, Hyderabad on 28.12.2022 to 30.12.2022.

- 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 Thirty Three) 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.

Digitally signed by BABU
RAJENDRA PRASAD MEESALA
Date: 2023.03.12 08:46:37 +05'30'

**DIRECTOR AND LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION**

To
M/s. AUROBINDO PHARMA LIMITED (Unit-XI),
Sy No's. 52, 53, 58, 59, 61 to 78, 127 & 128,
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Chittivalasa Village, Ranasthalam Mandal,
Srikakulam District, Andhra Pradesh State,
India, PIN: 532 409.



Attested

Page 6 of 6

**RAVI
Secretary**

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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 **B R P M**
acting in the capacity of **DIRECTOR**
bears the seal/stamp of **INDO LATIN AMERICAN CHAMBER OF
COMMERCE, NEW DELHI**

Certified
at **NEW DELHI, INDIA** the **28-Jun-2023**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **DLND0005608623**

Seal / Stamp is issued to **AUROBINDO PHARMA LTD**

OI 1180549

The Ministry of External Affairs
accepts no responsibility for the
contents of the above document



(संदीप कुमार)
(Sandeep Kumar)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Attested

RAVI
Secretary

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