Ph: (0832)- 2459226/2459230
Fax: (0832)- 2459223
Website: www.dfda.goa.gov.in

NOTARY Gulabdhar Upadhyay Greater Mumbai State of Maharashtra REGN. NO. 7063 GOVERNMENT OF INDIA

No: 721/MFG/CERT/DFDA/19/2548
Government of Goa,
Dte. of Food & Drugs Admn,
DHANWANTARI,
Opp The Shrine Of Holy Cross,
Bambolim, Goa – 403202
Dated: 07/10 /2019

CERTIFICATE

This is to certify that M/s Cipla Ltd., Plot no. L-139 to L-146, Verna Industrial Estate, Verna Goa, are holding drug manufacturing license No. 536 issued in form 25 and 546 issued in form 28 under the provisions of Drugs and Cosmetic Act 1940 and Rules made thereunder, to manufacture drugs / drug formulations at the above address.

It is further certified that the said firm is holding Certificates of Pharmaceutical Product granted under WHO-GMP Certificate schemes for the products mentioned below till 17.08.2019. Firm has submitted application for grant of fresh Certificates of Pharmaceutical Products, which is under consideration of this Directorate. Pending the joint inspection of the firm by officials of CDSCO and this Directorate for disposal of the application of the firm for the issue of fresh certificates, the validity of the below mentioned certificates is extended up to 17 February 2020.

Sr. No.	Product	Certificate No.	Dated
1.	Levosalbutamol Inhalation Solution **Levolin 1.25mg Respules**	721/MFG/WHO-GMP/DFDA/2019/01	16.04.2019
2.	Budesonide Respirator Suspension **Budecort 0.5 mg Respules**	721/MFG/WHO-GMP/DFDA/2017/03	10.10.2017
3.	Budesonide Respirator Suspension **Budecort 1 mg Respules**	721/MFG/WHO-GMP/DFDA/2018/04	09.03.2019
4.	Dorzolamide Eye drops IP 2% w/v	721/MFG/WHO-GMP/DFDA/2017/05	18.08.2017
5.	Ipratropium Bromide & Salbutamol Respirator Solution **Duolin Respules**	721/MFG/WHO-GMP/DFDA/2017/06	10.10.2017
6.	Salbutamol Respirator Solution **Asthalin Respules**	721/MFG/WHO-GMP/DFDA/2017/07	10.10.2017
7.	Dorzolamide Hydrochloride & Timolol Maleate Ophthalmic Solution **Dorzox-T Eye Drops**	721/MFG/WHO-GMP/DFDA/2017/10	10.10.2017
8.	Travoprost Eye Drops IP 0.004% w/v **Xovatra Eye Drops**	721/MFG/WHO-GMP/DFDA/2017/12	10.10.2017
9.	Loteprednol Etabonate & Tobramycin Ophthalmic Suspension **Tobaflam Eye Drops**	721/MFG/WHO-GMP/DFDA/2017/14	10.10.2017
10.	Beclomethasone Intranasal Solution **Beclate Aquanase**	721/MFG/WHO-GMP/DFDA/2019/17	10.10.2017
11.	Beclomethasone Dipropionate Aqueous Nasal Spray 0.1% w/v **Beclate Aquanase**	721/MFG/WHO-GMP/DFDA/2017/18	10.10.2017
12.	Mometasone Furoate Monohydrate Nasal Spray **Metaspray**	721/MFG/WHO-GMP/DFDA/2017/19	10.10.2017

No 330324

INDIAN CHAMBER OF COMMERCE AND INDUSTRY 10 OCT 2019 MUMBAI, INDIA

DIRECTORATE OF FOOD & DRUGS ADMN. BAMBOLIM-GOA

GOVT OF INDIA NOTARY GULABDHAR UPADHYAY GREATER MUMBAI STATE OF MAHARASHTRA REGN. NO. 7063

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13.	Fluticasone Propionate Aqueous Nasal Spray **Flomist**	721/MFG/WHO-GMP/DFDA/2017/20 (2)	11.12.2017
14.	Budesonide Inhalation Suspension 1mg/2ml **Budecort 1mg Respules**	721/MFG/WHO-GMP/DFDA/2018/21 (2)	25.04.2018
15.	Budesonide Nasal Spray 64 mcg **Budenase AQ 64 mcg/dose**	721/MFG/WHO-GMP/DFDA/2017/22	18.08.2017
16.	Levosalbutamol Inhalation Solution **Levoease Respules**	721/MFG/WHO-GMP/DFDA/2018/24 (01)	25.04.2018
17.	Ipratropium Bromide Aqueous Nasal Spray 0.03% w/v **Univent Nasal Spray**	721/MFG/WHO-GMP/DFDA/2017/25	03.10.2018
18.	Bimatoprost Ophthalmic Solution 0.01% w/v **Lowprost Eye Drops**	721/MFG/WHO-GMP/DFDA/2017/26	10.10.2017
19.	Travoprost and Timolol Maleate Ophthalmic Solution **XOVATRA T Eye Drops**	721/MFG/WHO-GMP/DFDA/2017/27	10.10.2017
20.	Salbutamol Inhalation IP(100mcg/ dose	721/MFG/WHO-GMP/DFDA/2017/29	10.10.2017
21.	Beclometasone and Salbutamol Inhaler **Aerocort HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/35	21.03.2018
22.	Levosalbutamol Inhaler 50mcg/dose **Levolin Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/37 (4)	23.01.2018
23.	Formoterol Fumarate Inhaler 12 mcg/dose **Foratec Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/38/1	11.12.2017
24.	Beclometasone Pressurised Inhalation BP 100mcg/dose **Beclate-100 Inhaler (CFC Free)**	721/MFG/WHO-GMP/DFDA/2017/39	16.11.2017
25.	Beclometasone Pressurised Inhalation BP 200mcg/dose **Beclate-200 Inhaler (CFC Free)**	721/MFG/WHO-GMP/DFDA/2017/40	16.11.2017
26.	Beclometasone Pressurised Inhalation BP 250mcg/dose **Beclate-250 Inhaler (CFC Free)**	721/MFG/WHO-GMP/DFDA/2017/41	06.09.2017
27.	Salbutamol Pressurised Inhalation BP 100 µg/dose **Asthalin HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/42	10.10.2017
28.	Beclometasone Pressurised Inhalation BP 50 µg/dose **Beclate-50 CFC Free**	721/MFG/WHO-GMP/DFDA/2017/43	16.11.2017
29.	Beclometasone Pressurised Inhalation BP	721/MFG/WHO-GMP/DFDA/2017/45 (1)	11.10.2017
30.	Beclometasone Pressurised Inhalation BP **Beclate-100 HFA**	721/MFG/WHO-GMP/DFDA/2017/46	21.03.2018
31.	Beclometasone Pressurised Inhalation BP **Beclate-250 HFA**	721/MFG/WHO-GMP/DFDA/2017/48	16.11.2018
32.	Beclometasone Pressurised Inhalation BP **Beclate-250 HFA**	721/MFG/WHO-GMP/DFDA/2017/48 (1)	08.03.2018
33.	Fluticasone Propionate Inhaler **Flohale-50 INHALER (CFC Free)**	721/MFG/WHO-GMP/DFDA/2017/51	20.02.2018

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10 OCT 2019
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Reg. No.7065
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34.	Flohale 125 mcg HFA Inhaler **Fluticasone 125 mcg HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/52 (3)	23.01.2018
35.	Fluticasone Propionate Inhaler **Flohale-250 INHALER (CFC Free)**	721/MFG/WHO-GMP/DFDA/2017/53	09.02.2018
36.	Salbutamol Pressurised Inhalation BP **ASTHALIN INHALER (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/54 (1)	11.12.2017
37.	Budesonide Inhaler (100 mcg/dose) **Budecort-100 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/55 (2)	10.08.2018
38.	Budesonide Inhaler (200 mcg/dose) **Budecort 200 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/56 (5)	10.08.2018
39.	Formoterol Fumarate & Budesonide Inhaler **Foracort-100 Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/57	20.07.2018
40.	Formoterol Fumarate & Budesonide Inhaler **Foracort-200 Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/58	20.07.2018
41.	Salbutamol & Ipratropium Bromide Inhaler **Duolin Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/65	09.11.2017
42.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 50 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/66 (2)	20.11.2017
43.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 125 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/67 (3)	20.11.2017
44.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 250 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/68 (5)	23.01.2018
45.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 50 Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/69 (3)	20.11.2017
46.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 125 Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/70 (5)	06.11.2017
47.	Salmeterol and Fluticasone Propionate Inhaler **Seroflo 250 Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/71 (3)	06.11.2017
48.	Salbutamol & Ipratropium Bromide Inhaler 100/20mcg/dose **Duolin HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/72	13.12.2017
49.	Salmeterol Inhaler (25mcg/dose) **Serobid Inhaler (CFC FREE)**	721/MFG/WHO-GMP/DFDA/2017/73	16.11.2017
50.	Salbutamol Pressurised Inhalation BP 100 µg/dose	721/MFG/WHO-GMP/DFDA/2017/74	16.11.2017
51.	Ciclesonide Inhaler 80mcg/dose **Ciclohale 80 inhaler**	721/MFG/WHO-GMP/DFDA/2017/75	29.09.2017
52.	Ciclesonide Inhaler 160 mcg/dose **Ciclohale 160 inhaler**	721/MFG/WHO-GMP/DFDA/2017/76	29.09.2017
53.	Fluticasone Propionate Inhaler 50 mcg **Flohale 50 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/80 (1)	11.10.2017
54.	Fluticasone Propionate Inhaler 125 mcg **Flohale 125 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/81	10.10.2017

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GOVT.

79.	Gabapentin Capsules USP 300 mg **CIPLAPENTIN 300**	721/MFG/WHO-GMP/DFDA/2017/219	20.12.2017
80.	Omeprazole Capsules 20 mg **LOMAC-20**	721/MFG/WHO-GMP/DFDA/2017/220	13.12.2017
81.	Fluconazole Capsules 150 mg **Pharmacist Fluconazole One**	721/MFG/WHO-GMP/DFDA/2017/222	02.11.2017
82.	Ipratropium Bromide Rotacap 40 mcg **Ipravent Rotacaps**	721/MFG/WHO-GMP/DFDA/2017/228	29.09.2017
83.	Tamsulosin Hydrochloride Modified Release Capsules 400 mcg **Urimax - 0.4 mg**	721/MFG/WHO-GMP/DFDA/2018/230 (01)	13.11.2018
84.	Duloxetine Hydrochloride Capsules 30 mg **Duocip-30**	721/MFG/WHO-GMP/DFDA/2018/231	20.07.2018
85.	Duloxetine Hydrochloride Capsules 60 mg **Duocip-60**	721/MFG/WHO-GMP/DFDA/2018/232	20.07.2018
86.	Tramadol Capsules BP 50 mg **TRAMACIP**	721/MFG/WHO-GMP/DFDA/2017/234	02.11.2017
87.	Lansoprazole Capsules 30 mg **Lansoloc OTC 30 mg**	721/MFG/WHO-GMP/DFDA/2017/237	20.12.2017
88.	Efavirenz Capsules 200 mg	721/MFG/WHO-GMP/DFDA/2018/242	20.02.2018
89.	Ribavirin Capsules 200 mg **Virocip- 200**	721/MFG/WHO-GMP/DFDA/2019/243	18.02.2019
90.	Fluticasone Propionate DP Caps 250 mcg **Flohale-250 DP Caps**	721/MFG/WHO-GMP/DFDA/2018/245	24.04.2018
91.	Salbutamol Sulphate DP Caps 200 mcg **Asthavent DP Caps**	721/MFG/WHO-GMP/DFDA/2018/246	24.04.2018
92.	Levofloxacin Tablets 250 mg **MYLAN – LEVOFLOXACIN 250 mg**	721/MFG/WHO-GMP/DFDA/2018/250	06.04.2018
93.	Levetiracetam Tablets 500 mg **ALVOTIRACETAM 500 MG**	721/MFG/WHO-GMP/DFDA/2018/259	09.02.2018
94.	Levetiracetam Tablets 1000 mg **ALVOTIRACETAM 1000 MG**	721/MFG/WHO-GMP/DFDA/2018/260	15.06.2018
95.	Bosentan Tablets 125 mg **BONTASS**	721/MFG/WHO-GMP/DFDA/2018/263	20.02.2018
96.	Trimetazidine Dihydrochloride Extended Release Tablets 35 mg **TRIMETAZIDINA ATB 35 MG**	721/MFG/WHO-GMP/DFDA/2019/264	20.05.2019

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10 OCT 2019
MUMBAI, INDIA

BAMBOLIM-GOA

55.	Fluticasone Propionate Inhaler 250mcg **Flohale 250 HFA Inhaler**	721/MFG/WHO-GMP/DFDA/2017/82	10.10.2017
56.	Fusidic Acid Cream BP **FUSIBACT**	721/MFG/WHO-GMP/DFDA/2017/32	19.09.2017
57.	Clotrimazole Vaginal Tablets USP 100 mg **CLOCIP – 100**	721/MFG/WHO-GMP/DFDA/2017/96	09.11.2017
58.	Donepezil Hydrochloride Tablets 5 mg	721/MFG/WHO-GMP/DFDA/2019/113	02.11.2017
59.	Donepezil Hydrochloride Tablets 10 mg	721/MFG/WHO-GMP/DFDA/2019/114	02.11.2017
60.	Secnidazole Tablets 1000 mg **ENTOSEC**	721/MFG/WHO-GMP/DFDA/2017/118	09.11.2017
61.	Clotrimazole Vaginal Inserts USP 100 mg **Fungicip-100**	721/MFG/WHO-GMP/DFDA/2017/120 (1)	26.12.2017
62.	Lamivudine Tablets 100 mg **LAMIVIR-HBV**	721/MFG/WHO-GMP/DFDA/2017/130 (2)	02.11.2017
63.	Lamivudine Tablets 150 mg Lamivir 150	721/MFG/WHO-GMP/DFDA/2018/135	28.07.2018
64.	Lamivudine Tablets 300 mg **Lamivir - 300**	721/MFG/WHO-GMP/DFDA/2018/136	15.06.2018
65.	Lamivudine and Stavudine Tablets **Lamivir – S 30**	721/MFG/WHO-GMP/DFDA/2017/140	16.11.2017
66.	Tenofovir Disoproxil Fumarate + Emtricitabine + Efavirenz Tablets **VIRADAY**	721/MFG/WHO-GMP/DFDA/2019/149	20.05.2019
67.	Tadalafil Tablets USP 20 mg	721/MFG/WHO-GMP/DFDA/2017/155 (1)	02.11.2017
68.	Tranexamic acid Tablets BP 500 mg **TRANFIB**	721/MFG/WHO-GMP/DFDA/2018/159 (01)	04.04.2018
69.	Norfloxacin Tablets USP **Utin – 400**	721/MFG/WHO-GMP/DFDA/2017/160	26.12.2017
70.	Clotrimazole Vaginal Cream USP 1 % w/w **Clozole Vaginal Cream**	721/MFG/WHO-GMP/DFDA/2017/177 (1)	02.11.2017
71.	Diclofenac Gel BP **Cofenac Gel**	721/MFG/WHO-GMP/DFDA/2017/178	02.11.2017
72.	Ketoconazole Cream 2 % w/w **Keto Cream**	721/MFG/WHO-GMP/DFDA/2017/181	09.11.2017
73.	Miconazole Nitrate Cream BP **Micogel Cream**	721/MFG/WHO-GMP/DFDA/2017/183	20.12.2017
74.	Piroxicam Gel BP 0.5%w/w **PIROX GEL**	721/MFG/WHO-GMP/DFDA/2017/185	26.12.2017
75.	Terbinafine Hydrochloride Cream **TERBIFIN**	721/MFG/WHO-GMP/DFDA/2018/193 (01)	14.01.2019
76.	Nevirapine Tablets IP 200 mg **Nevimune**	721/MFG/WHO-GMP/DFDA/2017/201	02.11.2017
77.	Aciclovir Cream BP **Acivir Cream**	721/MFG/WHO-GMP/DFDA/2017/202	02.11.2017
78.	Nevirapine Tablets USP 200 mg **Nevimune**	721/MFG/WHO-GMP/DFDA/2018/214	09.03.2018

No 33084
10 OCT 2019
MUMBAI, INDIA
BAMBOLIM-GOA

97.	Efavirenz Tablets 600 mg	721/MFG/WHO-GMP/DFDA/2017/267	29.09.2017
98.	Bosentan Tablets 62.5 mg **BOSENTAS 62.5**	721/MFG/WHO-GMP/DFDA/2017/270 (01)	20.11.2017
99.	Montelukast Tablets 10 mg **MONTIDE**	721/MFG/WHO-GMP/DFDA/2017/274 (2)	26.12.2017
100.	Nifedipine Extended Release **Tablets 30 mg**	721/MFG/WHO-GMP/DFDA/2018/279	09.03.2018
101.	Esomeprazole Magnesium Dihydrate Tablets 40 mg **ESOMAC 40 MUPS**	721/MFG/WHO-GMP/DFDA/2018/282 (09)	26.09.2018
102.	Montelukast Chewable Tablets 4 mg **MONTIDE**	721/MFG/WHO-GMP/DFDA/2017/287 (2)	26.12.2017
103.	Montelukast Sodium Tablets 5 mg	721/MFG/WHO-GMP/DFDA/2019/288	18.02.2019
104.	Clopidogrel Tablets USP 75 mg **CLOPICIP**	721/MFG/WHO-GMP/DFDA/2017/298	29.09.2017
105.	Donepezil Hydrochloride Tablets 5 mg **DESENIL – 5**	721/MFG/WHO-GMP/DFDA/2019/113 / (02)	26.02.2019
106.	Donepezil Hydrochloride Tablets 10 mg **DESENIL – 10**	721/MFG/WHO-GMP/DFDA/2019/114 / (02)	26.02.2019
107.	Fluconazole Capsules 200 mg **FORCAN-200**	721/MFG/WHO-GMP/DFDA/2017/309	02.11.2017

DIRECTORATE OF FOOD & DRUGS ADMINISTRATION PANJIM-GOA

(Jyoti J. Sardesai)
Director
Food and Drugs Administration

Cc: - To,
The Deputy Drugs Controller- India,
4th Floor, Zonal FDA Bhawan,
GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai – 400 008.

GULABDHAR UPADHYAY NOTARY GREATER MUMBAI Reg. No. 7053 GOVT. OF INDIA

No 33094

ATTESTED BY ME
18/10/19
GULABDHAR UPADHYAY
ADVOCATE & NOTARY
Chhabineth Pandey Compound
Marol Naka, Near Airport Road
Andheri (East), Mumbai-400059

IMC CHAMBER OF COMMERCE AND INDUSTRY
10 OCT 2019
MUMBAI, INDIA

ATTESTED
AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

Shailesh Joshi
Sr. Executive Asst.

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

Ministry of External Affairs no responsibility for the contents of the above documents

This public document

COMMERCIAL DOCUMENT

has been signed by N/A

acting in the capacity of N/A

bears the seal/stamp of ASST. DIRECTOR, IMC CHAMBER OF COMMERCE AND INDUSTRY, MUMBAI

Certified

at NEW DELHI, INDIA the 16-Oct-2019

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0018592219

Seal / Stamp

Signature

is issued to CIPLA LTD

(सुनील चनाना)
(SUNIL CHANANA)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 03.12.2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/PD/67677/2018/11/25860**

On the basis of the inspection carried out on **19/02/2018, 20/02/2018 and 07/09/2018** ,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 of the Firm : **CIPLA LTD.**
   Address : **D-7, M.I.D.C., INDUSTRIAL AREA, KURKUMBH, TAL: DAUND PUNE 413802 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PD46 In Form 25, PD42 In Form 26**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Oral Powders / Granules / Pellets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Paste	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Soft Gelatin Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Suppositories	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
1 2			

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 21 Nov 2021 . 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.

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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bendra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
IPIC1306767720181122

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**22 Nov 2018**

22 NOV 2018

MAHARASHTRA STATE

MIC CHAMBER OF COMMERCE AND INDUSTRY
24 JUN 2019
MUMBAI, INDIA

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Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 03.12.2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/PD/67677/2018/11/25860**

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   Address : **D-7, M.I.D.C., INDUSTRIAL AREA, KURKUMBH, TAL: DAUND PUNE 413802 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PD46 In Form 25, PD42 In Form 28**

14177

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
7	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 21 Nov 2021 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/6
Fax: +91-22-26591959
1PIC1306767720181122

Name of the Authorised person : **A. T. NIKHADE**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:22 Nov 2018

JIGNA KOTHARI
Asst. Director

ATTESTED

AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

22 NOV 2018

TRUE COPY

GAURAV K. LAMBAT

1 JUN 2019

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

94177

IMC CHAMBER OF COMMERCE AND INDUSTRY
24 JUN 2019
MUMBAI, INDIA

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 A.T NIKHADE

acting in the capacity of JT. COMMISSIONER

bears the seal/stamp of ASST. DIRECTOR, IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA

Certified

at NEW DELHI, INDIA the 28-Jun-2019

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0003395719

Seal / Stamp

Signature

is issued to CIPLA LTD.

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

2 copy

1041

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 19 DEC 2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/KD/73115/2018/11/26155**

On the basis of the inspection carried out on **08/08/2018,09/08/2018 and 10/08/2018** ,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 of the Firm : **CIPLA LIMITED**
   Address : **PLOT NOS. A-2, A-33 & A-37/2/2, M.I.D.C., PATALGANGA, RAIGAD 410220 MAHARASHTRA STATE, INDIA**
2. Licence No. : **845 In Form 25, 707 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 16 Dec 2021 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591969
E-mail: 73115201812...

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:17 Dec 2018

73149

17 DEC 2018

TRUE COPY

17 JUN 2019

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
   List the dosage forms, starting materials, categories and activities. Examples are given below.

   Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

   Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

   Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/73115/2018/11 /26155 **VALID UP TO :16 Dec 2021**

Name of Manufactring Firm : CIPLA LIMITED
PLOT NOS. A-2, A-33 & A-37/2/2, M.I.D.C.,
PATALGANGA, RAIGAD 410220 MAHARASHTRA
STATE, INDIA

Drug License No : 845 In Form 25, 707 In Form 28

Sr.No.	Name of the Product	Composition
1	A.Phenylephrine Hydrochloride and Paracetamol Tablets 5/500 mg(Day time tablet) (for Terry White Chemists Sinus Relief Day Night PE Tablets)(Kit)(Each strip contains 4 tablets of Day time)	Each Film coated tablet contains: Phenylephrine Hydrochloride BP/Ph.Eur 5 mg Paracetamol BP/Ph.Eur 500 mg Colour:Red Oxide of Iron, Titanium Dioxide
2	A.Phenylephrine Hydrochloride and Paracetamol Tablets 5/500 mg(Day time tablet)(for Chemmart Pharmacy Sinus Relief Day Night PE)(Kit) (Each strip contains 4 tablets of Day time)	Each film-coated tablet contains : Phenylephrine Hydrochloride BP/Ph.Eur 5 mg Paracetamol BP/Ph.Eur 500 mg Colour:Red Oxide of Iron, Titanium Dioxide
3	Abacavir (as sulfate) and Lamivudine Dispersible Tablets 120/60 mg	Each uncoated dispersible tablet contains: Abacavir Sulfate USP equivalent to Abacavir 120 mg Lamivudine USP 60 mg Aspartame 12 mg
4	Abacavir (as sulfate) and Lamivudine Dispersible Tablets 60/30 mg	Each uncoated dispersible tablet contains: Abacavir Sulfate USP equivalent to Abacavir 60 mg Lamivudine USP 30 mg
5	Abacavir (as Sulfate) and Lamivudine Tablets 600/300 mg	Each film-coated tablet contains: Abacavir Sulfate equivalent to Abacavir 600 mg Lamivudine USP 300 mg Colour:Sunset Yellow FCF, Titanium Dioxide
6	Abacavir (as sulfate) and Lamivudine Tablets 600/300 mg	Each film-coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 600 mg Lamivudine USP 300 mg Colour:Sunset Yellow FCF, Titanium Dioxide
7	Abacavir and Lamivudine Tablets for Oral Suspension 120 / 60 mg (Export to Lesotho, Ethiopia, Zimbabwe, Nigeria)	Each uncoated tablet contains: Abacavir Sulfate USP 140.6 mg equivalent to Abacavir 120 mg Lamivudine USP 60 mg
8	Abacavir and Lamivudine Tablets for Oral Suspension 120 / 60 mg (Export to Myanmar)	Each uncoated tablet for oral suspension contains: Abacavir Sulfate USP 140.6 mg equivalent to Abacavir 120 mg Lamivudine 60 mg

1 2 3 4 5 6 7 8 9 10

Address of certifying authority :
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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1PIC161731520181217

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:17 Dec 2018

13149

ATTESTED 17 DEC 2018

ROHIT YADAV IMC CHAMBER OF COMMERCE AND INDUSTRY

17 JUN 2019

Ministry of External Affairs
no responsibility for the
contents of the above documents.

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी.पी.वी. प्रभाग/C.P.V. Division