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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

GAURAV K. LAMBAT

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

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Tel: +91-22-26592363/64
Fax: +91-22-26591959
1PIC/161731152018/217

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


भारत सरकार GOVERNMENT OF INDIA
Ministry of External Affairs
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 MANAGER, IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA
Certified
at NEW DELHI, INDIA the 25-Jun-2019
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0002976519
Seal / Stamp
Signature
is issued to CIPLA LTD.
MINISTRY OF EXTERNAL AFFAIRS
M/o568
(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी.पी.वी. प्रभाग/C.P.V. Division