Ph.No.:0832-2459230 / 2459226
Tele.Fax: 0832-2459223
Website : www.dfda.goa.gov.in

No. 789/MFG/WHO-GMP/DFDA/2019/ 737
Dte. of Food & Drugs Admn.,
Government of Goa,
"DHANWANTARI",
Opposite Shrine of the Holy Cross,
Bambolim, Goa – 403 202
Dated: 28/5/19

CERTIFICATE

On the basis of the inspection carried out on 12/12/2018 to 14/12/2018 and 18/12/2018, 20/12/2018 & 21/12/2018 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 and address of site:
M/s Cipla Ltd. Plot No.S-103 to S- 105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna-Goa

2. Manufacturer's license number:
611 in Form 28
616 in Form 25
749 in Form 28-D

NOTARY RAM JI PANDEY Malad (W), Mumbai Maharashtra Reg. No. 10138 Expiry Dt. 10/09/23 GOVT. OF INDIA

3.Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Liquid Injections	Cytotoxic *	Production, packaging, quality control
	Hormone *	
Lyophilized Injection	Cytotoxic *	
Liposome Injection	Cytotoxic *	
Nano particle Injection	Cytotoxic *	
Tablets	Cytotoxic *	
	General	
	Hormone *	
Hard gelatin Capsules/Dry powder Inhalation	Cytotoxic *	
	General	
	Hormone *	
Soft gelatin capsules	Cytotoxic *	
Topical Preparations	Hormone *	

*** Manufactured in Dedicated facilities.**

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 **19.05.2022** 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:
Director, Directorate of Food & Drugs Administration, Govt. of Goa, "DHANWANTARI", Opposite Shrine of The Holy Cross, Bambolim, Goa – 403 202, INDIA

Name and function of responsible person:
Mr. Jyoti J. Sardesai, Director
Email:Website: www.dfda.goa.gov.in Telephone No.:**0832 – 2459230, 2459226** Fax no.:**0832-2459223**

Signature: Jeedesai

Stamp and date: 28 MAY 2019

DIRECTORATE OF FOOD & DRUGS ADMN. BAMBOLIM-GOA

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

INC CHAMBER OF COMMERCE AND INDUSTRY 09 JUN 2020 MUMBAI-INDIA

Mrs. JIGNA KOTHARI
Asst. Director

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Ministry of External Affairs
does not assume any responsibility for the contents of the above documents.

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 ASSTT. DIRECTOR, IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA

Certified

at NEW DELHI, INDIA *the* 06-Jul-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0010246020

Seal / Stamp

Signature

is issued to CIPLA LTD.

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS
भारत सरकार, नई दिल्ली GOVT. OF INDIA, NEW DELHI
सं० 568

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

[1]This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

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 case 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 give below.

Example 1

Pharmaceutical Products (s)[2]	Category(ies)	Activity(ies)
Dosage form(s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labeling
Injectables	Cefalosporin	Aseptic preparation, packaging, labeling

Example 2

Pharmaceutical Products(s)[2]	Category(ies)	Activity(ies)
Starting materials(s).3		
Paracetamol	Analgesic	Synthesis, purification, packing, labeling

[2] Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

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

(5) The Certificate remains valid until the specifies date: The certificate becomes invalid if the activities and/or categories certifies are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices in 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.

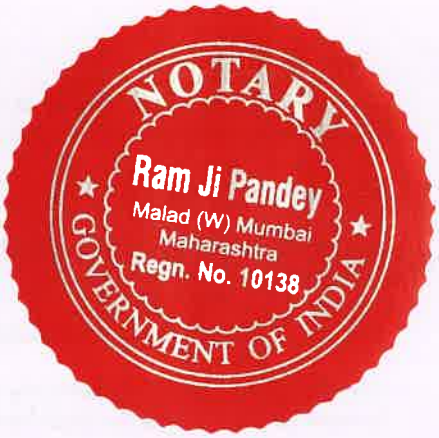
NOTARY RAM JI PANDEY Malad (W), Mumbai Maharashtra Reg. No. 10138 Expiry Dt. 10/09/23 GOVT. OF INDIA

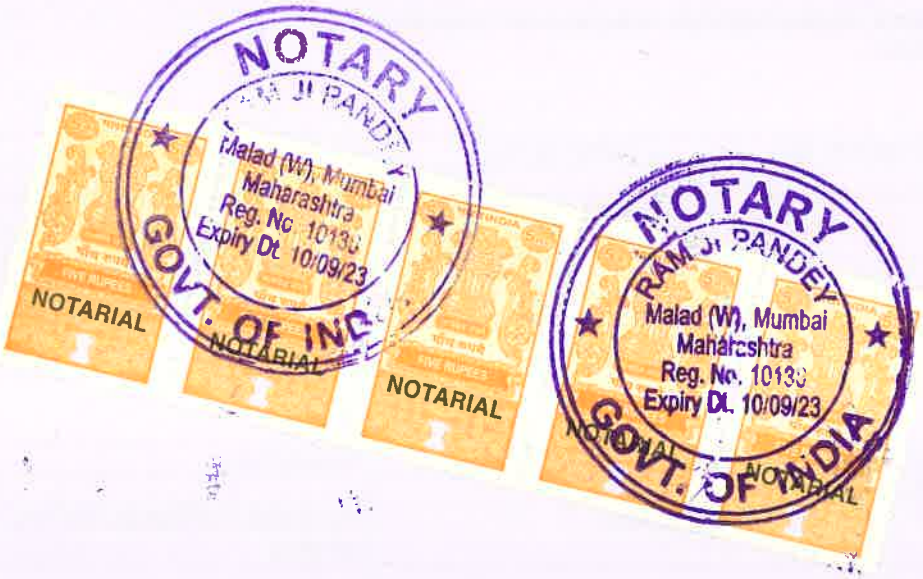
09 JUN 2020

Jyoti J. Sardesai
Director, Food & Drugs Administration

ATTESTED BY ME
17/06/2020

RAM JI PANDEY
ADVOCATE & NOTARY
GOVT. OF INDIA
Kharodi Village, Malwani,
Malad (W), Mumbai-400 095.


NOTARY
Ram Ji Pandey
Malad (W) Mumbai
Maharashtra
Regn. No. 10138
GOVERNMENT OF INDIA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