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No: 831/MFG/WHO-GMP/DFDA/2019/ 3071
Government of Goa,
Dte. of Food & Drugs Admn,
DHANWANTARI,
Opp. The Shrine Of Holy Cross,
Bambolim, Goa – 403202
Dated: 13 / 4 /2019

CERTIFICATE

On the basis of the inspection carried out on **9th April 2019 to 11th April 2019** 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. M-61, M-62 & M-63, Verna Industrial Estate, Verna – Goa

2. Manufacturer's license number:
   704 in Form 28
   744 in Form 28-D

3. Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Liquid Injections	General	Production, Packaging, Quality Control
Lyophilized Injection	General	
Prefilled Syringe	General	

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 **20th October 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:
Directorate of Food & Drugs Administration, Govt. of Goa, DHANWANTARI', Opp. Shrine of The Holy Cross, BAMBOLIM, GOA – 403202, INDIA

Name and function of responsible person:
Jyoti J. Sardesai, Director

Email: -- Telephone no.: **(0832)-2459230, 2459226** Fax no.: **(0832)-2459223**
Website: **www.dfda.goa.gov.in**

Jyoti J. Sardesai
Director, Food & Drugs Admn.
Bambolim Goa

[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)		
	Cytotoxic	Packaging
Tablets	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 Pharmceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organisation, Geneva and subsequent updates.