

**OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

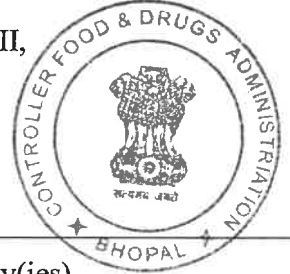
This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).¹

Certificate No.03/2010

Valid up to: **13 JUN 2025**

Based on the inspection carried out on **29th & 30th Mar 2022** 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.

Name and address of site: M/s. Cipla Limited
Plot no. 9 & 10, Indore Special Economic Zone, Phase – II,
Pithampur, Dist. Dhar, Pin code 454775
Madhya Pradesh, India.



1. Manufacturer's License number: **25 / 2 / 2010 (Form-25)**
28 / 2 / 2010 (Form-28)

2. Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Liquid orals	General	Production, Packing, Labelling, Quality Control
Respiratory Solution / Suspension (Unit dose)	General	Production, Packing, Labelling, Quality Control
Eye drops (Multiple dose)	General	Production, Packing, Labelling, Quality Control
Metered Dose Inhalers	General	Production, Packing, Labelling, Quality Control
Nasal Preparation (Solution / Suspension) Unit Dose Nasal Spray	General	Production, Packing, Labelling, Quality Control
Tablets (Uncoated /coated tablets, Effervescent granules / tablets)	General	Production, Packing, Labelling, Quality Control
Capsules (Hard Gelatin Capsules)	General	Production, Packing, Labelling, Quality Control
Granules, Powders, Pellets, Dry Powder Inhalers.	General	Production, Packing, Labelling, Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

3. This certificate remains valid until **13 JUN 2025** 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:

Office of the Controller
Food & Drug Administration
Idgah Hills, Bhopal (Madhya Pradesh)
Telephone No.: 0755-2666058
Fax No. : 0755-2665385

Name of authorized person:

Signature:

Stamp and date:

**Licensing Authority,
Food & Drugs Administration
Idgah Hills,
Bhopal (Madhya Pradesh)**

14 JUN 2022

SHOBHIT
Dy. Drugs Controller
State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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) 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, Labelling



Example 2.

Pharmaceutical Product(s) ²	Category(ies)	Activity(ies)
Starting material(s): ³		
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 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.