Office of the Controller Food and Drugs Administration

Madhya Pradesh, Idgah Hills, Bhopal (M.P.)-462001
Tel: 0755-2665385, E-mail: cfdamp@rediffmail.com, fdampbhopal@gmail.com

No. V/WHO-GMP/Grant/M-1/2024 | 6782 **Bhopal dated** 30/10/2024

To,

M/s Mylan Laboratories Limited,
Plot No. 11, 12 & 13, Indore SEZ,
Phase-II, Pharma Zone, Sector-III,
Pithampur, District - Dhar (M.P.)

Sub: - Issue of Model Certificate of WHO GMP.

Please find enclosed herewith the Model Certificate as desired.

Encl.: As above

30/10/Dcrs

Deputy Drugs Controller
&
Licensing Authority
Food and Drugs Administration
Madhya Pradesh

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

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

Certificate No: **07/2014** **Valid up to** 29 OCT 2027

On the basis of the inspection carried out on **14.10.2024 and 15.10.2024,** 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. Mylan Laboratories Limited, Plot No. 11, 12 & 13, Indore SEZ, Phase-II, Pharma Zone, Sector-III, Pithampur, Dist. Dhar, Madhya Pradesh-454775, INDIA**

2. Manufacturer's licence number: **25/1/2014 & 28/1/2014 in Form - 25 & 28 Dated 17/01/2014.**

3. Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
TABLETS, CAPSULES & DRY POWDER/ GRANULES FOR ORAL SUSPENSION	General (Other Than Penicillin, Cephalosporin, Hormones & Cytotoxic	Production, Packing & Labeling, Quality Control
TABLETS	Hormones	Production, Packing & Labeling, Quality Control

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 29 OCT 2027 . 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:

Office of the Controller
Food & Drug Administration
Idgah Hills, Bhopal (Madhya Pradesh)
E-mail ID : cfdamp@rediffmail.com
Telephone No.: 0755-2666058
Fax No. : 0755-2665385

Name of authorized person: Shobhit

Signature:

Stamp and date:

Shobhit
Dy. Drugs Controller
& Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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

30 OCT 2024

[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 Product(s)[2]	***Category(ies)***	***Activity(ies)***
Dosage form(s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labelling
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.

[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.