OFFICE OF THE CONTROLLER, FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. :V/WHO-GMP/M-2/2018/ 5862 **Bhopal, dated:** 26-11-18

To,

M/s Mylan Laboratories Limited,

Plot No.11, 12 & 13, Indore SEZ, Pharma Zone,

Phase-II, Sector-III, Pithampur-454775, Dist. Dhar

Madhya Pradesh

Sub. : Revalidation of Certificate of Pharmaceutical Products.

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Please find enclosed herewith the Certificate of Pharmaceutical products under WHO-GMP Certification Scheme under **Certificate No. 7/2014**, Valid up 27 NOV 2021 in respect of finished Drugs granted as per list enclosed under license no. **25/1/2014** in **Form 25** and **28/1/2014** in **Form 28** as per recommendation by the office of the Deputy Drugs Controller (I) CDSCO Sub Zone, Indore vide letter No. **SZI/2017/COPP/Mylan/001/1063-64 dated 12.10.2018.**

Total No. of Items: 43

Enclosed; As Above.

22/11/18

LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

Endt. No. :V/WHO-GMP/M-2/2018/ **Bhopal, dated:**

Copy to;

1. The Asst. Drug Controller (India)Sub zonal office, 67-72, Type-I Griffins Colony, M.Y. Hospital to Piplyahana Main Road, Near St. Raphael's School – Indore -452 001
2. Drug Inspector, Food and Drugs Administration, District – Dhar (M.P.) for Information.

LICENSING AUTHORITY
FOOD & DRUG ADMINISTRATION
MADHYA PRADESH

Digitally signed by Dicusar Vladimir
Date: 2021.09.13 11:46:50 EEST
Reason: MoldSign Signature
Location: Moldova

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION MADHYA PRADESH

No.: V/WHO-GMP/M-2/2018/ **Bhopal, dated**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This one page certificate conforms to the format recommended by the World Health Organization (general instruction and explanatory notes attached)

Certificate No. 07/2014

On the basis of the inspection carried out on dated 22/09/2018, 24/09/2018 & 25/09/2018, 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 Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh.**

2. Manufacturer's License 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

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 **21/11/2021**. 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: **Idgah Hills, Bhopal**

Name and function of responsible person: **Licensing Authority**
Food & Drugs Administration,
Idgah Hills, Bhopal (M.P.)
Email: cfdamp@rediffmail.com
Telephone No. 0755-2666058
Fax No.0755-2665385

6/12/18
Shobhit Koshta
Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

Signature
Stamp and date

[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 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, 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 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 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.

Annexure I

Mylan Laboratories Limited
Plot No. 11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II,
Sector- III, Pithampur- 454775, Dist.: Dhar, Madhya Pradesh, INDIA

Certificate No. 07/2014

11	**Sulfamethoxazole and Trimethoprim Tablets USP 800mg/160mg**	Each tablet Contains: Sulfamethoxazole Ph. Eur. 800 mg Trimethoprim Ph. Eur. 160 mg
12	**Sulfamethoxazole and Trimethoprim Tablets USP 400mg/80mg**	Each tablet Contains: Sulfamethoxazole Ph. Eur. 400 mg Trimethoprim Ph. Eur. 80 mg
13	**Tenofovir Alafenamide Tablets 25mg [HepBest]** (Trade Name Given by Manufacturer)	Each tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25mg
14	**Lamivudine and Zidovudine Tablets USP 150mg/300mg [ZOVILAM] (Trade Name Given by Manufacturer)**	Each film coated tablet Contains:Lamivudine USP 150 mg Zidovudine USP 300 mg
15	**Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/ 25mg/50mg[KOCITAF]** (Trade Name Given by Manufacturer)	Each film coated tablet Contains:Emtricitabine 200 mgTenofovir Alafenamide Fumarate equivalent toTenofovir Alafenamide 25 mgDolutegravir Sodium equivalent to Dolutegravir 50 mg
16	**Emtricitabine and Tenofovir Alafenamide Tablets 200mg/25mg**	Each tablet Contains: Emtricitabine 200 mg Tenofovir Alafenamide Fumarate Equivalent to Tenofovir Alafenamide 25 mg

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

Mylan Laboratories Ltd. Plot 13

22/11/18

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh