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/M-1/2024/ 6784 **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,
Dist. Dhar, Madhya Pradesh – 454775, INDIA.

Sub: - Issue of **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. 07/2014**, Valid up **to** 29 OCT 2027 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 /(Pt -2) / 859 dated 21.10.2024.**

Enclosed; As Above.

30/10/2024

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

Endt. No. : V/WHO-GMP/M-1/2024/ **Bhopal, dated:**

Copy to;

- The Deputy Drugs Controller (India), CDSCO Sub Zone Indore, CDSCO BHAWAN, GPO Square, Residency Area A.B. Road Indore (M.P.), Pin. Code – 452001.
- Drug Inspector, Food and Drugs Administration, District – Dhar (M.P.) for Information.

sd/-

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

OFFICE OF THE CONTROLLER, FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH
CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (WHO).
(General instructions and explanatory notes are attached.)

No. of Certificate: 07/ 2014 **Valid Up To:** 29 OCT 2027

Exporting (Certifying) Country : INDIA

Importing (Requesting) Country(s) : AS PER ANNEXURE – "A" ATTACHED

1. Basic information

1.1 Name and dosage form of the product: As per Appendix I

1.2 Composition:

Active ingredient(s) and amount(s) per unit dose[1]: As per Appendix I

For complete composition including all excipients, see attached.[1] As per Appendix I

1.3 Is this product authorized by the Exporting (Certifying) authority to be marketed in the Exporting (Certifying) country or within the jurisdiction of the certifying regional authority? Yes ☒ No ☐

1.3.1 Are there restrictions of the sale, distribution or administration of the product specified in the Product License?
Yes ☐ No ☒ See attached information if Yes.

1.4. Is this product actually on the market in the Exporting (Certifying) country or within the jurisdiction of the certifying regional authority?
Yes ☒ No ☐ Unknown ☐

Sections 2A and 2B below are mutually exclusive, therefore:

- If the answer to 1.3 above is yes, continue with section 2A and omit section 2B.
- If the answer to 1.3 above is no, omit section 2A and continue with section 2B.

2. Information on Marketing authorization

2.A Product that is authorized for marketing by the certifying authority

2.A.1 Number of Product License and date of issue: **25/1/2014 dated 29/04/2022**

2.A.2 Product License holder (name and address):
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.A.3 Status of Product License holder (one of the options of 3.1, if manufacturer, or specify the status as importer or any other):
a ☒ b ☐ c ☐ d ☒ e ☒ f ☒ g ☒ h ☐

2.A.4. Is a summary basis for approval appended?
Yes ☐ No ☒
See attached information if answer is Yes.

2.A.5. Is the attached officially approved product information complete and consistent with the Product License (such as the Summary of Product Characteristics – SPC- or similar)?
Yes ☐ No ☐ Not Provided ☒
See attached information if answer is Yes.

2.A.6. Name and address of applicant for the certificate as provided by the Marketing authorization holder, if different: Not Applicable

2.A.7. Web-link to the product Marketing authorization information (if available) Not Available

2.B Product that is not authorized for marketing by the certifying authority

2.B.1. Applicant for certificate (name and address):
Not Applicable

2.B.2. Why is Marketing authorization lacking?

Not Required	☐
Not Requested	☐
Under Consideration	☐
Refused	☐
Withdrawal for commercial reasons	☐
Withdrawal for sanitary reasons	☐

2.B.3. Reason provided by the applicant for not requesting registration
(a) The product has been developed exclusively for the treatment of conditions *(e.g. tropical diseases – not endemic in the exporting country):*
(b) The product has been reformulated - *please specify:*
(c) Any other reason, *please specify:*

3. Information on manufacturing and inspections

3.1. List of name and address of the manufacturing site(s) and activities:

Name of manufacturing site	Address	Activity			
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	a) manufacturing of all steps of the finished pharmaceutical product (FPP);	☒	e) batch release of the FPP;	☒
		b) manufacturing the bulk finished product;	☐	f) primary packaging of the dosage form;	☒
		c) manufacturing of solvent and diluents;	☐	g) secondary packaging of the product;	☒
		d) quality control of the FPP;	☒	h) other(s) (specify and list in new arrows).	☐

3.2 Does the certifying authority arrange for periodic inspection of the manufacturing site in which the of the FPP is produced? If not, proceed to question 4. Yes ☒ No ☐

3.3 Periodicity of routine inspections (years): **Once in a year**

3.4. Has the manufacturer of the dosage form of the FPP been inspected? Yes ☒ No ☐
If Yes, when feasible, insert date of inspection(s) (14/10/2024 & 15/10/2024)

3.5 Do the facilities and operations of the manufacturer of the FPP conform to good manufacturing practices (GMP) as recommended by WHO? Yes ☒ No ☐

3.6. It is recommended that for products approved, but not manufactured in the country of the certifying authority, the source of information that assures the GMP compliance of the manufacturer(es) is declared Yes ☒ No ☐

4.0 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
Yes ☒ No ☐ If the answer is No, please explain:

Address of certifying authority:
Office of the Controller,
Food & Drugs Administration,
Bhopal, Madhya Pradesh, India
Telephone Number: 0091 0755-2665385,
Fax number: 0091 0755-2665385
Website: www.cfdamp.nic.in; Email: cfdamp@rediffmail.com

Name of the Authorized Person:

Signature:

Stamp and Date:

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

30 OCT 2024

Cont.. 02/03

ANNEXURE- (A) WHO GMP CERTIFICATE

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

Name and Address of Manufacturer: **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.

Name of the Product: As per "Appendix – I" enclosed

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P. BHOPAL

List of Countries where the product will be exported

Sr. No.	Country	Sr. No	Country	Sr. No.	Country	Sr. No.	Country
1	Afghanistan	31	Brunei	61	Ecuador	91	Honduras
2	Albania	32	Brunei Darussalam	62	Egypt	92	Hong Kong
3	Algeria	33	Bulgaria	63	El Salvador	93	Hungary
4	Andorra	34	Burkina Faso	64	England	94	Iceland
5	Anglia	35	Burundi	65	Equatorial Guinea	95	Lithonia
6	Angola	36	Cambodia	66	Erites	96	India
7	Anguilla	37	Cameroon	67	Eritrea	97	Indonesia
8	Antigua	38	Canada	68	Estonia	98	Iran
9	Antigua & Barbuda	39	Cape Verde	69	Ethiopia	99	Iraq
10	Argentina	40	Cayman Islands	70	Fiji Island	100	Ireland
11	Armenia	41	Central African Republic	71	Finland	101	Israel
12	Aruba	42	Chad	72	France	102	Italy
13	Australia	43	Czechoslovakia	73	French Guiana	103	Ivory Coast
14	Austria	44	Chile	74	Gabon	104	Jamaica
15	Azerbaijan	45	China	75	Gambia	105	Japan
16	Bahamas	46	Colombia	76	Georgia	106	Jordan
17	Bahrain	47	Comoros	77	Germany	107	Kazakhstan
18	Bangladesh	48	Congo	78	Ghana	108	Kenya
19	Barbados	49	Costa Rica	79	Global Fund	109	Kiribati
20	Belarus	50	Coste D'Ivoire	80	Grand Cayman	110	Korea
21	Belgium	51	Croatia	81	Greece	111	Kosovo
22	Belize	52	Cuba	82	Grenada	112	Kurdistan
23	Belorussia	53	Curacao	83	Guadeloupe	113	Kuwait
24	Benin	54	Cyprus	84	Guatemala	114	Kyrgyzstan
25	Bermuda	55	Czech Republic	85	Guinea	115	Lao People's Democratic Rep
26	Bhutan	56	Denmark	86	Guinea-Bissau	116	Laos
27	Bolivia	57	Djibouti	87	Guyana	117	Latvia
28	Botswana	58	Dominica	88	Haiti	118	Lebanon
29	Brazil	59	Dominican Republic	89	Herzegovina	119	Leon
30	British Virgin Islands	60	East Timor	90	Holland	120	Lesotho
121	Liberia	152	Netherlands Antilles	183	Saudi Arabia	215	Togo
122	Libya	153	New Zealand	184	Senegal	216	Tongo
123	Liechtenstein	154	Nicaragua	185	Serbia	217	Trinidad & Tobago
124	Lithuania	155	Niger	186	Seychelles	218	Tunisia
125	Luxembourg	156	Nigeria	187	Sierra -Leone	219	Turkey
126	Macau	157	North Korea	188	Singapore	220	Turkmenistan
127	Macedonia	158	Norway	189	Slovak Republic	221	Turks & Caicos Islands
128	Madagascar	159	Oman	190	Slovenia	222	UAE
129	Malawi	160	PAHO	191	Solomon Island	223	Uganda
130	Malaysia	161	Pakistan	192	Somalia	224	Ukraine
131	Maldives	162	Palau	193	South Africa	225	Ulan Battar
132	Mali	163	Palestine	194	South Korea	226	UNHCR
133	Malta	164	Panama	195	Spain	227	UNICEF

Cont.. 03/03

ANNEXURE- (A) WHO GMP CERTIFICATE

No. of Certificate:- 07/2014

Valid up to: 29 OCT 2027

Name and Address of Manufacturer: **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.

Name of the Product: As per "Appendix – I" enclosed

List of Countries where the product will be exported

134	Marshall Islands	165	Papua New Guinea	196	Sri Lanka	228	United Kingdom
135	Martinique	166	Paraguay	197	St. Kittie	229	UNOPS
136	Mauritania	167	Peru	198	St. Kitts & Nevis	230	Uruguay
137	Mauritius	168	Philippines	199	St. Lucia	231	US
138	MCGM	169	Poland	200	St. Martin	232	Uzbekistan
139	Mexico	170	Porte Rico	201	St. Vincent	233	Vanuatu
140	Moldova	171	Portugal	202	St. Vincent & the Grenadines	234	Vatican City
141	Monaco	172	Qatar	203	Sudan	235	Venezuela
142	Mongolia	173	Republic of Congo	204	Suriname	236	Vientiane
143	Monserrat	174	Republic of South Africa	205	Sweden	237	Vietnam
144	Montenegro	175	Reunion	206	Switzerland	238	Western Samoa
145	Morocco	176	RITES	207	Syria	239	WHO
146	Mozambique	177	Romania	208	Taiwan	240	Yemen
147	Myanmar	178	Russia	209	Tajikistan	241	Yugoslavia
148	Namibia	179	Rwanda	210	Tanzania	242	Zaire
149	Nauru	180	Samoa	211	Chad [Tchad]	243	Zambia
150	Nepal	181	San Marino	212	Thailand	244	Zimbabwe
151	Netherland	182	Sao Tome and Principe	214	Timor Leste		

CONTROLLER FOOD & DRUGS ADMINISTRATION

Address of certifying authority:
Office of the Controller,
Food & Drugs Administration,
Bhopal, Madhya Pradesh, India
Telephone Number: 0091 0755-2665385,
Fax number: 0091 0755-2665385
Website: www.cfdamp.nic.in; Email: cfdamp@rediffmail.com

Name of the Authorized Person:

Signature:

Stamp and Date:

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

30 OCT 2024

No. of Certificate: 07/ 2014 **Appendix I** **Valid Up To: 29 OCT 2027**

List of Products Proposed for WHO GMP Certification

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

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P. BHOPAL

S. No.	Product Details	Label Claim
24	Dolutegravir, Lamivudine, Tenofovir Disoproxil Fumarate Tablets 50mg /300mg/ 300mg [ACRIPTEGA] (Trade Name Given by Manufacturer) (For Export)	Each film coated tablet Contains: Dolutegravir (as Dolutegravir Sodium) 50 mg Lamivudine USP 300 mg Tenofovir Disoproxil Fumarate (equivalent to 245mg of Tenofovir Disoproxil) 300 mg
25	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets IP 50 mg /300 mg /300 mg [ACRIPTEGA] (Trade Name Given by Manufacturer)	Each film coated tablet Contains: Dolutegravir (as Dolutegravir Sodium) IP 50 mg Lamivudine IP 300 mg Tenofovir Disoproxil Fumarate (Eq. to 245mg of Tenofovir Disoproxil) IP 300 mg
26	Sulfamethoxazole and Trimethoprim Tablets USP 800mg/160mg (For Export)	Each tablet Contains: Sulfamethoxazole Ph. Eur. 800 mg Trimethoprim Ph. Eur. 160 mg
27	Sulfamethoxazole and Trimethoprim Tablets USP 400mg/80mg (For Export)	Each tablet Contains: Sulfamethoxazole Ph. Eur. 400 mg Trimethoprim Ph. Eur. 80 mg
28	Tenofovir Alafenamide Tablets 25mg [HepBest] (Trade Name Given by Manufacturer) (For Export)	Each tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25mg
29	Tenofovir Alafenamide Tablets IP 25 mg	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate IP equivalent to Tenofovir Alafenamide 25 mg
30	Lamivudine and Zidovudine Tablets USP 150mg/300mg [ZOVILAM] (Trade Name Given by Manufacturer) (For Export)	Each film coated tablet Contains: Lamivudine USP 150 mg Zidovudine USP 300 mg
31	Lamivudine and Zidovudine Tablets IP 150mg/ 300mg	Each film coated tablet contains Lamivudine IP-150mg Zidovudine IP- 300mg
32	Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/ 25mg/50mg [KOCITAF] (Trade Name Given by Manufacturer) (For Export)	Each film coated tablet Contains: Emtricitabine 200 mg Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Dolutegravir Sodium equivalent to Dolutegravir 50 mg
33	Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/ 25mg/50mg [KOCITAF] (Trade Name Given by Manufacturer)	Each film coated tablet Contains: Dolutegravir Sodium IP equivalent to Dolutegravir 50 mg Emtricitabine IP 200 mg Tenofovir Alafenamide Fumarate IP equivalent to Tenofovir Alafenamide 25 mg

Mylan Laboratories Ltd. * Industrial Area * Plot 11 to 13

Kamlesh Kumar
Drugs Inspector
CDSCO, Sub Zone, Indore

Pushpraj Singh
Drugs Inspector
CDSCO, Sub Zone, Indore

Shobhit
Dy. Drugs Controller
& Licensing Authority
Food & Drugs Administration
Madhya Pradesh
30 OCT 2024

Dharmesh Bigoniya
Drugs Inspector
Pithampur, FDA, M.P.