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-1/2021/ 3522 **Bhopal, Dated:** 22/06/23

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 Certificate of Pharmaceutical Products **(COPP).**

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Please find enclosed herewith the Certificate of Pharmaceutical Products (**COPP**) as desired by you in two copies.

Encl: As above

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

Digitally signed by Moraru Grigore
Date: 2023.10.09 11:03:46 EEST
Reason: MoldSign Signature
Location: Moldova

OFFICE OF THE CONTROLLER, FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH
CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached)

No. of Certificate : **7/ 2014** **Valid Up To: 25-10-2024**

Exporting (certifying) Country : **INDIA**

Importing (requesting) Country : **AS PER ANNEXURE – II ATTACHED**

1. Name and dosage form of the product : **Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/25mg 50mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : Each film coated tablet Contains:
Emtricitabine 200 mg
Dolutegravir (as Dolutegravir Sodium) 50 mg
Tenofovir alafenamide fumarate equivalent to Tenofovir alafenamide 25 mg

For complete composition including excipients, see attached.[4] **As per "Annexure -I"**

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country? Yes ☒ No ☐ Unknown ☐
If the answer to 1.2 is yes, continue with section 2A and omit section 2B.
If the answer to 1.2 is no, omit section 2A and continue with section 2B[6] .

2.A.1 Number of product licence[7] and date of issue:
25/1/2014 dated 25/04/2023

2.A.2 Product Licence 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[8]
a ☒ b ☐ c ☐

2.A.3.1 For categories b & c the Name and Address of the Manufacturer producing the dosage Form is[9] : Not Applicable

2.A.4. Is a summary basis for Approval appended?[10]
Yes ☐ No ☒

2.A.5 Is the attached, officially approved product Information complete and consonent with the licence?[11]
Yes ☐ No ☐ Not Provided ☒

2.A.6 Applicant for certificate, if different from License Holder (Name and Address)[12] : Not Applicable

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

2.B.2 Status of applicant: Not applicable (key in as appropriate category as defined in footnote 8)

a ☐ b ☐ c ☐

2.B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9] – Not Applicable

2.B.3 Why is marketing authorization lacking? Not Applicable

Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐

2.B.4 Remark:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? If no or not applicable, proceed to question 4. Yes ☒ No ☐ Not Applicable[14] ☐

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

3.2 Has the manufacturer of this type of dosage form been inspected? Yes ☒ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organization?[15]
Yes ☒ No ☐ Not applicable[14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes ☒ No ☐
If no, 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

Name of the Authorized Person: Shobhit

Signature:

Stamp and Date: Dy. Drugs Controller & Licensing Authority Food & Drugs Administratic Madhya Pradesh

22 JUN 2023

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GENERAL INSTRUCTIONS:

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme.

The forms are available for generation by computer. They should always be submitted as hard copy, with response presented in type rather than hand written.
Additional; sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market;

    a) Manufactures the dosage form
    b) Packages and/or labels a dosage form manufactured by an independent company; or
    c) is involved in none of the above

9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:

    a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b) the product has been reformulated with a view to improving its stability under tropical conditions;
    c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e) any other reason, please specify.

14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The layout this model certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.

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OFFICE OF THE CONTROLLER, FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH
CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]
Annexure -I

No. of Certificate:- 7/2014 **Valid up to: 25-10-2024**

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 and dosage form of product: -
Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/25mg 50mg
Each film coated tablet Contains:
Emtricitabine 200 mg
Dolutegravir (as Dolutegravir Sodium) 50 mg
Tenofovir alafenamide fumarate equivalent to Tenofovir alafenamide 25 mg

ACTIVE INGREDIENTS	Specification	Qty. (mg/tablet)
Dolutegravir Sodium	IH	52.600
Emtricitabine	IH	200.00
Tenofovir Alafenamide Fumarate	IH	28.040
EXCIPIENTS		
Mannitol	USP	145.400
Microcrystalline Cellulose (Flocel-101)	NF	60.000
Microcrystalline Cellulose (Flocel-112)	USP-NF	126.46
Povidone	USP	15.000
Sodium Starch Glycolate	USP	15.000
Lactose monohydrate	USP	120.000
Croscarmellose sodium	USP-NF	70.000
Magnesium stearate	USP-NF	17.500
Insta Moist Shield Aqua-II White	IH	25.000
Purified water	USP	q.s

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

Name of the Authorized Person:

Signature:

Stamp and Date:

Shobhit
Dy. Drugs Controller
& Licensing Authority
Food & Drugs Administrat
Madhya Pradesh
22 JUN 2020

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OFFICE OF THE CONTROLLER, FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH
CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]
Annexure -II

No. of Certificate:- 7/2014 **Valid up to: 25-10-2024**

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.

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

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Annexure -II

No. of Certificate:- 7/2014 **Valid up to: 25-10-2024**

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

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. Kitties	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		

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Signature:

Stamp and Date:

Shobhit
Dy. Drugs Controller
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Madhya Pradesh

22 JUN 2023