File No.HMF07-14052/1/2024-ADMIN-DCA

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

CERTIFICATE OF PHARMACEUTICAL PRODUCT[1]

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

Certificate No.: **HMF07-14052/1/2024-ADMIN-DCA** Valid up to: **31.12.2026**
Exporting or (certifying) country: **INDIA** Importing or (requesting) country: **ATTACHMENT**

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

1.1 1.1 Active ingredients (s)[2] and amounts (s) per unit dose[3]: **Each film coated tablet contains**
Dolutegravir Sodium equivalent to 50 mg of Dolutegravir
Emtricitabine 200 mg
Tenofovir Alafenamide 25 mg (equivalent to 28 mg of Tenofovir Alafenamide Fumarate).

Complete composition including excipients4: Mannitol (Pearlitol 50C) – **137.280 mg**, Microcrystalline Cellulose (Pharmacel 101) – **60.000 mg**, Sodium Starch Glycolate (Type A) (Primojel) – **32.100 mg**, Povidone (Kollidone K 30) – **15.000 mg**, Microcrystalline Cellulose (Pharmacel 102) - **88.695 mg**, Croscarmellose sodium (Ac-Di-Sol) - **28.000 mg**, Magnesium stearate (Ligamed MF-2-V) – **8.260 mg**, Opadry II White 85F580019 - **19.500 mg** and Purified water – **q.s.**

1.2 Is this product licenced 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 2 A and omit section 2 B
If the answer to 1.2 is No, omit section 2 A and continue section 2 B[6]

2.A.
A.1 Number of product license[7] and date of issue
Mfg Lic. No.: 16/VSP/AP/2015/F&B/CC/R; Date: 15-09-2015
A.2 Product license holder:
M/s. Laurus Labs Limited.
Unit-II, Plot No. 19, 20 & 21, Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli Dist-531 011, Andhra Pradesh, India.
A.3 Status of Product-license Holder[8]
a. ☒ b. ☐ c. ☐
A.3.1 For Categories b and c the name and address of the manufacturer producing the dosage form are[9]:
Not Applicable
A.4 ls summary basis of approval appended?[10]
Yes ☐ No ☒
A.5 Is the attached officially approved product information complete and consonant with the license?[11]
Yes ☐ No ☐ Not provided ☒
A.6 Application for certificate if different from license Holder.
Name and address[12]: **Not applicable**

2.B.
B.1 Applicant for Certificate (Name and Address)

B.2 Status of Applicant:[8]

a. ☐ b. ☐ c. ☐ d. ☐

B.2.1 For categories band c the name and address of the Manufacturer producing the dosage form are [9]

B.3 Why is marketing authorization lacking?

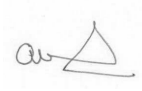
☐	☐	☐	☐
Not Required	Not Requested	under consideration	Refused

B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14]
Yes ☒ No ☐ Not applicable ☐
If no or not applicable proceed to question 4
3.1 Periodicity of routine inspection (years): Once in a year.
3.2 Has the manufacture 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 ☐
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: **The Director, O/o The Director General, Drugs Control Administration, Siddhartha Medical College Campus, Gunadala, Vijayawada-520 008, Andhra Pradesh, India.**

Telephone and Fax numbers: **Tel 08632339246**
Name of Authorized Person: **M.B.R. PRASAD M. Pharm., M.Phil. A.I.C.**
Director and licensing authority.

Signature:
Stamp & Date



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GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

General Instructions:

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten. 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 Non-proprietary Name (INNs) or National non-proprietary name.
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 License holder.
5. When applicable, append details of any restriction applied to the safe, distribution or administration of the product that is specified in the product License.
6. Section 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license 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 is none of the above.
9. This information can be provided only with the consent of the product-license 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 License. If the production site is changed, the License must be updated or it will cease to be 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 the product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product-License holder. This permission must 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 exports; (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 that 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 export committee on biological standardization (WHO technical report series, No. 822.1992.Annex 1).
16. This section is to be completed when the product- License holder or applicant conforms to status (b) or (c) as described in note 7 above. It is 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.

ATTACHMENT

No. of Certificate: HMF07-14052/1/2024-ADMIN-DCA **Valid Up to: 31.12.2026**

List of Importing Countries:

S. No.	Country	S. No.	Country	S. No.	Country
01	Afghanistan	39	Costa Rica	77	Guadeloupe
02	Algeria	40	Cape Verde	78	Guatemala
03	Anguilla	41	Central African Republic	79	Guyana
04	Antigua and Barbuda	42	Côte d'Ivoire	80	Guinea
05	Argentina	43	Comoros	81	Guinea-Bissau
06	Armenia	44	Congo	82	Haiti
07	Angola	45	Cyprus	83	Honduras
08	Aruba	46	Czech Republic	84	Hong Kong
09	Austria	47	Cuba	85	Hungary
10	Australia	48	Denmark	86	Iceland
11	Azerbaijan	49	Djibouti	87	Indonesia
12	Bahamas	50	Dominica	88	Iran
13	Bangladesh	51	Dominican Republic	89	Iraq
14	Barbados	52	DR Congo	90	Ireland
15	Belarus	53	Ecuador	91	Israel
16	Belgium	54	Egypt	92	Italy
17	Belize	55	El Salvador	93	Jamaica
18	Benin	56	Erites	94	Japan
19	Bermuda	57	Estonia	95	Jordan
20	Bhutan	58	Ethiopia	96	Kenya
21	Bolivia	59	Equatorial Guinea	97	Kazakhstan
22	Botswana	60	Eritrea	98	Kyrgyzstan
23	Brazil	61	Finland	99	Kiribati
24	British Virgin Islands	62	France	100	Lao, PDR
25	Bulgaria	63	French Guyana	101	Latvia
26	Burkina Faso	64	Fiji Islands	102	Lebanon
27	Burundi	65	Gabon	103	Lesotho
28	Cambodia	66	Gambia	104	Liberia
29	Cameroon	67	Georgia	105	Libya
30	Canada	68	Germany	106	Luthiana
31	Caymen Islands	69	Ghana	107	Luxembourg
32	Chad	70	Greece	108	Macau
33	Chile	71	Grenada	109	Madagascar
34	China	72	Senegal	110	Malawi
35	Colombia	73	Sierra Leone	111	Malaysia
36	Maldives	74	Singapore	112	Uganda
37	Mali	75	Slovakia	113	Ukraine
38	Malta	76	Slovenia	114	Ulan Battar

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S. No.	Country	S. No.	Country	S. No.	Country
115	Marshall Islands	150	Saint Kitts and Nevis	185	Uzbekistan
116	Martinique	151	Saint Lucia	186	Vanuatu
117	Mauritania	152	Saint Vincent & the Grenadines	187	Venezuela
118	Mauritius	153	Samoa	188	Vietnam
119	Mexico	154	São Tomé and Príncipe	189	Yemen
120	Moldova	155	Seychelles		
121	Mongolia	156	Solomon Islands		
122	Montserrat	157	Somalia		
123	Morocco	158	South Africa		
124	Mozambique	159	Sudan		
125	Myanmar	160	Suriname		
126	Namibia	161	Swaziland		
127	Nepal	162	Syria		
128	Nauru	163	Sweden		
129	Netherlands	164	Switzerland		
130	Netherlands Antilles	165	Taiwan		
131	New Zealand	166	Tajikistan		
132	Nicaragua	167	Tanzania		
133	Niger	168	Thailand		
134	Nigeria	169	Timor-Leste		
135	Norway	170	Togo		
136	Pakistan	171	Tonga		
137	Panama	172	Trinidad and Tobago		
138	Papua New Guinea	173	Tunisia		
139	Peru	174	Turkey		
140	Philippines	175	Turkmenistan		
141	Poland	176	Turks and Caicos islands		
142	Paraguay	177	Tuvalu		
143	Palau	178	Tuvalu		
144	Portugal	179	Zambia		
145	Rwanda	180	Zimbabwe		
146	Russia	181	Uruguay		
147	Saudi Arabia	182	UAE		
148	Spain	183	United Kingdom		
149	Sri Lanka	184	US		

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