FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **COPP/CERT/KD/58050/2017/11/19169/98606** **Valid Upto :20 Apr 2019**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **Lamivudine and Tenofovir Disoproxil Fumarate Tablets 300/300 mg**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each film-coated tablet contains:

Lamivudine USP 300 mg	Tenofovir Disoproxil Fumarate 300 mg	(equivalent to 245 mg of Tenofovir Disoproxil)

Colour:Titanium Dioxide

For complete qualitative composition including excipients :[4]

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 ☐

2A.1 Number of product license:[7] **KD620 In Form 25**
and date of issue: **18 Nov 2014**

2A.2 Product License holder (Name and address) :
CIPLA LTD. PLOT NO. A-42, M.I.D.C., PATALGANGA, RAIGAD 410220 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder :[8]
A ☒ B ☐ C ☐

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[9]

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

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

2A.6 Applicant for certificate if different from License holder :[12]
Not Applicable

2B.1 Applicant for certificate (name and address) :

2B.2 Status of applicant :
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks :[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 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 Organisation ?[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 :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959
5PIC1555805020170505059

Name of the Authorised person : **O S SADHWANI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**05 May 2017**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Digitally signed by Margină Veaceslav
Date: 2019.03.04 12:43:24 EET
Reason: MoldSign Signature
Location: Moldova

05 MAY 2017

GENERAL INSTRUCTION :

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 suitable for generation by computer. They should always be submitted as hard copy, with responses printed 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, wherever 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. Sections 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 dosages 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 be provided only 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 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 on which the product has been licensed.
11. This refers to 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 Licence 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 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 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 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. The 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 for 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.

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : **COPP/CERT/KD/58050/2017/11/19169/98606** **Valid up to: 20 Apr 2019**

Name of the Product License Holder : **CIPLA LTD. PLOT NO. A-42, M.I.D.C., PATALGANGA, RAIGAD 410220 MAHARASHTRA STATE, INDIA**

Name of the Product : **Lamivudine and Tenofovir Disoproxil Fumarate Tablets 300/300 mg**

List of Countries For Export

Afghanistan	Brazil	Ecuador	Hungary	Macao	Norway	Singapore	Tongo
Albania	British Virgin	Egypt	India	Macedonia	Oman	Slovakia	Trinidad & Tobago
Algeria	Brunei	El Salvador	Indonesia	Madagascar	PAHO	Slovenia	Tunisia
Andorra	Brunei Darussalam	England	Iran	Malawi	Pakistan	Solomom Island	Turkey
Anglia	Bulgaria	Equatorial Guinea	Iraq	Malaysia	Palau	Somalia	Turkmenistan
Angola	Burkina Faso	Eritrea	Ireland	Maldives	Palestine	South Africa	Turks and Calicos
Anguilla	Burundi	Estonia	Italy	Mali	Panama	South Korea	Uganda
Antigua	Cambodia	Ethiopia	Ivory Coast	Malta	Papua New Guinea	Spain	Ukraine
Antigua and Barbuda	Cameroon	Fiji Island	Jamaica	Marshal Island	Paraguay	Sri Lanka	UNHCR
Argentina	Canada	Finland	Japan	Mauritania	Peru	St. Kitties	UNICEF
Armenia	Cape Verde	France	Jordan	Mauritius	Philippines	st. Kitties and Nevi	United Arab Emirates
Aruba	Cayman Island	French Guiana	Kazakhstan	MCGM	Poland	St. Lucia	United Kingdom
Australia	Central African Republic	Gabon	Kenya	Mexico	Porte Rico	St. Maarten	United State
Austria	Chad	Gambia	Kiribati	Moldova	Portugal	St. Vincent	UNOPS
Azerbaijan	Chile	Georgia	Korea	Monaco	Qatar	St. Vincent and the Grenadines	Uruguay
Bahamas	China	Germany	Kosovo	Mongolia	R.D. Congo	Sudan	Uzbekistan
Bahrain	Colombia	Ghana	Kurdistan	Monstserrat	Rep. of Congo	Sultanate of Oman	Vanuata
Bangladesh	Comoros	Global Fund	Kuwait	Montenegro	Reunion	Suriname	Vatican City
Barbados	Congo	Grand Cayman	Kyrgyzstan	Morocco	RITES	Swaziland	Venezuela
Belarus	Costa Rica	Greece	LaO PDR	Mozambique	Romania	Swedan	Vietiane
Belgium	Croatia	Grenada	Laos	Myanmar	Russia	switzerland	Vietnam
Belize	Cuba	Guatemala	Latvia	Namibia	Rwanda	Syria	Western Samoa
Belorussia	Curacao	Guinea	Lebanon	Nauru	Samao	Taiwan	WHO
Benin	Cyprus	Guinea-Bissau	Leone	Nepal	San Marino	Tajikistan	Yemen
Bermuda	Czechoslovakia	Guyana	Lesotho	Netherlands	Sao Tome and Principe	Tanzania	Yugoslavia
Bhutan	Denmark	Haiti	Liberia	New Zealand	Saudi Arabia	Tchad	Zaire
Bolivia	Djibouti	Herzegovina	Libya	Nicaragua	Senegal	Thailand	Zambia
Bosnia	Dominica	Holland	Liechtenstein	Niger	Serbia	The Netherlands	Zanzibar
Bosnia and Herzegovina	Dominican Republic	Honduras	Lithuania	Nigeria	Seychelles	Togo	Zimbabwe
Botswana	East Timor	Hong-Kong	Luxembourg	North Korea	Sierra Leone		

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Tel: +91-22-26592363/64
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