## 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/80659/2019/11/26417/137082** **Valid Upto :16 Dec 2021**

**Exporting Country** : INDIA

**Importing Country** : **As per Annexure**

**1.** Name and dosage form of product : **Abacavir and Lamivudine Tablets USP 600/300 mg**

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

| | |
|---|---|
| Abacavir Sulfate USP equivalent to Abacavir 600 mg | Lamivudine USP 300 mg |
| **Colour:Sunset Yellow FCF, 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] **845 In Form 25**
and date of issue: **18 Jul 2016**

2A.2 Product License holder (Name and address) :
**CIPLA LIMITED PLOT NOS. A-2, A-33 & A-37/2/2, 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
5PIC1618065920190105059

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
**Food & Drug Administration, M.S.**
**Bandra (E), Mumbai.**
**Maharashtra State, India**
Date:**05 Jan 2019**

05 JAN 2019

Digitally signed by Margină Veaceslav
Date: 2019.03.04 12:44:35 EET
Reason: MoldSign Signature
Location: Moldova

**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, 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. 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/80659/2019/11/26417/137082** **Valid up to: 16 Dec 2021**

Name of the Product License Holder : **CIPLA LIMITED PLOT NOS. A-2, A-33 & A-37/2/2, M.I.D.C., PATALGANGA, RAIGAD 410220 MAHARASHTRA STATE, INDIA**

Name of the Product : **Abacavir and Lamivudine Tablets USP 600/300 mg**

### List of Countries For Export

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

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
5PIC1618065920190105059

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
**Food & Drug Administration, M.S.**
**Bandra (E), Mumbai.**
**Maharashtra State, India**
Date:**05 Jan 2019**

05 JAN 2019

**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/80659/2019/11/26417/137084** **Valid Upto :16 Dec 2021**

**Exporting Country** : INDIA

**Importing Country** : **As per Annexure**

**1.** Name and dosage form of product : **Abacavir Sulfate Dispersible Tablets 60 mg**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each dispersible uncoated tablet contains:

Abacavir Sulfate equivalent to Abacavir 60 mg

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] **845 In Form 25**
and date of issue: **04 Feb 2008**

2A.2 Product License holder (Name and address) :
**CIPLA LIMITED PLOT NOS. A-2, A-33 & A-37/2/2, 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]

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

**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 :
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Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
**Food & Drug Administration, M.S.**
**Bandra (E), Mumbai.**
**Maharashtra State, India**
Date:**05 Jan 2019**

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