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: ***03/2010*** **Valid Up to: 13 / 06 / 2025**

Exporting (certifying country) : India

Importing (requesting country) : As per "Annexure-A" enclosed.

1. Name and dosage form of the product : Abacavir (as a sulphate) and Lamivudine Dispersible tablet 120 / 60 mg

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : Composition:
Each Uncoated Dispersible Tablet Contains:
Abacavir Sulphate (equivalent to Abacavir) USP .....120 mg
Lamivudine USP ..... 60 mg

For complete composition including excipients, see attached[4] : NA

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 section 2B[6]:

2 A

A.1 Number of product licence[7] and date of issue: 25 / 2 / 2010
27.04.2020

A.2 Product licence holder: (name and address) M/s. Cipla Limited
Plot no. 9 & 10, Indore Special Economic Zone, Phase – II, Pithampur,
Dist. Dhar, Pin code 454775,
Madhya Pradesh, India.

A.3 Status of product licence holder[8]:
a ☒ b ☐ c ☐

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]: Not applicable

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

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

A.6 Applicant for certificate, if different from licence holder (name and address)[12]: Not applicable

2 B

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

B.2 Status of applicant:
a ☐ b ☐ c ☐

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

B.3 Why is marketing authorization lacking?
not Required ☐ not requested ☐ under consideration ☐ refused ☐

B.4 Remarks[13]:

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

3.1 Periodicity of routine inspections (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 the 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:

The Licensing Authority
Office of the Controller
Food & Drugs Administration
Madhya Pradesh

Digitally signed by Moraru Grigore
Date: 2023.10.09 09:12:43 EEST
Reason: MoldSign Signature
Location: Moldova

Name of authorized person:

Signature:

Stamp and date:
The Licensing Authority,
Office of the Controller
Food & Drugs Administration
Madhya Pradesh

SHOBHIT
Dy. Drugs Controller
State Licensing Auth
Food & Drugs Adminis
Madhya Pradesh

29 JUL 2022

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 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 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 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.

ANNEXURE- (A) WHO GMP CERTIFICATE[1]

CONTROLLER FOOD & DRUGS ADMINISTRATION BHOPAL

No. of certificate: *03/2010*

Valid Up to: 13 / 06 / 2025

Name of the product License Holder : M/s. Cipla Limited
Plot no. 9 & 10, Indore Special Economic Zone, Phase – II,
Pithampur, Dist. Dhar, Pin code 454775
Madhya Pradesh, India.

Name of the product : Abacavir (as a sulphate) and Lamivudine Dispersible tablet 120 / 60 mg

: Composition:
Each Uncoated Dispersible Tablet Contains:
Abacavir Sulphate (equivalent to Abacavir) USP .....120 mg
Lamivudine USP ..... 60 mg

List of Importing Countries :

01. Afghanistan	45. Democratic Republic of the Congo	89. Kuwait	133. Paraguay	177. Trinidad
02. Albania	46. Denmark	90. Kyrgyzstan	134. Peru	178. Tunisia
03. Algeria	47. Djibouti	91. Laos	135. Philippines	179. Turkey
04. Andorra	48. Dominica	92. Latvia	136. Poland	180. Turkmenistan
05. Angola	49. Dominican Republic	93. Lebanon	137. Portugal	181. Tuvalu
06. Antigua and Barbuda	50. Ecuador	94. Lesotho	138. Qatar	182. Uganda
07. Argentina	51. Egypt	95. Liberia	139. Romania	183. Ukraine
08. Armenia	52. El Salvador	96. Libyan Arab Jamahiriyan	140. Russia	184. United Arab Emirates
09. Australia	53. Equatorial Guinea	97. Lithuania	141. Rwanda	185. United Kingdom
10. Austria	54. Eritrea	98. Luxembourg	142. Saint Kitts and Nevis	186. United State of America
11. Azerbaijan	55. Estonia	99. Madagascar	143. Saint Lucia	187. Uruguay
12. Bahamas	56. Ethiopia	100. Malawi	144. Saint Vincent and the Grenadines	188. Uzbekistan
13. Bahrain	57. Fiji	101. Malaysia	145. Samoa	189. Vanuatu
14. Bangladesh	58. Finland	102. Maldives	146. San Marino	190. Venezuela
15. Barbados	59. France	103. Mali	147. Sao Tome and Principe	191. Vietnam
16. Belarus	60. Gabon	104. Malta	148. Saudi Arabia	192. Yemen
17. Belgium	61. Gambia	105. Marshall Islands	149. Senegal	193. Zambia
18. Belize	62. Georgia	106. Mauritania	150. Serbia	194. Zimbabwe
19. Benin	63. Germany	107. Mauritius	151. Seychelles	195. Aruba
20. Bhutan	64. Ghana	108. Mexico	152. Sierra Leone	196. Brunei
21. Bolivia	65. Greece	109. Micronesia	153. Singapore	197. Curacao
22. Bosnia	66. Grenada	110. Moldova	154. Slovakia	198. Guinea
23. Botswana	67. Guatemala	111. Monaco	155. Slovenia	199. Hong Kong
24. Brazil	68. Guinea	112. Mongolia	156. Solomon Islands	200. Jamahiriya
25. Brunei Darussalam	69. Guinea-Bissau	113. Montenegro	157. Somalia	201. Kosovo
26. Bulgaria	70. Guyana	114. Morocco	158. South Africa	202. Kurdistan
27. Burkina Faso	71. Haiti	115. Mozambique	159. South Korea	203. Libya
28. Burundi	72. Herzegovina	116. Myanmar	160. Spain	204. Liechtenstein
29. Cambodia	73. Honduras	117. Namibia	161. Sri Lanka	205. Macau
30. Cameroon	74. Hungary	118. Nauru	162. Sudan	206. Netherlands Antilles
31. Canada	75. Iceland	119. Nepal	163. Suriname	207. Palestine
32. Cape Verde	76. Indonesia	120. Netherlands	164. Swaziland	208. Puerto Rico
33. Central African Republic	77. Iran	121. New Zealand	165. Sweden	209. Republic de Guinea
34. Chile	78. Iraq	122. Nicaragua	166. Switzerland	210. Republic of Maldives
35. China	79. Ireland	123. Niger	167. Syria	211. Somaliland
36. Colombia	80. Israel	124. Nigeria	168. Tajikistan	212. Tajikistan
37. Comoros	81. Italy	125. Niue	169. Tanzania	213. Taiwan
38. Congo	82. Ivory Coast	126. North Korea	170. Tchad	214. Vatican City
39. Cook Islands	83. Jamaica	127. Norway	171. Thailand	215. West Indies
40. Costa Rica	84. Japan	128. Oman	172. The former Yugoslav Republic of Macedonia	216. Western Sahara
41. Croatia	85. Jordan	129. Pakistan	173. Timor-Leste	217.Yugoslavia
42. Cuba	86. Kazakhstan	130. Palau	174. Tobago	
43. Cyprus	87. Kenya	131. Panama	175. Togo	
44. Czech Republic	88. Kiribati	132.Papua New Guinea	176. Tonga	

Address of certifying authority:

The Licensing Authority
Office of the Controller
Food & Drugs Administration
Madhya Pradesh

Name of authorized person:

Signature:

Stamp and date:
The Licensing Authority,
Office of the Controller
Food & Drugs Administration
Madhya Pradesh

SHOBHIT
Dy. Drugs Controller
State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

29 JUL 2022