Health & Family Welfare Department
Himachal Pradesh
Baddi, Distt. Solan

Certificate of Good Manufacturing Practices

This one page certificate conforms to the format recommended by the **World Health Organization** [General Instructions and Explanatory Notes attached].

Certificate No. HFW-H [Drugs] 152/07

On the basis of the inspection carried out on 08th & 09th June 2018, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:

1. Names and Address of Site:

M/s Macleods Pharmaceuticals Ltd.
Block N-2, Village Theda, Post Office Lodhimajra
Tehsil Baddi, Distt. Solan,
Himachal Pradesh-174101, INDIA

Digitally signed by Margină Veaceslav
Date: 2019.03.04 13:25:17 EET
Reason: MoldSign Signature
Location: Moldova

2. Manufacturing License No:

MNB/07/594 **Form 25**
MB/07/593 **Form 28**
Valid up to **06-07-2022.**

Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Tablets	**General**	**Production, Packing & Quality Control**
Capsules	**General**	**Production, Packing & Quality Control**
Liquid Oral	**General**	**Production, Packing & Quality Control**
Sachet (Pellets & Granules)	**General**	**Production, Packing & Quality Control**

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate now remains valid until **14.06.2021.** It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of Certifying Authority:

State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi, Distt. Solan [H.P.] 173 205, INDIA.

Name & Function of Responsible person:

Navneet Marwaha
State Drugs Controller
Controlling- cum- Licensing Authority
01795-244288, sdc4hp@gmail.com

Telephone/Fax No:

Date: 15.06.2018

Licensing Authority cum Drug Controller * Himachal Pradesh *

Signature:

Stamp:

(NAVNEET MARWAHA) 15.6.18
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

ADMINISTRATION OF DAMAN & DIU (UT)
DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTER
DAMAN – 396 220

No. DCD / D&D / LA / 2017-2018 /962 ***DATED: -20/09/2017.***

WHO-GMP CERTIFICATE

THIS IS TO CERTIFY THAT ***M/S. MACLEODS PHARMACEUTICALS LIMITED.***, PHASE-II, PLOT NO. 25-27, SURVEY NO. 366, PREMIER INDUSTRIAL ESTATE, KACHIGAM, DAMAN -396210, INDIA IS HOLDING VALID DRUG MANUFACTURING LICENCES IN ***FORM NO. 25 & FORM NO. 28*** BEARING LICENCE NO. ***DD/375 & DD/376,*** **DATED 18/03/2003** RESPECTIVELY, ISSUED BY THIS ADMINISTRATION UNDER THE PROVISIONS OF DRUGS & COSMETICS ACT, 1940 AND RULES THEREUNDER. UNDER THE SAID LICENCES THE FIRM IS PERMITTED TO MANUFACTURE AND SELL THEIR PRODUCTS COVERED UNDER THE CATEGORIES OF GENERAL: TABLETS, CAPSULES, GRANULES AND PELLETS.

THE FIRM HAS EMPLOYED COMPETENT PERSONS IN MANUFACTURING AND QUALITY CONTROL DEPARTMENTS. THE FIRM IS FOLLOWING ***GOOD MANUFACTURING PRACTICES AS PER WORLD HEALTH ORGANIZATION RECOMMENDATIONS*** IN THE MANUFACTURING AND TESTING OF THE SAID CATEGORIES OF GENERAL: TABLETS, CAPSULES, GRANULES AND PELLETS.

LICENSING AUTHORITY
दमण/Daman
U.T. OF DAMAN & DIU

THE MANUFACTURING PLANT IS SUBJECT TO REGULAR INSPECTION BY THE COMPETENT AUTHORITY UNDER THE ACT.

THIS CERTIFICATE IS VALID UP TO TWO YEARS FROM THE DATE OF ISSUE.

(DR. DHARMESH AGRAWAL)
DRUGS LICENSING AUTHORITY,
UT OF DAMAN & DIU,
DAMAN.

GOVERNMENT OF HIMACHAL PRADESH
HEA LTH AND FAMILY WELFARE DEPARTMENT
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 : **WHO-GMP-CERT/HFW-H (Drugs) 152/07/18-355 Valid Upto : 14.06.2021**

Exporting Country : **INDIA**

Importing (requesting) country : **HAITI**

1. Name and dosage form of product : **Dolutegravir 50 mg, Lamivudine 300 mg & Tenofovir Disoproxil Fumarate 300 mg Tablets**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]

Each film coated tablet contains:
Dolutegravir 50 mg
equivalent to 52.6 mg of Dolutegravir
Lamivudine USP 300 mg
Tenofovir Disoproxil Fumarate 300 mg
equivalent to 245 mg of Tenofovir Disoproxil

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 2 A and omit section 2B
If the answer to 1.2 is no, omit section 2A and continue section 2B[6 fd]

2A

A.1 Number of product license[7] and date of issue:
MNB/07/594 Dated 15.02.2018

A.2 Product License holder: (Name and address)
Macleods Pharmaceuticals Ltd.
Office: Atlanta Arcade, Church Road, Near Leela Hotel, Andheri – Kurla Road, Andheri (East), Mumbai – 400 059,India
Factory : Block N-2 , Village Theda, Post Office Lodhimajra Tehsil Baddi, Distt. Solan, Himachal Pradesh - 174101,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 Is 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 Applicant for certificate if different from license holder:[12] : **Not Applicable**

2B

B.1 Applicant for certificate (name and address)

B.2 Status of applicant
a ☐ b ☐ c ☐ d ☐

B.2.1 For categories b and 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 Remark:[13]

3. 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 no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years) : **Yearly**

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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.] 173 205, INDIA
01795-244288, sdc4hp@gmail.com

Name of the authorized person: **Navneet Marwaha**

Signature:

Stamp and date

Licensing Authority cum Drug Controller Himachal Pradesh

(NAVNEET MARWAHA) 1-8-18
State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

EXPLANATORY NOTES

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceuticals 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 strength 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-License 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 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) Manufacturers the dosage forms.
   (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-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 change 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 product information approved by the competent national regulator, 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 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 dosages 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 Pharmaceuticals Preparations (WHO) Technical Report Series, No.823, 1992, Annex 1). Recommendations specifically applicable to biological product has been formulated by the WHO Expert Committee on Biological Standarazation (WHO) Technical Report Series No. 822, 1992, Annex 1).

16. The 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 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

QUALITATIVE AND QUANTITATIVE FORMULA

Product: Dolutegravir 50mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300mg Tablets.

Composition: Each film coated tablet contains:
Dolutegravir 50 mg equivalent to 52.6 mg of Dolutegravir Sodium
Lamivudine USP..... 300 mg
Tenofovir disoproxil Fumarate 300 mg equivalent to
Tenofovir disoproxil..... 245 mg

Sr. No.	Ingredients	Reference to quality standards @	Quantity/tablet (mg)	Functions
Lamivudine and Tenofovir Disoproxil Fumarate part				
Dry Mixing				
1.	Lamivudine**	USP + In House	300.00	Active ingredient
2.	Tenofovir disoproxil	In- house	300.00	Active ingredient
3.	Microcrystalline cellulose	USP-NF/Ph. Eur	39.00	Diluent
4.	Pregelatinized starch	USP-NF/Ph. Eur	42.50	Binder
5.	Croscarmellose sodium (Ac-di-sol)	USP-NF/Ph. Eur + In- house	60.00	Disintegrant
Granulation				
6.	Isopropyl alcohol*	USP-NF/Ph. Eur	q.s.	Binder
Pre-Lubrication				
7.	Microcrystalline cellulose (Avicel PH 112)#	USP-NF/Ph. Eur	37.00	Diluent
8.	Croscarmellose sodium (Ac-di-sol)	USP-NF/Ph. Eur	60.00	Disintegrant
Lubrication				
9.	Magnesium stearate (Liga-MF-2V)	USP-NF/Ph. Eur + In- house	11.50	Lubricant
Lamivudine and Tenofovir Disoproxil Fumarate layer weight			**850.00**	
Dolutegravir part				
Dry Mixing				
10.	Dolutegravir sodium##	In- house	52.60	Active ingredient
11.	Mannitol (Pearlitol 25 C)	USP-NF/Ph. Eur + In- house	120.00	Diluent
12.	Microcrystalline cellulose (Avicel PH 101)###	USP-NF/Ph. Eur	138.385	Diluent
13.	Ferric oxide yellow (10E 172)	USP-NF	0.015	Colorant
14.	Sodium starch glycolate (Type A)	USP-NF/Ph. Eur + In- house	14.00	Disintegrant
Sr. No.	**Ingredients**	**Reference to quality standards @**	**Quantity/tablet (mg)**	**Functions**
Granulation				
15.	Povidone (Kollidone 30)	USP-NF/Ph. Eur + In- house	9.00	Binder
16.	Purified water*	In- house	q.s.	Solvent
Pre-Lubrication				
17.	Sodium starch glycolate (Type A)	USP-NF/Ph. Eur + In- house	7.00	Disintegrant

Licensing Authority cum Drug Controller * Himachal Pradesh *

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.)-173205
01795 244388,sdc4hp@gmail.com

Sr. No.	Ingredients	Reference to quality standards @	Quantity/tablet (mg)	Functions
Lubrication				
18.	Sodium stearyl fumarate	USP-NF/Ph. Eur + In- house	9.00	Lubricant
Dolutegravir layer weight			**350.00**	
Weight of core tablet (mg)			**1200.00**	--
Film Coating$				
19.	Instacoat universal white A05E00041($)	In-house	36.00	Coating agent
20.	Purified water *	In- house	q.s.	Solvent
Total Weight of coated tablets (mg)			**1236.00**	--

USP-NF United states Pharmacopoeia-National formulary
Ph.Eur European Pharmacopoeia
IHS In-House Specification
q.s. Quantity sufficient
52.60 mg of Dolutegravir sodium is equivalent to 50 mg of Dolutegravir.
@ The current effective version of the pharmacopoeia to be followed.
* Removed during manufacturing process by evaporation during drying process. Not considered in the final weight of the tablet.
$ Composition of Instacoat universal white A05E00041

$ - Composition of Instacoat universal white A05E00041

Sr. No.	Ingredient	Reference to quality standards	EEC No.	% *w/w*	(mg/tablet)
01	HPMC 2910 / Hypromellose	USP/BP/EP	E464	65.00 %	23.40
02	Triacetin	USP/EP/BP	E1518	8.00 %	2.88
03	Titanium Dioxide (CI No: 77891)	USP/BP/EP	E171	27.00 %	9.72
Total				**100 %**	**36.00**

Licensing Authority cum Drug Controller * Himachal Pradesh *

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

Drugs Licensing Authority,
Administration of Daman and Diu.
Drug Control Department,
Primary Health Center, DAMAN – 396220.

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 : **DD/375/0014/** **Valid up to: 19/09/2019**

Exporting (Certifying) Country : **INDIA**

Importing (Requesting) Country : **AS PER ANNEXURE**

1. Name and dosage form of product : **Efavirenz 600mg, Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300mg Tablets**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]

Each tablet contains:
Efavirenz 600mg
Emtricitabine 200mg
Tenofovir Disoproxil Fumarate 300mg
equiv. to Tenofovir Disoproxil .. 245 mg

For complete qualitative 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

1.3 Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2 B.
If the answer to 1.2 is no, omit section 2A and continue section 2B [6].

2 A

2.A.1 Number of product license[7] and date of issue: **DD/375 dated 27.08.2009**

2.A.2 Product licence holder : **Macleods Pharmaceuticals Ltd.**
Office : Atlanta Arcade, 3rd Floor, Marol Church Road, Near Leela Hotel, Andheri (East), Mumbai – 400 059
Factory : Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman –396210 (U.T.)

2.A.3 Status of product licence holder [8] :

Manufacturers the dosage forms

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

2.A.4 Is summary basis of Approval appended?[10]

: No

2.A.5 Is the attached, officially approved product information complete and consonant with the licence?[11]

: Not provided

2.A.6 Applicant for certificate if different from licence holder: [12] : **Not applicable.**

2 B Not applicable.

2.B.1 Application for certificate: (Name and address)

2.B.2 Status of applicant

: **Not applicable**

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

: **Not applicable**

2. B.3 Why is marketing authorization lacking?

: **Not applicable**

2.B.4 Remark : [13] --

LICENSING AUTHORITY
अनुज्ञापन प्राधिकारी
U.T. OF DAMAN & DIU

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization ?[15] Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

Yes

If no, explain.

Address of certifying authority:

Drugs Licensing Authority
Administration of Daman and Diu,
Drug Control Department,
Primary Health Center, DAMAN-396220

Telephone Number : **(0260) 2230470**
Fax Number : **(0260) 2230570**

Name of the authorised person: DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

Signature:

Stamp and date: – 7 OCT 2017

ANNEXURE

No. of Certificate : DD/375/0014/ VALID UPTO : 19/09/2019

Name of the Product : **Efavirenz 600mg, Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300mg Tablets**

List of Countries / Institution to which the above product will be Exported / Locally Supplied.

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. Ecuadorp	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. Guinee
23. Botswana	67. Guatemala	111. Monaco	155. Slovenia	199. Hong Kong
24. Brazil	68. Guinea	112. Mongolia	156. Solomon	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 Rica
33. Central African Republic	77. Iran	121. New Zealand	165. Sweden	209. Republic de Guinee
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. Tadzhikistan
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:
Drugs Licensing Authority
Administration of Daman and Diu, Drug Control Department
Primary Health Center, DAMAN-396220
Telephone Number : (0260) 2230470
Fax Number: (0260) 2230570

Name of the authorised person: Dr. Dharmesh Agrawal

Signature:

Stamp and date:

- 7 OCT 2017

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

GOVERNMENT OF HIMACHAL PRADESH
HEA LTH AND FAMILY WELFARE DEPARTMENT
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 : **WHO-GMP-CERT/HFW-H (Drugs) 152/07/18-305 Valid Upto : 14.06.2021**

Exporting Country : **INDIA**

Importing (requesting) country : **AS PER ANNEXURE**

1. Name and dosage form of product : **Efavirenz Tablets 600 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]

Each film coated tablet contains:
Efavirenz USP 600 mg

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 2 A and omit section 2B
If the answer to 1.2 is no, omit section 2A and continue section 2B[6 fd]

2A

A.1 Number of product license[7] and date of issue:
MNB/07/594 Dated 07.07.2017

A.2 Product License holder: (Name and address)
Macleods Pharmaceuticals Ltd.
Office: Atlanta Arcade, Church Road, Near Leela Hotel, Andheri – Kurla Road, Andheri (East), Mumbai – 400 059,India
Factory : Block N-2 , Village Theda, Post Office Lodhimajra Tehsil Baddi, Distt. Solan, Himachal Pradesh - 174101,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 Is 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 Applicant for certificate if different from license holder:[12] : **Not Applicable**

2B

B.1 Applicant for certificate (name and address)

B.2 Status of applicant
a ☐ b ☐ c ☐ d ☐

B.2.1 For categories b and 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 Remark:[13]

3. 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 no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years) : **Yearly**

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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.] 173 205, INDIA
01795-244288, sdc4hp@gmail.com

Name of the authorized person: **Navneet Marwaha**

Signature:

Stamp and date

(NAVNEET MARWAHA) 21.2.18
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H.P.)-173205
01795-244288, sdc4hp@gmail.com

Licensing Authority cum State Drugs Controller * Himachal Pradesh *
सत्यमेव जयते

EXPLANATORY NOTES

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceuticals 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 strength 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-License 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 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) Manufacturers the dosage forms.
   (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-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 change 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 product information approved by the competent national regulator, 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 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 dosages 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 Pharmaceuticals Preparations (WHO) Technical Report Series, No.823, 1992, Annex 1). Recommendations specifically applicable to biological product has been formulated by the WHO Expert Committee on Biological Standarazation (WHO) Technical Report Series No. 822, 1992, Annex 1).

16. The 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 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

No. of Certificate : WHO-GMP-CERT/HFW-H (Drugs) 152/07/18-305 **VALID UPTO : 14.06.2021**

Name of the Product : Efavirenz Tablets 600 mg

List of Countries / Institution to which the above product will be Exported / Locally Supplied.

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. EI 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. Guinee
23. Botswana	67. Guatemala	111. Monaco	155. Slovenia	199. Hong Kong
24. Brazil	68. Guinea	112. Mongolia	156. Solomon	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 Rica
33. Central African Republic	77. Iran	121. New Zealand	165. Sweden	209. Republic de Guinee
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. Tadzhikistan
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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.] 173 205, INDIA
01795-244288, sdc4hp@gmail.com

Licensing Authority cum Drug Controller * Himachal Pradesh *

Name of the authorized person: **Navneet Marwaha**

Signature:

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Ba... (H.P.)-173205
...@gmail.com

Stamp and date

GOVERNMENT OF HIMACHAL PRADESH
HEA LTH AND FAMILY WELFARE DEPARTMENT
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 : **WHO-GMP-CERT/HFW-H (Drugs) 152/07/18-306 Valid Upto : 14.06.2021**

Exporting Country : **INDIA**

Importing (requesting) country : **AS PER ANNEXURE**

1. Name and dosage form of product : **Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]

Each film coated tablet contains:

Lamivudine	**USP**	**300 mg**
Efavirenz	**USP**	**600 mg**
Tenofovir Disoproxil Fumarate		**300 mg**
equivalent to 245 mg Tenofovir Disoproxil		

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 2 A and omit section 2B
If the answer to 1.2 is no, omit section 2A and continue section 2B[6 fd]

2A

A.1 Number of product license[7] and date of issue:
MNB/07/594 Dated 27.07.2017

A.2 Product License holder: (Name and address)
Macleods Pharmaceuticals Ltd.
Office: Atlanta Arcade, Church Road, Near Leela Hotel, Andheri – Kurla Road, Andheri (East), Mumbai – 400 059,India
Factory : Block N-2 , Village Theda, Post Office Lodhimajra Tehsil Baddi, Distt. Solan, Himachal Pradesh - 174101,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 Is 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 Applicant for certificate if different from license holder:[12] : **Not Applicable**

2B

B.1 Applicant for certificate (name and address)

B.2 Status of applicant
a ☐ b ☐ c ☐ d ☐

B.2.1 For categories b and 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 Remark:[13]

3. 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 no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years) : **Yearly**

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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.] 173 205, INDIA
01795-244288, sdc4hp@gmail.com

Controlling Authority cum Drug Controller * सत्यमेव जयते * Himachal Pradesh

Name of the authorized person: **Navneet Marwaha**

Signature:

(NAVNEET MARWAHA) 21.7.18
State Drugs Controller
Controlling Licensing Authority
Ba... 173205
P... ...@gmail.com

Stamp and date

EXPLANATORY NOTES

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceuticals 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 strength 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-License 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 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) Manufacturers the dosage forms.
   (b) packages and/or labels a dosage form manufactured by an independent company : or
   (c) is involved in none of the above.

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   (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 dosages limit for an active ingredient
   (e) Any other reason, please specify.

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16. The 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 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

No. of Certificate : WHO-GMP-CERT/HFW-H (Drugs) 152/07/18-306 **VALID UPTO : 14.06.2021**

Name of the Product : Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets

List of Countries / Institution to which the above product will be Exported / Locally Supplied.

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. EI 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. Guinee
23. Botswana	67. Guatemala	111. Monaco	155. Slovenia	199. Hong Kong
24. Brazil	68. Guinea	112. Mongolia	156. Solomon	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 Rica
33. Central African Republic	77. Iran	121. New Zealand	165. Sweden	209. Republic de Guinee
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. Tadzhikistan
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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.] 173 205, INDIA
01795-244288, sdc4hp@gmail.com

Name of the authorized person: **Navneet Marwaha**

Signature:

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H.P.) 173205
01795-244288, sdc4hp@gmail.com

Stamp and date

7.18

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int
In reply please refer to: CPH82/MS/mc/HA562
Your reference:

Ms Sandhya Jadhav
Manager - Drug Regulatory Affairs
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Marol Church Road
Andher-Kurla Road Andheri (E)
Mumbai 400 059
Maharashtra
Inde

11 December 2014

Dear Ms Jadhav,

WHO Prequalification Team – Medicines Assessment

I refer to your letter expressing Macleods Pharmaceuticals Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

HA562 - Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated, 600/200/300mg

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCLS: (2)

.../...

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data by email to **prequalassessment@who.int**, and in hard copy, clearly marked as indicated, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref. Number: HA562
  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Macleods Pharmaceuticals Ltd and the WHO Prequalification Team – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Macleods Pharmaceuticals Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
HIS/EMP/RHT/PQT Room 613
20 Avenue Appia
1211 Geneva 27
Switzerland

.../...

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: CPH71/MS/CB/HA562E

Your reference:

Mr Rakesh Chaurasia
General Manager – Drug Regulatory Affairs
Macleods Pharmaceutical Limited
304 Atlanta Arcade
Marol-Church Road
Andheri (East)
Mumbai 400 059
Inde

5 February 2013

Dear Mr Chaurasia,

WHO Prequalification of Medicines Programme
Efficacy/safety part of a product dossier

Thank you for submitting the data and information requested for the assessment of the product dossier for the WHO Prequalification of Medicines Programme.

A team of evaluators recently assessed the dossier:

HA562 - *Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate - 600mg/200mg/300mg tablets*

As a result of this assessment, you are informed that the efficacy/safety part of the dossier is considered acceptable. Please note that the outcome of the assessment of quality part of the dossier may affect the final acceptability of the efficacy/safety part of the dossier.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Head of Assessments
Prequalification of Medicines Programme
Quality Assurance and Safety: Medicines

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: CPH85/**HA611**/MS/SC

Your reference:

Ms Sandhya Jadhav
Manager - Drug Regulatory Affairs
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Marol Church Road
Andher-Kurla Road Andheri (E)
Mumbai 400 059
Maharashtra
Inde

13 July 2015

Dear Ms Jadhav,

WHO Prequalification Team – Medicines Assessment

I refer to your letter expressing Macleods Pharmaceuticals Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

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- **HA611 - Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg**

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCLS: (2)

.../...

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and

- submit the respective information about the intended variations and the required additional data by email to **prequalassessment@who.int**, and in hard copy, clearly marked as indicated, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: HA611

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Macleods Pharmaceuticals Ltd and the WHO Prequalification Team – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Macleods Pharmaceuticals Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
HIS/EMP/RHT/PQT Room 613
20 Avenue Appia
1211 Geneva 27
Switzerland

.../...

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: CPH78/HA611/MS/hh

Your reference:

Ms Sandhya Jadhav
Manager - Drug Regulatory Affairs
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Marol Church Road
Andher-Kurla Road Andheri (E)
Mumbai 400059
Maharashtra
Inde

31 March 2014

Dear Ms Jadhav,

WHO Prequalification Team
Efficacy/safety part of a product dossier

Thank you for submitting the data and information requested for the assessment of the product dossier for the WHO Prequalification Team – Medicines.

A team of evaluators recently assessed the dossier:

- **HA611** - Efavirenz/Lamivudine/Tenofovir disoproxil (fumarate) Tablet. Film-coated 600mg/300mg/300mg

As a result of this assessment, you are informed that the efficacy/safety part of the dossier is considered acceptable. Please note that the outcome of the assessment of quality part of the dossier may affect the final acceptability of the efficacy/safety part of the dossier.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: CPH61/MS/HA506E

Your reference:

Mr Rakesh Chaurasia
General Manager - Regulatory Affairs
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade
Marol - Church road
Andheri East
400 059 Mumbai
Inde

25 May 2011

Dear Mr Chaurasia,

WHO Prequalification of Medicines Programme
Efficacy/safety part of a product dossier

Thank you for submitting the data and information requested for the assessment of the product dossier within the WHO Prequalification of Medicines Programme.

A team of evaluators recently assessed the dossier

HA506 *Efavirenz 600mg tablets*

As a result of this assessment, you are kindly informed that the efficacy/safety part of the dossier is considered acceptable. Please note, that the outcome of the assessment of quality part of the dossier may affect the final acceptability of the efficacy/safety part of the dossier.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Head of Assessments
Prequalification of Medicines Programme
Quality Assurance and Safety: Medicines

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3717
Fax direct: +41 22 791 4730
E-mail : prequalassessment@who.int

In reply please
refer to the WHO product Ref N°: HA506/MS/ac

Your reference:

Mr Rakesh Chaurasia
General Manager – Drug Regulatory Affairs
Macleods Pharmaceutical Limited
304 Atlanta Arcade
Marol-Church Road
Andheri (East)
Mumbai 400 059
Inde

7 January 2013

Dear Mr Chaurasia,

WHO Prequalification of Medicines Programme

I refer to your letter expressing Macleods Pharmaceuticals Limited 's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently in the Forty-first report, as published in the WHO Technical Report Series N° 943 in 2007.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- Efavirenz 600 mg Tablets

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therfore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

ENCLS: (2)

.../...

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "Guidance on variations to a prequalified product dossier", as adopted in 2006 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 6 of the WHO Technical Report Series N° 943 in 2007, and
- submit the respective information about the intended variations and the required additional data by e-mail to – prequalassessment@who.int, and in hard copy, clearly marked as indicated, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification of Medicines Programme

  UNICEF Supply Division
  Oceanvej 10-12
  2100 Copenhagen Ø
  Denmark

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. Failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Macleods Pharmaceuticals Limited and the WHO Prequalification of Medicines Programme, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Macleods Pharmaceuticals Limited, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification of Medicines Programme
HSS/EMP/QSM
20 Avenue Appia
1211 Geneva 27
Switzerland

I look forward to receiving this information from you by ***23 January 2013*** at the latest. For further information please use the e-mail address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Head of Assessments
Prequalification Programme
Quality Assurance and Safety: Medicines