GOVERNMENT OF HIMACHAL PRADESH
HEALTH 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) 152/07/22-575 Valid Upto : 16.06.2024**

Exporting Country : **INDIA**

Importing (requesting) country : **UKRAINE**

1. Name and dosage form of product : **Zidovudine Oral Solution 50 mg / 5 ml**

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

Each 5 ml of oral solution contains:
Zidovudine USP 50 mg
Sodium Benzoate USP/NF 0.2 %
(added as preservative)

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 12.07.2022

A.2 Product License holder: (Name and address)
Macleods Pharmaceuticals Limited
Head Office: Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai – 400 059, India
Factory : Village Theda, Post Office Lodhimajra, Tehsil Baddi, District 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:

Digitally signed by Moraru Gr
Date: 2023.10.09 11:05:49 EE
Reason: MoldSign Signature
Location: Moldova

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