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 Organisation
(General instructions and explanatory notes attached)

Certificate No. : **DCA/SLN/DML/N (ADC) 86/10/2020/55**
Exporting (Certifying) Country: **INDIA**
Importing (requesting) Country: **BURUNDI**

1. Name and dosage form of product: **ZEELYTE ORS (Oral Rehydration Salts B.P.)**

Digitally signed by Sharea Stefan
Date: 2023.01.31 12:39:48 EET
Reason: MoldSign Signature
Location: Moldova

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3].
Each 20.5gm contains
Sodium Chloride B.P. 2.6 gm
Potassium Chloride B.P. 1.5 gm
Sodium Citrate B.P. 2.9 gm
Anhydrous Glucose B.P. 13.5 gm
(Dextrose)

1.2 Is this product licensed to be placed on the market for use in the Exporting country?[5] YES ☒ NO ☐ Unknown ☐

1.3 Is this product actually on the market in 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 with section 2B.[6]

2A
A.1 Number of Product license : S-MNB/10/67 & S-MB/10/68
And date of issue: 07th January 2016
A.2 Product-License holder **ZEE LABORATORIES LTD.**
(Name and Address): Behind 47, Industrial Area,
Paonta Sahib, District Sirmour, Himachal Pradesh
A.3 Status of the Product-license Holder:
a ☒ b ☐ c ☐
A.3.1 For categories B & C the name and address of the manufacturer producing the dosage form are:[9] **N.A**
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 Application 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:[8]

2B.3 Why is marketing authorization lacking?
Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐

B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing Plant in which the dosages form is produced? Yes ☒ No ☐ Not Applicable ☐

3.1 Periodicity of routine inspections (years): ONCE IN A YEAR
3.2 Has the manufacturer of this dosage form been inspected? YES ☒ No ☐
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisation?[15] ?
YES ☒ No ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of product?[16] Yes ☐ No ☐ NA ☒
If no explain.

Address of the certifying Authority:
Assistant Drugs Controller
cum- Drugs Licensing Authority
Distt. Sirmour at Nahan, 173001 (H.P.)

Name of Authorized person:
SUNNY KAUSHAL
Signature Stamp & Date: 12/02/2020

ASSTT. DRUGS CONTROLLER CUM-DRUGS LICENSING AUTHORITY NAHAN (H.P.) H.P. INDIA

(SUNNY KAUSHAL)
Assistant Drugs Controller
-Cum-Drugs Licensing Authority
District Sirmour, HQ. Nahan, H.P.
01702-222543, adc3sirmaur@gmail.com
12 FEB 2020