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)

Certificate No. : **DCA/SLN/DML/86/10/2020/166**
Exporting (Certifying) Country: **INDIA**
Importing (requesting) Country: **IVORY COAST**

Digitally signed by Harea Ştefan
Date: 2023.01.31 12:40:53 EET
Reason: MoldSign Signature
Location: Moldova

1. Name and dosage form of product: **HALO Injection (Haloperidol Injection B.P. 5mg/ml)**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3].
Each ml contains:

Haloperidol	B.P.	5mg
Water for Injection	B.P.	q.s.

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: 25th October 2017

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:

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

(SUNNY KAUSHAL) 28.01.2020
Assistant Drugs Controller
-Cum-Drugs Licensing Authority
District Sirmour, HQ. Nahan, H.P.
01702-222543, adc3sirmaur@gmail.com