

**GOVERNMENT OF HIMACHAL PRADESH  
HEALTH AND FAMILY WELFARE DEPARTMENT  
CERTIFICATE OF A PHARMACEUTICAL PRODUCT<sup>1</sup>**

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

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

1.1 Active ingredient(s)<sup>2</sup> and amount(s) per unit dose<sup>3</sup>.

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?<sup>5</sup> 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.<sup>6</sup>

2A

A.1 Number of Product license : S-MNB/10/67 & S-MB/10/68  
And date of issue: 25<sup>th</sup> 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:<sup>9</sup> N.A

A.4 Is summary basis of approval appended?<sup>10</sup>

YES ☒ NO ☐

A.5 Is the attached, officially approved product information complete and Consonant with the license?<sup>11</sup>

YES ☒ NO ☐ Not Provided ☐

A.6 Application for Certificate if different from license holder:<sup>12</sup>  
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:<sup>8</sup>

2B.3 Why is marketing authorization lacking?

Not ☐ Not ☐ Under ☐ Refused

☐

Required Requested Consideration

B.4 Remarks:<sup>13</sup>

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?<sup>15</sup> ?

YES ☒ No ☐

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

Address of the certifying Authority:

Assistant Drugs Controller

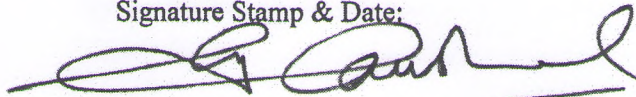
cum- Drugs Licensing Authority

Distt. Sirmour at Nahan, 173001 (H.P.)

Name of Authorized person:

SUNNY KAUSHAL

Signature Stamp & Date:



(SUNNY KAUSHAL)

Assistant Drugs Controller

-Cum-Drugs Licensing Authority

District Sirmour, HQ. Nahan, H.P.

01702-222543, adc3sirmaur@gmail.com

