

Certificate of Pharmaceutical Product(s)¹

This Certificate conforms to the format recommended by the World Health Organization
(General instruction and explanatory notes attached)

No. of Certificate : 17P/1/48/2010/ 15641 Date : 01/10/18

Exporting (Certifying) Country : INDIA

Importing (requesting) Country : ALL COUNTRY

1. Name and dosage form of product : VERMOR-20[Morphine Sulphate Tablets BP]

1.1 Active ingredient(s)² and amount(s) per unit dose³: Each uncoated tablet contains:

Morphine Sulphate BP 20 mg

Excipients q.s

Colour : Sunset Yellow FCF

1.2 Is this product licensed to be placed on the market for use in exporting country?⁵ Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country?⁵ Yes ☒ No ☐

The answer to 1.2 is Yes continue with section 2A and omit section 2B

The answer to 1.2 is No Omit Section 2A and Continue with section 2B⁶

2A.1 Number of product license ⁷ : 33/UA/2010 (Form-25) And date of issue : 25/03/2010	2B.1 Applicant for certificate (name and address) :
2A.2 Product License holder (Name & Address) Verve Humancare Laboratories, Plot No. 15-A, Pharmacy, Selaqui, Dehradun, Uttarakhand (India).	2B.2 Status of Applicant :
2A.3 Status of product License holder ⁸ : a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>	2B.2.1 For categories b and c the name and address of the manufacturer producing dosage form are ⁹ :
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : N.A	2B.3 Why is marketing authorization lacking? :
2A.4 Is Summary Basis of Approval appended? ¹⁰ : No	2B.4 Remarks ¹³ :
2A.5 Is the attached, officially approved product Information complete and consonant with the License? : Not Provided	
2A.6 Applicant for certificate different from license holder (name and address) ¹² : N.A	

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

Yes

3.1 Periodicity of routine inspections (years):

Annual

3.2 Has the manufacturer of this type of dosage form been inspected?

Yes

3.3 Do the facilities and operations confirm to GMP as recommended by 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

N.A

If no, explain :

This certificate valid upto : 28-08-2021

Address of certifying authority:

Drug Controller,

Directorate General of Health Services,

Sahastradhara Road, Dehradun, Uttarakhand, India.

Name of the authorized Person: Mr. Tajber Singh



Tajber Singh
11/10/18
(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)