

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 : 26/1/औषधि/44/2019/ 3049 Date : 26/03/2022

Exporting (Certifying) Country : INDIA

Importing (requesting) Country : All Country

1. Name and dosage form of product : Midaver [Midazolam Injection BP 1mg/ml-5ml]

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

Midazolam	BP	1mg
Water for Injection	BP	q.s

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 34/UA/SC/P-2010 (Form-28) And date of issue : 05-11-2020	2B.1 Applicant for certificate (name and address) :
2A.2 Product License holder (Name & Address) Verve Human care Laboratories, Plot No. 15-A, Pharmacity, 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

Annual

Yes

Yes

3.1 Periodicity of routine inspections (years):

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

3.3 Do the facilities and operations confirm to GMP as recommended by World Health Organization?¹¹

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 : 27-02-2025

Address of certifying authority:

Drug Controller,

Directorate General of Health Services,

Sahastradhara Road, Dehradun, Uttarakhand, India.

(Hemant Singh Negi)
Drug Controlling & Licensing Authority
(31/3) Garwal Mandal
Uttarakhand

Name of the authorized Person: Mr. Hemant Singh Negi