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/1/48/2010/15090** **Date** : 03-11-2018

Exporting (Certifying) Country : **INDIA**

Importing (requesting) Country : **All Country**

1. Name and dosage form of product : **N-XONE [Naloxone Injection BP, 0.4mg/ml-1ml]**

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

Naloxone Hydrochloride (Anhydrous)	**BP**	**0.4 mg**
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 2B[6]

2A.1 Number of product license[7] **34/UA/SC/P-2010 (Form-28)** And date of issue : **25/03/2010**	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 :
	2B.2.1 For categories b and c the name and address of the manufacturer producing dosage form are[9] :
2A.3 Status of product License holder[8]: a [√] b [ ] c [ ]	2B.3 Why is marketing authorization lacking ? :
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **N.A**	
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?[14] **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 :

Digitally signed by Chirtoacă Iurie
Date: 2021.09.21 08:59:12 EEST
Reason: MoldSign Signature
Location: Moldova

This certificate valid upto : 28-08-2021

Address of certifying authority:
Drug Controller,
Directorate General of Health Services,
Sahastradhara Road, Dehradun, Uttarakhand, India.

3/11/18
(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)

DRUG LICENSING CUM CONTROLLING AUTHORITY * UTTARAKHAND *

Name of the authorized Person: Mr. Tajber Singh