OFFICE OF THE DRUG CONTROLLING & LICENSING AUTHORITY
Directorate General of Medical Health & Family Welfare
Sahastradhara Road, Dehradun (Uttarakhand)

F.No. 17P/1/48/2010/ 13642 *Dated:* 07 *Sept 2018*

Certificate of Good Manufacturing Practices

On the basis of the Joint Inspection carried out on 24.08.2018 & 25-08-2018 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

Digitally signed by Margină Veaceslav
Date: 2019.03.18 22:06:45 EET
Reason: MoldSign Signature
Location: Moldova

1. ***Name & Address of the*** *M/s Verve Human Care Pharmaceuticals*
   Plot No. 15-A, Pharmacity, Selaqui,
   Dehradun -248011, Uttarakhand
   INDIA

2. ***Manufacturer's license number:-***
   Form 25-33/UA/2010
   Form 28-34/UA/SC/P-2010
   Form 28B-29/UA/X/SC/P-2014
   Form 25F-1/UA/X/2012

3. ***Table 1:***

Dosage form (s)	*Category(s)*	*Activity (ies)*
Tablets	*Non Betalactum*	*Manufacturing*
Injectable	*Non Betalactum*	*Manufacturing*

The responsibility for the quality for the quality of the individual batches of the pharmaceutical products manufacture through this process lies with the manufacturer.

This certificate remains valid until 28.08.2021. It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in completion with GMP.

The firm is following ***Good Manufacturing Practices as per World Health Organization (WHO) TRS Guidelines,*** *in the manufacturing & testing of the said categories of Products and Items in respect of which the Certificate of Pharmaceuticals products have been issued.*

Address of certifying Authority:

Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun (Uttarakhand) INDIA,

Name & function of responsible person:
Shri Tajber Singh
Drug Controlling & Licensing (Mfg.)
(Uttarakhand)

Email: *drugcontroluk@gmail.com*
Tel. no. NA
Fax No. 0135260874

DRUG LICENCING CUM CONTROLLING AUTHORITY * UTTARAKHAND * UTTARAKHAND

7/9/18

(Tajber Singh)
Drug Controlling & Licensing (Mfg.)
(Uttarakhand)

(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)

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/** 12250 **Date** : 06 - 11 - 2018

Exporting (Certifying) Country : **INDIA**

Importing (requesting) Country : **ALL COUNTRY**

1. Name and dosage form of product : **LABETALOL HYDROCHLORIDE INJECTION USP 5mg/ml-20 ml**

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

Labetalol Hydrochloride	**USP**	**5 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 Humancare 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?[11] **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 up to : 28-08-2021

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

Tajber Singh

6/11/2018

Name of the authorized Person: Mr. Tajber Singh

DRUGS LICENCING CUM CONTROLLING AUTHORITY UTTARAKHAND UTTARKHAND

(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
Garhwal Mandal (Uttarakhand)

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/** 15088 **Date** : 03-11-2018

Exporting (Certifying) Country : **INDIA**

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

1. Name and dosage form of product : **VERALINE (Norepinrphrine Bitartrate Injection USP 1 mg/ml,1 ml)**

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

Norepinephrine Bitartrate	**USP**	**2mg**
Eq. to Norepinephrine Base		**1 mg**
Water for Injection	**USP**	**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	2B
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 :
2A.3 Status of product License holder[8]: a [√] b [ ] c [ ]	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.

DRUG LICENCING CUM CONTROLLING AUTHORITY * UTTARAKHAND * UTTARAKHAND

Tajber Singh
3/11/2018
(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)

Name of the authorized Person: Mr. Tajber Singh

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/** 15080 **Date** : 03-11-2018

Exporting (Certifying) Country : **INDIA**

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

1. Name and dosage form of product : **VERALINE (Norepinrphrine Bitartrate Injection USP 1 mg/ml)**

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

Norepinephrine Bitartrate	**USP**	**2mg**
Eq. to Norepinephrine Base		**1 mg**
Water for Injection	**USP**	**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**

2A.2 Product License holder (Name & Address)
Verve Human care Laboratories,
Plot No. 15-A, Pharmacity, Selaqui,
Dehradun, Uttarakhand (India).

2A.3 Status of product License holder[8]:
a [√] b [ ] c [ ]

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**

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**

2B.1 Applicant for certificate (name and address) :

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] :

2B.3 Why is marketing authorization lacking ? :

2B.4 Remarks[13] :

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 :

This certificate valid upto : 28-08-2021

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

DRUG LICENCING CUM CONTROLLING AUTHORITY * UTTARAKHAND * UTTARAKHAND

Tajber Singh 3/11/18

(Tajber Singh)
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)

Name of the authorized Person: Mr. Tajber Singh