GOVERNMENT OF HIMACHAL PRADESH
Health & Family Welfare- Department, Himachal Pradesh
CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/22-142 Exporting (certifying) Country: INDIA
Valid up to : 22.02.2024 Importing (requesting) Country: PERU

1.0 Proprietary Name (If applicable) and Dosages form of Product : **DOBUSOL 50**
Dobutamine Injection USP 250mg/50ml

Active ingredients(s) and amount per unit dose :

Each Vial contains	
Dobutamine Hydrochloride USP	
eq. to Dobutamine	250.0 mg
Water for Injection USP	q.s.

1.1 Is this product is licensed to be placed on the market for use in exporting country?
Yes [X] No [ ] Not applicable [ ]

1.2 Is this product naturally on the market in the exporting country? Yes [ ] No [ ] Unknown [ ]

(If the answer to 1.2 is yes, continue with Question 2A & omit Question 2B & if answer to 1.2 is No, omit the Question 2A and continue with Question 2B)

2A

1. Product License & date of Issue.
   MB/05/255, 08/03/2021
2. Product License holder (Name and add.)
   United Biotech (P) Limited
   Bagbania, Baddi-Nalagarh Road
   District-Solan (HP) 174101 India
3. Status of applicant a/b/c (key in appropriate Category as define in note)
   a [ ] b [ ] c [ ]
4. Permission letter no.
   Is an approved technical summary appended?
   Yes [ ] No [X] Not provided [ ]
5. Is the attached officially approved product Information complete and consonant with the License
   Yes [ ] No [ ] Not provided [X]
6. Applicant for certificate, if different from license holder (name & add.) : SAME

2B

1. Applicant for certificate (Name & Address)
2. Status of applicant a/b/c (key in appropriate category as define in note)
   a [ ] b [ ] c [ ]
3. Why is authorization lacking?
   Not Required [ ]
   Not Required [ ]
   Under consideration [ ]
   Refused [ ]
4. Remarks:

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced? [14] Yes [X] No [ ] Not applicable [ ]

3.1 Periodicity of routine inspection: Once in a year.

3.2 Has the manufacturer of this type of dosage forms been inspected? : Yes [X] No [ ]

3.3 Does the facility and operation conform to GMP as recommended by the World Health Organization?

Yes / No / Not applicable Yes [ ] No [ ] Not applicable [ ]

4. Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacturer of the product? Yes [ ] No [ ] if no explain [ ]

Address of certifying authority:
State Drugs Controller
Controller-Cum-Licensing Authority
Health and Family Welfare Department
Sai Road, Baddi, Distt. - Solan, 173205 (H.P.) India

Name of the Authorizing person: Mr. Navneet Marwaha

Signature :

Stamp & Date :

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com
04 MAR 2022

Digitally signed by Harea Stefan
Date: 2023.08.14 11:09:27 BST
Reason: MoldSign Signature
Location: Moldova

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION
(GENERAL INSTRUCTION AND EXPLANATORY NOTES ATTACHED)

GENERAL INSTRUCTION: Please refer to the guidelines for full instructions how to complete with form an information on the implementation of the scheme. The forms are suitable for generation by computers. They should always be submitted as hard copy with responses printed in type rather hand written additional sheets should be appended, as necessary, to accommodate remarks and explanations.

EXPLANATORY NOTES

1. This certificate which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country, it is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, where possible, international Nonproprietary Name (INNs) or national nonproprietary names.
3. The formula (Complete composition) of the dosage from should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product –licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market ;

(a) Manufactures the dosage form;
(b) Packages and / or label a dosage form manufactured by an independent company ; or
(c) Is involved in none of the above.

9. This information can be provided only with the consent of the product –licence holder or , in the case of non –registered products , the applicant . Non –completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licnece. If the production site is changed, the licence must be updated or it will cease to be valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of Product Characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:

(a) The product has been developed exclusively for the treatment of conditions-particularly tropical diseases not endemic in the country of export;
(b) The product has been reformulated with a view to improving its stability under tropical conditions.
(c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the expert committee on specifications for pharmaceutical preparations (WHO technical report series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO expert committee on biological standardization (WHO technical report series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.