No. of Certificate: 17P/1/13/2014/*15487*
Date: 30 NOV 2016

Exporting (Certifying) Country: **India**
Importing (Requesting) Country: **Costa-Rica**

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

Proprietary name (if applicable) and dosage form: **BDMUSTIN** **Bendamustin for Injection 100 mg (Lyophilized)**

1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] (complete qualitative composition including excipients, see attached)

Each vial contains:
Bendamustin … 100 mg
Mannitol BP…170 mg

1.2 Is this product licensed to be placed on the market for use in the exporting country? **YES**
If yes, complete box A, if no, complete box B:

1.3 Is this product actually on the market in the exporting country?[5] **YES**

A	B
2A.1 Number of product licence[7] & date of issued : **20UA/LL/SC/P-2014 dated 22.02.2014**	2B.1 Applicant for certificate (name & address)
2A.2 Product licence holder: **M/s BDR Pharmaceuticals International Pvt. Ltd., c/o M/s Plot no. 20-22 & 49-51, IIE, Sector-5, SIDCUL, Pantnagar, Udhamsingh Nagar, Uttarakhand (India)**	2B.2 Status of applicant: (a) ☐ (b) ☐ (c) ☐ (d) ☐
	2B.2.1 For categories b and c the names and address of the manufacturer producing the dosage form are[9]:
2A.3 Status of product licence holder[8]: (a) ☑ (b) ☐ (c) ☐	2B.3 Why is marketing authorization lacking? Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9]: Not Applicable	
2A.4 Is summary basis of Approval appended[10]? Yes ☐ No ☑	
2A.5 Is the attached, officially approved product information complete and consonant with the licence[11]? Yes ☐ No ☐ Not provided ☑	2B.4 Remark:[13]
2A.6 Applicant for certificate if different from licenced holder: Not Applicable[12]	

3.Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes ☑ No ☐ NA ☐

3.1 Periodically of routine inspection (years): **Once in a year**

3.2 Has the manufacture of this type of dosage form been inspected Yes ☑ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] Yes ☑ No ☐

3.4 Does the information submitted by the applicant satisfycertifying authority on all aspects of the manufacture of the product?[16] Yes ☐ No ☐ NA ☑

WHO-GMP-CERT.NO.:- 17P/1/13/2014/15503 valid upto 19.10.2017

Name of the authorized person: **Shri. Hemant Singh Negi**

Address of certifying authority:
Drug Licencing cum Controlling Authority
Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun-248001 (INDIA)
Telephone no. NA

Signature:

Stamp & Date

DRUG LICENCING CUM CONTROLLING AUTHORITY UTTARAKHAND

Digitally signed by Sîli Oleg
Date: 2019.03.05 10:14:09 EET
Reason: MoldSign Signature
Location: Moldova

1. This certificate which is in the form recommended by WHO, establishes the status of the pharmaceuticals 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, whenever possible, International Nonproprietary Names (INNs) or National Nonproprietary Names.
3. The formula (complete composition) of the dosage form 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 labels 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 inclusion of this information.
   It should be noted that information concerning the site of production is part of the product licence. 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 of improving its stability under tropical conditions.
(c) The product has been reformulated to exclude excipients not approved for use in pharmaceuticals products in the country on 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 qualify control of drugs referred to in the certificate are those included in the thirty-second report of the Export Committee on specifications of 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 (WHP 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 identity 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.
17. The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.