CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

(This certificate conforms to the format recommended by World Health Organization)
(General instructions and explanatory notes overleaf)

Certificate No.: **MFG/WHO-COPP/BDR Pharma/2018/CRI-I** 700728
Exporting (certifying country): **INDIA** Importing (requesting country): **COSTA RICA**

1. Name and dosage form of product: **LEUPROLIDE ACETATE DEPOT FOR INJECTION 3.75 MG**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3] : Each Vial Contains:
Leuprolide Acetate (Leuprorelin) BP.....3.75 mg

For Complete qualitative composition including excipients,[4] : **Yes**

EXCIPIENTS		
Poly-(D-L-Lactide-co-glycolide)	BP	37.5 mg
Gelatin (purified)	BP	0.8 mg
D- Mannitol	BP	7.95 mg
Water for Injections	BP	q.s.

Diluent for Leuprolide Acetate Depot for Injection 3.75 mg (2 ml)
Each ml Contains:

Sodium Carboxymethylcellulose	USP	5 mg
Polysorbate 80	BP	1 mg
D- Mannitol	BP	50 mg
Glacial Acetic Acid	USP	
to adjust pH		
Water for Injections	BP	q.s.

Digitally signed by Sîli Oleg
Date: 2019.03.05 10:16:20 EET
Reason: MoldSign Signature
Location: Moldova

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] : **Yes**
1.3 Is the product actually on the market in the exporting country? : **Yes**
If the answer to 1.2 is yes, continue with section 2A and omit section 2B,
If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

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2A.1	Number of product licence[7] and date of issue: **G/28A/4626-A dtd. 16/06/2015**	2B.1	Applicant for certificate (name and address): **Not Applicable**
2A.2	Product license holder: (Name and Address) **BDR Pharmaceuticals International Pvt. Ltd., Mfgd At: - National Highway No. - 8, Near GRID, KABILPORE-396 424, Navsari. Gujarat State, India**	2B2	Status of applicant [8]: **Not Applicable**
2A.3	Status of product – license holder[8] : **Manufactures the dosage form.** No 050 94	2B.2.1	For categories b and c the name and address of the manufacturer producing the dosage form is:[9] **Not Applicable**
2A.3.1	For categories b & c the name and address of the Manufacturer Producing the dosage form are[9]. : **Not Applicable**	2B.3	Why is marketing authorization lacking? **Not Applicable**
2A.4	Is summary basis of approval appended[10]? : **No**	2B.4	Remarks:[13] **Not Applicable**
2A.5	Is the attached officially approved product information Complete and consonant with the licence[11]? : **Not Provided**		
2A.6	Applicant for certificate, (name and address)[12]: (If different from license holder) **Not Applicable**		

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3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14] : **Yes**
(If not or not applicable, proceed to question 4)
3.1 Periodicity of routine inspection (years) : **Yearly**
3.2 Has the manufacture of this type of dosage form been inspected? : **Yes**
3.3 Does the facilities and operations conform to GMP as recommended by World Health Organization? [15] : **Yes**

4. Does the information submitted by the applicant satisfy the certifying authority in all aspects of the manufacture of the product? [16]: **Yes**
If no, explain

This certificate is valid up to: **20/07/2019**

Address of certifying authority :

Food and Drugs Control Administration,
Gujarat State, Block No. 8,
1st Floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat, India

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

28 MAR 2018

Name of authorized person:

Signature:
Stamp and date:

ATTESTED
Joint. Commissioner

NOTARY Name G. H. Shukla Area Gr. Mumbai Reg. No. 121/84 GOV. OF MAHARASHTRA

AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

SANJAY A. WAKKAR
Deputy Director

General Instructions

1. Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.
2. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.
3. Additional Sheets should be appended, ass 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, 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-license 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 license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   a. manu[illegible] the dosage form;
   b. packa[illegible] company; or
   c. is inv[illegible]
9. This informati[illegible] holder or, in the case of non-registered p[illegible] at the party concerned has not agreed to in[illegible] cerning the site of production is part of the p[illegible] to be updated or it is no longer valid.
10. This refers t[illegible], that summarizes the technical basis on wh[illegible]
11. This refers t[illegible] ory authority, such as Summary Product Cha[illegible]
12. In this circu[illegible] ne product-license holder. This permission [illegible]
13. Please indic[illegible] gistration.
    a. the p[illegible] nditions — particularly tropical dis[illegible]
    b. the p[illegible] nder tropical conditions;
    c. the p[illegible] ved for use in pharmaceutical pro[illegible]
    d. the p[illegible] limit for an active ingredient;
    e. any c[illegible]
14. Not applica[illegible] than that issuing the product certificate a[illegible] acture.
15. The require[illegible] ol of drugs referred to in the certificate a[illegible] mmittee 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-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country: INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to BDR PHARMACEUTICALS INTL. PVT. LTD.
has been signed by SANJAY A. WAKKAR
with the seal / stamp of DY. DIRECTOR, IMC HAMBER OF COMMERCE AND INDUSTRY, MUMBAI
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 20-Apr-2018 at NEW DELHI, INDIA
with reference no. MHMC0013679818
Seal / Stamp
Signature

The Ministry of External Affairs accepts no responsibility for the contents of the document

NOTARY Name G. H. Shukla Area Gr. Mumbai Reg. No. 121/84 GOVT. OF MAHARASHTRA

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ATTESTED TRUE COPY

G. H. SHUKLA,
NOTARY GREATER MUMBAI
Jagdamba Bhavan, Ground Floor,
Ganpatrao Kadam Marg, Lower Parel,
MUMBAI - 400 013.

13 APR 2018