## CERTIFICATE OF A PHARMACEUTICAL PRODUCT

(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)<sup>2</sup> and amount (s) per unit dose <sup>3</sup> : Each Vial Contains:

Leuprolide Acetate (Leuprorelin) BP.....3.75 mg

For Complete qualitative composition including excipients,4: Yes

Diluent for Leuprolide Acetate Depot for Injection **EXCIPIENTS** Poly-(D-L-Lactide-co-glycolide) BP 3.75 mg (2 ml) 37.5 mg Each ml Contains: BP Gelatin (purified) 0.8 mg 7.95 mg Sodium Carboxymethylcellulose USP 5 mg D- Mannitol BP Polysorbate 80 1 mg Water for Injections BP q.s. BP D- Mannitol 50 mg **USP** Glacial Acetic Acid to adjust pH BP Water for Injections q.s.

Is this product licensed to be placed on the market for use in the exporting country? 5: Yes 1.2

Is the product actually on the market in the exporting country? 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

2

2A.1	Number of product licence <sup>7</sup> and date of issue:	2B.1	Applicant for certificate (name and address):
27 (. 1	G/28A/4626-A dtd. 16/06/2015		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 <sup>8</sup> :  Manufactures the dosage form.	2B.2.1	For categories b and c the name and address of the mapufacturer producing the dosage form is:9
2A.3.1	For categories b & c the name and address of the Manufacturer Producing the dosage form are <sup>9</sup> . : <b>Not Applicable</b>	2B.3	Why is marketing authorization lacking?  Not Applicable
2A.4	Is summary basis of approval appended 10?: No	CZBME	Remarks: Not Applicable
2A.5	Is the attached officially approved product information Complete and consonant with the licence <sup>11</sup> ?: Not Revided		AND IN
2A.6	Applicant for certificate, (name and address) <sup>12</sup> // (If different from license holder) <b>Not Applicable</b>	APR	2018

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 Yes

3.2 Has the manufacture of this type of dosage form been inspected.

3.3 Does the facilities and operations conform to GMP as recommended by World Health Organization? 15

Yes

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, 1<sup>st</sup> Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat, India

Name of authorized person:

Signature: Stamp and date:

Commissioner

Name G. H. Shukla Area Gr. Mumbai Reg. No. 121/84

AUTHORISED SIGNATORY

MUMBALINDIA

Deputy Director

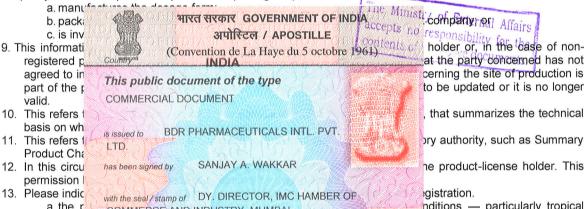
## **General Instructions**

- Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.
- The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.
- Additional Sheets should be appended, ass necessary, to accommodate remarks and explanations.

## **Explanatory notes**

valid

- 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
- 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 productlicense 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:



13. Please indic a. the p COMMERCE AND INDUSTRY, MUMBAI dis

Certified by b. the p c. the p Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS prc on 20-Apr-2018 at NEW DELHI, INDIA d. the p

e. any o with reference no MHMC0013679818 14. Not applica certificate ar Viseal / Stamp

ol of drugs referred to in the certificate a product of drugs referred to in the 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 15. The require 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.





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

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