시점확인필
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정부시점확인센터

Ministry of Food and Drug Safety
Daejeon Regional Office of Food and Drug Safety

166, Cheongsa-ro, Seo-gu, Daejeon, 35209, Republic of Korea,
Tel: +82-42-480-8710, Fax: +82-42-480-8715

Certificate of a Pharmaceutical Product

No. of Certificate : 2021-G1-0275
Exporting (certifying) country : Republic of Korea
Importing (requesting) country : Philippines

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Dongkook Pharmaceutical Co., Ltd.
- Address : 33-19, Yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea

2. Name and dosage form of product
: Lorelin Depot Injection 3.75 mg / Powder for injection
Product Name in Korean : 로렐린데포주사(류프로렐린아세트산염)

2.1. Number of product license and date of issue
: 34 / Dec. 14, 1999

2.2. Active ingredient(s) and amount(s) per unit dose
(For complete quantitative composition including excipients, see attached.)
: Each vial (43.17 mg) contains
Leuprolide acetate ---------- 3.75 mg

You can verify the Certificate through VERIFICATION NO. on the webpage(https://nedrug.mfds.go.kr/pbp/CCBSC03/certificate)
or by checking the barcode with the mobile scanner App (MaSmartDetector).

2.3. Is this product licensed to be placed on the market for use in the exporting country ?

┌ Yes (O) ⇒ fill out section A, omit section B.
└ No ( ) ⇒ omit section A, fill out section B.

A.1. Is this product actually on the market in the exporting country? Yes(O) / No( ) / Unknown( ) A.2. Is Summary Technical Basis of Approval appended? Yes( ) / No(O) A.3. Is the attached, officially approved product information complete and consonant with the license? Yes(O) / No( ) / Not provided( )
B.1. Why is marketing authorization lacking? ┌ not required (just Applicant"s option, even possible) ( ) ├ not requested (not reviewed for marketing) ( ) ├ under consideration ( ) └ refused ( ) B.2. Remarks (the reason not requesting registration) :

2.4. Status of product-license holder

a (O) manufactures the dosage form

b ( ) consigns wholly or partially the manufacturing process to other company :

- the manufacturer"s
· Name :
· Address :
· Consigned process :

c ( ) is not involved in manufacturing process :

- the manufacturer"s
· Name :
· Address :
· Consigned process :

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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 inspection(years) : 3 years
Inspection is determined by risk-based assessment under the provisions of the Pharmaceutical Affairs Act.

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

3.3. Do the facilities and operations conform to the WHO-GMP?
Yes, It conforms to PIC/S and WHO GMP.

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? YES

※ Attached, if necessary : approved product information (O)

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Issued date :JAN. 27, 2021 (Certificate No.2021-G1-0275)

Certified by **Park nam soo**

Park Nam Soo

Director
General Services Division
Daejeon Regional Food & Drug Administration

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<Attachment>

Formulation

Each vial (43.17 mg) contains

Active Ingredient :
Leuprolide acetate ---------- 3.75 mg

Inactive Ingredients :
Poly (D,L-lactide-co-glycolide) ---------- 32.82 mg
D-mannitol ---------- 6.6 mg

Attached sterile vehicle (2 mL) contains
D-mannitol ---------- 100 mg
Carboxymethylcellulose sodium ---------- 10 mg
Polysorbate 80 ---------- 2 mg
Water for Injection ---------- q.s.

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