Daejeon Regional Office of Food and Drug Safety

166 Cheongsa-ro, Seo-gu, Daejeon, 302828, Korea

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Certificate of a Pharmaceutical Product

┌ No. of Certificate : 2016-G1-0329
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : Bangladesh

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
: Hyaron Prefilled Injection / Solution for injection in prefilled syringe
Product Name in Korean : 히야론프리필드주사(히알루론산나트륨)

2.1. Number of product license and date of issue
: No. 1416-143 / Oct. 27, 1993

2.2. Active ingredient(s) and amount(s) per unit dose
(For Complete quantitative composition including excipients, see attached.)
: Each mL contains
Active ingredient : Sodium Hyaluronate ---------- 10 mg

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( ) / No( ) / Not provided(O)
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 partially the manufacturing process to other company

- In case of "b", the manufacturer's

· Name :

· Address :

· Consigned process :

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? : YES

※ Inspection of each dosage form is implemented by the administrative authority under the provision of the Pharmaceutical Affairs Act.

3.1. Periodicity of routine inspection(years) : 3 years

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

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

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Issued date : Feb. 05, 2016

Certified by

OK GI SUK

Director
of General Services Division
Daejeon Regional Commissioner
Food & Drug Administration

<Attachment>

Formulation

Each mL contains

Active Ingredient :
Sodium Hyaluronate (EP) ---------- 10 mg

Inactive Ingredients :
Sodium chloride (KP) ---------- 8.5 mg
Dibasic Sodium Phosphate Hydrate (KP) ---------- q.s.
Monobasic Sodium Phosphate (USP) ---------- q.s.
Water for Injection (KP) ---------- q.s.