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

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

Tel: 82-42-480-8710, Fax: 82-42-480-8715

JUAN RICARDO SAN MARTIN URREJOLA NOTARIO PUBLICO Huerfanos 835 Piso 28 Santiago MAS

Certificate of a Pharmaceutical Product

┌ No. of Certificate : 2017-G1-0273
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : Chile

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Korea United Pharm. Inc.
- Address : 107 Gongdan-ro, Yeonseo-myeon, Sejong-si, Republic of Korea

2. Name and dosage form of product
: Bleomycin Sulfate for Injection 15 units
Product Name in Korean : 브로이신에스주

2.1. Number of product license and date of issue
: 1752-574 / May 12, 1998

2.2. Active ingredient(s) and amount(s) per unit dose
(For Complete quantitative composition including excipients, see attached.)
: Each vial contains
Bleomycin Sulfate ····· 15 units (Potency)

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

┌ Yes (V) ⇒ 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(V) / No( ) / Unknown( )
A.2. Is Summary Technical Basis of Approval appended ? Yes( ) / No(V)
A.3. Is the attached, officially approved product information complete and consonant with the license ? : Yes( ) / No( ) / Not provided(V)
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 (V) manufactures the dosage form

b ( ) consigns 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 : FEB. 03, 2017

Certified by

Director
of General Services Division
Daejeon Regional Food & Drug Administration


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<Attachment>

PRODUCT NAME : BLEOMYCIN SULFATE FOR INJECTION 15 UNITS

Ingredients	**Per Vial**
Active Ingredient:	
Bleomycin Sulfate	15 units
	(Potency)
Inactive Ingredients:	
Water for Injection*	q.s. to 1.5 mL

* Evaporated during manufacturing.


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(Convention de La Haye du 5 octobre 1961)

1. Country : Republic of Korea

This public document

2. has been signed by Director

3. acting in the capacity of Director

4. bears the seal/stamp of Daejeon Regional Food and Drug Administration

Certified

5. at Seoul 6. 10/02/2017

7. by The Ministry of Foreign Affairs

8. No. XXA201703JE2PN

9. Seal/ stamp 10. Signature

Kim byoungho

Kim Byoung Ho

MINISTRY OF FOREIGN AFFAIRS OF THE REPUBLIC OF KOREA

외교부

AUTORIZACION
NOTARIAL AL DORSO

CERTIFICO QUE LA PRESENTE FOTOCOPIA ES FIEL DEL ORIGINAL TENIDO A LA VISTA, COMPUESTO DE ..... FOJAS, Y QUE DEVUELVO AL SOLICITANTE.-

STGO. 01 MAR 2017

JUAN RICARDO SAN MARTIN URREJOLA
NOTARIO PUBLICO SANTIAGO

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