

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

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

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

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)

N RICARDO SAN / 1951





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

☐ Yes (V) $\Rightarrow$ fill out section A, omit section B.

☐ No () $\Rightarrow$ 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 :

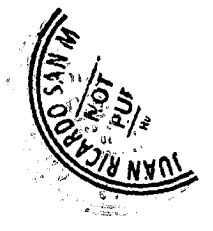
c () is not involved in manufacturing process :

- the manufacturer's

· Name :

· Address :

· Consigned process :



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





<Attachment>

**PRODUCT NAME : BLEOMYCIN SULFATE FOR INJECTION 15
UNITS**

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

* Evaporated during manufacturing.



APOSTILLE
(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

Kimbyoungho

Kim Byoung Ho



**AUTORIZACION
NOTARIAL AL DORSO**

