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

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Certificate of a Pharmaceutical Product

No. of Certificate : 2025-D1-1277
Exporting (certifying) country : Republic of Korea
Importing (requesting) country : Mexico

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : APROGEN BIOLOGICS Inc.
- Address : 16, Dumeori-gil, Yanggam-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea

2. Name and dosage form of product
: GLUTA-1 INJ. 1,200MG
Product Name in Korean : 에이프로젠글루타티온주1200mg(글루타티온(환원형))
Dosage form : Injection

2.1. Number of product license and date of issue
: No. 5209 and Nov. 20, 2018

2.2. Active ingredient(s) and amount(s) per unit dose
(For complete quantitative composition including excipients, see attached.)
Each injection contains :
Active ingredient :
Glutathione(Reduced) ... 1,200 mg

(See attachment)

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 ( ) manufactures the dosage form

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

- the manufacturer's
· Name : PENMIX Co., LTD.
· Address : 33, Georimak-gil, Jiksan-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea
· Consigned process : All 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 by the certifying authority? 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 :AUG. 22, 2025 (Certificate No.2025-D1-1277)
Certified by **Jung Young Sook**

JUNG YOUNG SOOK

Director General Services Division
Gyeongin Regional Food & Drug Administration

<Attachment>

1. Name of product : GLUTA-1 INJ. 1,200MG
2. Dosage form : Injection
3. Composition :

Each injection contains :

Active ingredient :

Glutathione(Reduced) ... 1,200 mg

Inactive ingredient :

Sodium Bicarbonate ... Proper quantity