CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

- Name of Manufacturer(License No.) : SK Plasma Co., Ltd. (352)
- Address of Manufacturer : 157, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea
- Manufacturing Operation(s) : see attachment(s)

We hereby certify that the above manufacturer complies with Good Manufacturing Practices of Pharmaceutical Product(s) according to the Korea Pharmaceutical Affairs Act and PIC/S GMP guides.

End date of Last Inspection : MAR. 11, 2021
Date of Expiration : MAR. 10, 2024

Issue Date : MAY. 03, 2021 2021-E1-0129
Signature Hong Heon Woo

COMMISSIONER OF Daegu Regional Office of Food and Drug Safety

Ministry of Food and Drug Safety
Daegu Regional Office of Food and Drug Safety
405, Seongseo-ro, Dalseo-gu, Daegu, 42612, Republic of Korea,
Tel: +82-53-592-7133, Fax: +82-53-592-2709
Ministry of Food and Drug Safety

2021-E1-0129

* This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if the date of expiration has passed.

Attachment(s)

Finished Products
I. Dosage forms of Product(s)
1. Oral solids
2. Injections
3. Ophthalmic solutions
4. Oral liquids
5. Topical liquids
6. Ointments
7. Other dosage forms
8. Special preparation(penicillin preparations, sex hormone preparations, cephalosporin preparations, cytotoxic anti-cancer agents, biopharmaceutical products)
Biopharmaceutical products and etc. [Injection(plasma derived products)]
II. Laboratory Control
1. Address of Laboratory
Same as the address stated in the front page.
2. Quality Control testing
Chemical/Physical, Microbiological(non-sterility), Sterility test.

2021-E1-0129

Ministry of Food and Drug Safety

Osong Health Technololgy Administration Complex, 187, Osongsaengmyeong 2-ro,
Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28159, Republic of Korea,
Tel: +82-43-719-1010, Fax: +82-43-719-1000

Certificate of a Pharmaceutical Product

No. of Certificate : 2023-A1-0857
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 : SK Plasma Co., Ltd.
- Address : 157, Saneopdanji-gil, Pungsan-eup, Andong-si,
Gyeongsangbuk-do, Republic of Korea

2. Name and dosage form of product
: Liv-Gamma SN Inj. (Human Normal Immunoglobulin in Maltose (pH4.25))
Product Name in Korean : 리브감마에스앤주[말토즈첨가사람면역글로불린(pH4.25)]

2.1. Number of product license and date of issue
: 5022 / APR. 28, 2011

2.2. Active ingredient(s) and amount(s) per unit dose
(For complete quantitative composition including excipients, see attached.)
: Each 1mL contains,
Human Normal Immunoglobulin-G.....50mg

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 :

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 :MAY. 10. 2023 (Certificate No.2023-A1-0857)
Certified by **Kim Nam Soo**

김 남 수

Director for Novel Products Approval Ministry of Food and Drug Safety

<Attachment>

[COMPOSITION]

Each 1mL contains

Human Normal Immunoglobulin-G..... 50mg

Maltose Hydrate..... 100mg

Water for Injection..... q.s.

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country : Republic of Korea

This public document

2. has been signed by Kim Nam Soo

3. acting in the capacity of Director

4. bears the seal/stamp of Ministry of Food and Drug Safety

Certified

To verify the Apostille, please refer to the website below.
https://www.apostille.go.kr

5. at Seoul 6. the 22/05/2023

7. by The Ministry of Foreign Affairs

8. No. XXA2023U6Y69AN

9. Seal/stamp

MINISTRY OF FOREIGN AFFAIRS OF THE REPUBLIC OF KOREA
(4-4)
외교부

10. Signature

Jeong Hyo Youn