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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

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







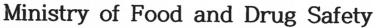
 * This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if the date of expiration has passed.

Attachment(s)					
Finished Products					
I. Dosage forms of Product(s)					
1. Oral solids					
OOD ANA					
2. Injections					
0' 7'					
3. Ophthalmic solutions					
18/0					
4. Oral liquids					
E. Thailaide					
5. Topical liquids					
6. Ointments					
of ominions					
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







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 issue5022 / 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





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2.3. Is this product licensed to be placed on the market for use in the exporting country?
Yes (O) \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(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:



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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 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,	n nece	ssary . ap	pproved p	roduct in	normation	(0)
	•••	• • • • • • • • • • • • • • • • • • • •		••••••	• • • • • • • • • • • • • • • • • • • •	*******************	•••••

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

以近今

Director for Novel Products Approval Ministry of Food and Drug Safety



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<Attachment>

[COMPOSITION]

Each 1mL contains

Human Normal Immunoglobulin-G.	50mg
Maltose Hydrate	100mg
Water for Injection	q.s.





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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

10. Signature

Myoun

Jeong Hyo Youn