CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

- Name of Manufacturer(License No.) :
  Hanlim Pharm. Co., Ltd. (No.1496)
- Address of Manufacturer : 2-27, Yeongmun-ro, Cheoin-gu, Yongin-si, Gyeonggi-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 : 2022.06.24
Date of Expiration : 2025.06.23

Issue Date : MAY. 11, 2023 (Certificate No.2023-D1-0790)
Signature Rhee Seong Do

Rhee, Seong Do

COMMISSIONER OF Gyeongin Regional Office of Food and Drug Safety

Ministry of Food and Drug Safety
Gyeongin Regional Office of Food and Drug Safety
Building #5, Gwacheon Government Complex, 47, Gwanmun-ro, Gwacheon-si, Gyeonggi-do, 13809, Republic of Korea,
Tel: +82-2-2110-8000, Fax: +82-2-2110-0801
Ministry of Food and Drug Safety

* 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.

2023-D1-0790

Attachment(s)

Finished Products
Ⅰ. Dosage forms of Product(s)
1. Oral solids
Tablets, Capsules
2. Injections
Injections, Lyophilized powder for injections
3. Ophthalmic solutions
Ophthalmic solutions, Ophthalmic suspensions
4. Oral liquids
Solution for oral, Elixirs, Nasal solutions(Spray), Nasal suspensions(Spray)
5. Topical liquids
6. Ointments
Ophthalmic ointments
7. Other dosage forms
Otic solutions
8. Special preparation(penicillin preparations, sex hormone preparations, cephalosporin preparations, cytotoxic anti-cancer agents, biopharmaceutical products)
Ⅱ. Laboratory Control
1. Address of Laboratory
2-27, Yeongmun-ro, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea
2. Quality Control testing
Chemical/Physical, Microbiological(non-sterility), Sterility, Animal

2023-D1-0790

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country : Republic of Korea

This public document

2. has been signed by Rhee Seong Do

3. acting in the capacity of Commissioner

4. bears the seal/stamp of Gyeongin Regional Office 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 02/06/2023

7. by The Ministry of Foreign Affairs

8. No. XXA2023Y3JT7RL

9. Seal/stamp

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

10. Signature

Jeong Hyo Youn

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

Building #5, Gwacheon Government Complex, 47, Gwanmun-ro, Gwacheon-si,
Gyeonggi-do, 13809, Republic of Korea,
Tel: +82-2-2110-8000, Fax: +82-2-2110-0801

Certificate of a Pharmaceutical Product

┌ No. of Certificate : 2023-D1-0898
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : Georgia

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Hanlim Pharm. Co., Ltd.
- Address : 2-27, Yeongmun-ro, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea

2. Name and dosage form of product
: Hanlim Vasopressin Injection
Product Name in Korean : 한림바소프레신주

2.1. Number of product license and date of issue
: 27 and April 14, 1984

2.2. Active ingredient(s) and amount(s) per unit dose
(For Complete quantitative composition including excipients, see attached.)
: Each mL contains
Active ingredient
Vasopressin ---------- 20 Vasopressin IU

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( ) / No( ) / Not provided(O)
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 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 the 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 (X)

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Issued date :MAY. 31, 2023 (Certificate No.2023-D1-0898)

Certified by **Oh Un Hwan**

Oh Un Hwan

Director General Services Division
Gyeongin Regional Food & Drug Administration

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country : Republic of Korea

This public document

2. has been signed by Oh Un Hwan

3. acting in the capacity of Director

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

Certified

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

5. at Seoul 6. the 02/06/2023

7. by The Ministry of Foreign Affairs

8. No. XXA2023I7RB9IE

9. Seal/stamp

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

10. Signature

Jeong Hyo Youn

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

Building #5, Gwacheon Government Complex, 47, Gwanmun-ro, Gwacheon-si,
Gyeonggi-do, 13809, Republic of Korea,
Tel: +82-2-2110-8000, Fax: +82-2-2110-0801

Certificate of a Pharmaceutical Product

┌ No. of Certificate : 2023-D1-0816
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : Republic of Iraq

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Hanlim Pharm. Co., Ltd.
- Address : 2-27, Yeongmun-ro, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea

2. Name and dosage form of product
Name : Quinovid eye ointment (Exporting Name: Floxiforce eye ointment)
Product Name in Korean : 퀴노비드안연고

2.1. Number of product license and date of issue
: 206, July. 26. 1988

2.2. Active ingredient(s) and amount(s) per unit dose
(For Complete quantitative composition including excipients, see attached.)
: Each g contains
Ofloxacin ---------- 3.0mg

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( ) / No( ) / Not provided(O)
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 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 (X)

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Issued date : MAY. 18, 2023 (Certificate No.2023-D1-0816)
Certified by **Oh Un Hwan**

Oh Un Hwan

Director General Services Division
Gyeongin Regional Food & Drug Administration