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

Certificate of a Pharmaceutical Product

┌ No. of Certificate : 2018-D1-2601
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : ISLAMIC REPUBLIC OF IRAN

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
: Vasopressin Inj.
Product Name in Korean : 한림 바소프레신 주사액

2.1. Number of product license and date of issue
: 378-27, 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 Ingredients
Vasopressin ---------- 20 Vasopressin Unit

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

┌ Yes (√) ⇒ 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(√) / No( ) / Unknown( ) A.2. Is Summary Technical Basis of Approval appended ? Yes( ) / No(√) A.3. Is the attached, officially approved product information complete and consonant with the license ? : Yes( ) / 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 ( ) 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 :NOV. 12, 2018 (Certificate No.2018-D1-2601)

Certified by Jang heung sun

Jang heung sun

Director of General Services Division
Gyeongin Regional Food & Drug Administration

«MEDEFERENT GRUP» S.R.L.

<Attachment>

Product Name

Hanlim Vasopressin Inj.

Composition of the product

Each mL contains

Active Ingredients

Vasopressin ---------- 20 Vasopressin Unit

Inactive Ingredients

Chlorobutanol ---------- 0.05mg

Sodium Chloride ---------- 9mg

Acetic Acid ---------- Q.S

Water for injection ---------- Q.S

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 : 2019.08.30
Date of Expiration : 2022.08.29

Issue Date : FEB. 06, 2020 (Certificate No.2020-D1-0325)
Signature Kim Young-gyuen

Kim Young-gyuen

COMMISSIONER OF Gyeongin Regional Office of Food and Drug Safety

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* 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.

2020-D1-0325

Attachment(s)

Finished Products
Ⅰ. Dosage forms of Product(s)
1. Oral solids
Tablets, Capsules
2. Injections
Injections, Lyophilized powder for injection
3. Ophthalmic solutions
Ophthalmic solutions, Ophthalmic suspensions
4. Oral liquids
Solution for oral, Syrups(solution), Elixirs, Nasal solutions(Spray), Nasal suspensions(Spray)
5. Topical liquids
6. Ointments
Ophthalmic ointments, Gels
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

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