Ministry of Food and Drug Safety
Daejeon Regional Office of Food and Drug Safety
166, Cheongsa-ro, Seo-gu, Daejeon, 35209, Republic of Korea,
Tel: +82-42-480-8710, Fax: +82-42-480-8715

Certificate of a Pharmaceutical Product

No. of Certificate : 2021-G1-0063
Exporting (certifying) country : Republic of Korea
Importing (requesting) country : Switzerland

1. Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)
- Name : Dong-A ST Co., Ltd.
- Address : 200-23, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea (2/F Section B, 3/F, 4/F Section B)

2. Name and dosage form of product
: Closerin Capsules 250mg (Cycloserine) (Dong-A Cycloserine 250mg)
Product Name in Korean : 크로세린캡슐250밀리그램(시클로세린)
(수출명: Dong-A Cycloserine 250mg)

2.1. Number of product license and date of issue
: 7 / October 23, 1964

2.2. Active ingredient(s) and amount(s) per unit dose
(For complete quantitative composition including excipients, see attached.)
: 1 tablet (275mg) contains
Cycloserine ····· 250mg

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? 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 :JAN. 08, 2021 (Certificate No.2021-G1-0063)

Certified by **Park nam soo**

Park Nam Soo

Director
General Services Division
Daejeon Regional Food & Drug Administration

Attachment

Composition of Closerin Capsules 250mg (Cycloserine)

(Dong-A Cycloserine 250mg)

Function	Component	Specification	Amount (mg/tablet)
Active ingredient	Cycloserine	USP	250 mg
Lubricant	Talc	USP	25 mg
Capsule	Capsule	KP	q.s.
Coated tablet weight (mg)			275mg