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**1. 약사법 제31조제1항의 규정에 의한 제조·품질관리에 필요한 시설에 관한 자료**

-Site master file을 첨부하였습니다.

- 제조사인 Jing Jing Pharmaceutical Co., Ltd에서 Restricted Part에 제조소 평면도, 작업환경 관리구역 표시도면, 공조시설계통도, 압축공기계통도 및 용수처리계통도를 식약처로 직접 송부할 예정입니다.

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**2. 품목별로 실시상황이 별표 1의2 의약품제조 및 품질관리기준에 적합하거나 이와 동등이상임을**

**입증하는 자료**

해당 자료는 민원 신청 후 식약처 홈페이지를 통해 제조사가 직접 업로드 할 예정입니다.

## 3. 물리화학적 특성과 안정성자료

### 3.2.S.1 일반정보

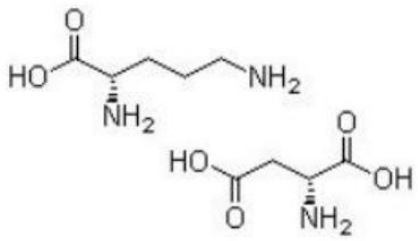
엘-오르니틴-엘-아스파르트산은 간 보호 및 해독작용을 하여 간경변 및 간성뇌병증 치료, 만성감염 해독의 보조 치료제 등으로 사용되며, Jing Jing Pharmaceutical Co., Ltd에서 연구 개발한 제품이다.

### 3.2.S.1.1 명칭

제품명 : 엘-오르니틴-엘-아스파르트산
기타 이름 : L-ornithine-L-aspartate
화학명 : (2S)-2-aminobutanedioic acid;(2S)-2,5-diaminopentanoic acid
CAS No. : 3230-94-2

### 3.2.S.1.2 구조

- 구조식



- Molecular Formula: $C_9H_{19}N_3O_6$
- Molecular Weight :265.26

**3.3.S.1.3 일반적 특성**

엘-오르니틴-엘-아스파르트산의 구조는 원소분석 데이터를 기본으로 하여 핵자기공명스펙트럼 (NMR), 질량분석스펙트럼(MS), 원소분석, X선 회절분석(XRD), 적외선스펙트럼(IR)을 종합하여 화합물의 구조를 규명하였다.

### 3.2.S.3 특성

#### 3.2.S.3.1 구조 및 기타 특성

1) 핵자기공명스펙트럼 (NMR)

엘-오르니틴-엘-아스파르트산을 AV Ⅱ- 500 BKUKER nuclear magnetic resonance spectrometer를 사용하여 $^{1}$HNMR, $^{13}$CNMR을 측정하였다.

- $^{1}$HNMR data

| Chemical shift(δ) | | Proton number | Multiplicity | Hydrogen identification |
|---|---|---|---|---|
| Sample (C552202010)) | Standard product (07125-SLBW4848) | | | |
| 1.716-1.743 | 1.694-1.709 | 2 | m | H-2 |
| 1.787-1.805 | 1.769-1.783 | 2 | m | H-3 |
| 2.622-2.809 | 2.615-2.783 | 2 | m | H-8 |
| 3.011-3.041 | 2.989-3.019 | 2 | t | H-1 |
| 3.745-3.769 | 3.727-3.751 | 1 | t | H-4 |
| 3.858-3.883 | 3.838-3.862 | 1 | dd | H-7 |

- $^{13}$CNMR data

| Chemical shift(δ) | | Carbon type | Carbon identification |
|---|---|---|---|
| Sample (C552202010)) | Standard product (07125-SLBW4848) | | |
| 22.12 | 22.13 | Secondary carbon | C-2 |
| 26.79 | 26.81 | Secondary carbon | C-3 |
| 35.93 | 35.93 | Secondary carbon | C-1 |
| 38.24 | 38.27 | Secondary carbon | C-8 |
| 51.56 | 51.62 | Tertiary carbon | C-7 |
| 53.48 | 53.51 | Tertiary carbon | C-4 |
| 173.53 | 173.51 | Quaternary carbon | C-5 |
| 173.53 | 173.64 | Quaternary carbon | C-6 |
| 176.92 | 176.96 | Quaternary carbon | C-9 |

2) 질량분석스펙트럼 (Mass spectrum)

Thermofisher LTQ을 사용하여 질량 분석하였다.

| Batch number | Mass-to-charge ratio(m/z) | Relative abundance | Remarks |
|---|---|---|---|
| Sample | 264.90 | 100 | --- |
| Standard product | 264.18 | 100 | --- |

3) 원소분석

엘-오르니틴-엘-아스파르트산의 원소분석을 실시하고, 이론값과 측정값을 다음의 표로 정리하였다.

그 결과 시료와 대조품 C, H, N의 비율이 기준과 일치함을 확인하였다.

| Element | | Actual test value (%) | Theoretical value (%) | Atomic weight |
|---|---|---|---|---|
| Standard | C | 39.49% | 40.71% | 12.0107 |
| | H | 7.50% | 7.22% | 1.00794 |
| | N | 15.21% | 15.84% | 15.9999 |
| sample | C | 39.96% | 40.71% | 12.0107 |
| | H | 7.49% | 7.22% | 1.00794 |
| | N | 15.63% | 15.84% | 15.9999 |

4) X선 회절분석(X-ray Diffraction)

분석 결과, 시료의 X-선 회절 피크의 위치가 기준값과 동일하며, 결정의 경우도 비슷함을 보였다.

5) 적외부스펙트럼(IR)

엘-오르니틴-엘-아스파르트산의 적외선 실험 결과, 시료가 기준물질의 적외선 스펙트럼과 일치함을 확인하였다.

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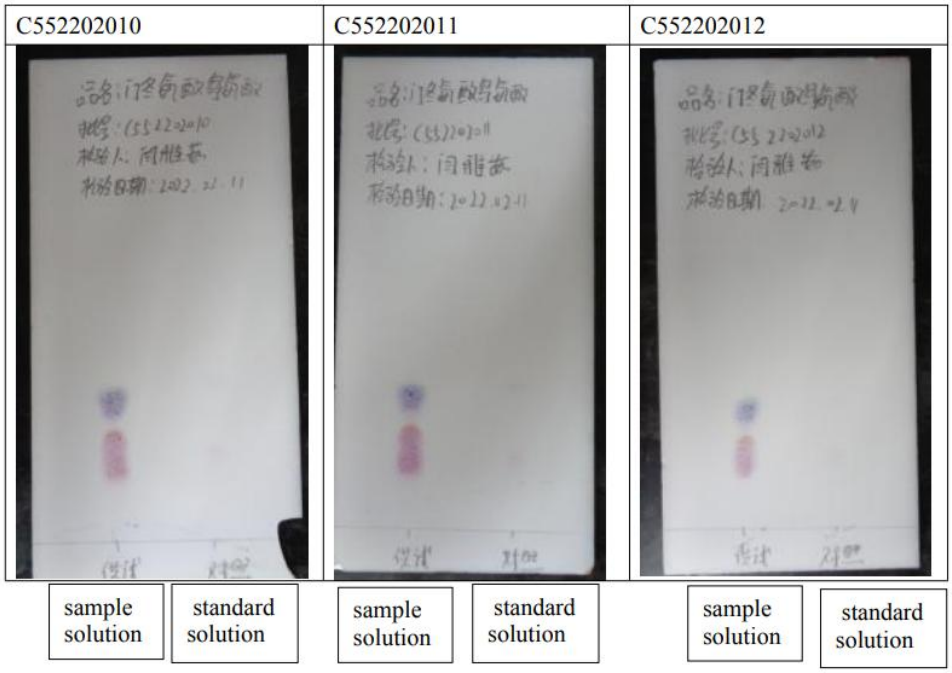
7) 유연물질

엘-오르니틴-엘-아스파르트산에 대해 시험한 유연물질 결과를 다음과 같이 정리하였다.



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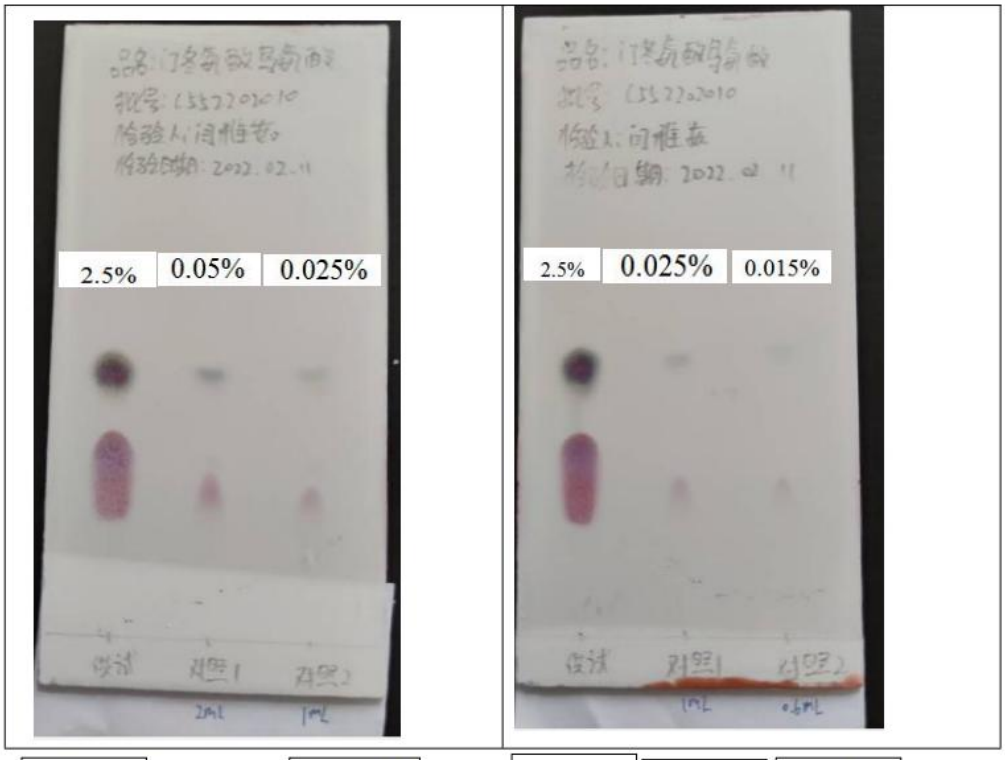
- 결과

| Maximum Daily Dose | Reporting Threshold | Identification Threshold | Qualification Threshold |
|---|---|---|---|
| ≤ 2g/day | 0.05% | 0.1%or1.0mg<br>Per day intake (whichever is lower) | 0.15% or 1.0mg<br>Per day intake (whichever is lower) |
| > 2g/day | 0.03% | 0.05% | 0.05% |

[ ICH Q3AR2, Attachment 1 Thresholds]



## 4. 제조방법, 포장, 용기, 취급상의 주의사항 등에 관한 자료

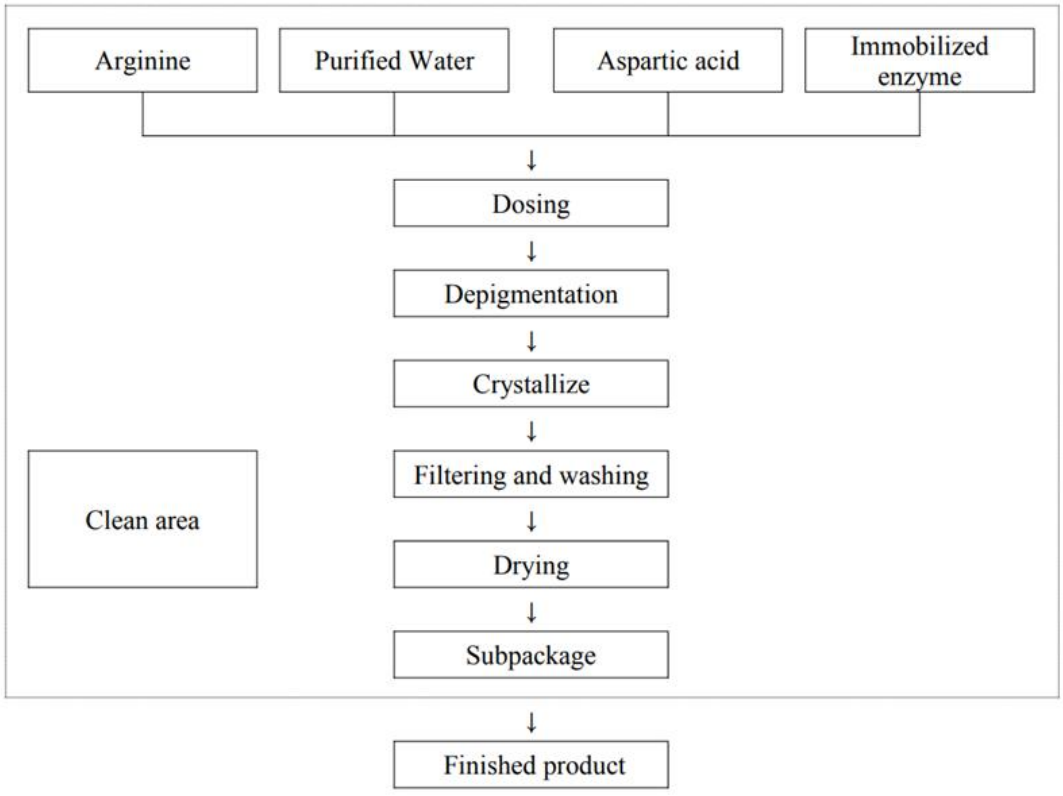
### 3.2.S.2. 제조

#### 3.2.S.2.1 제조원

Jing Jing Pharmaceutical Co., Ltd

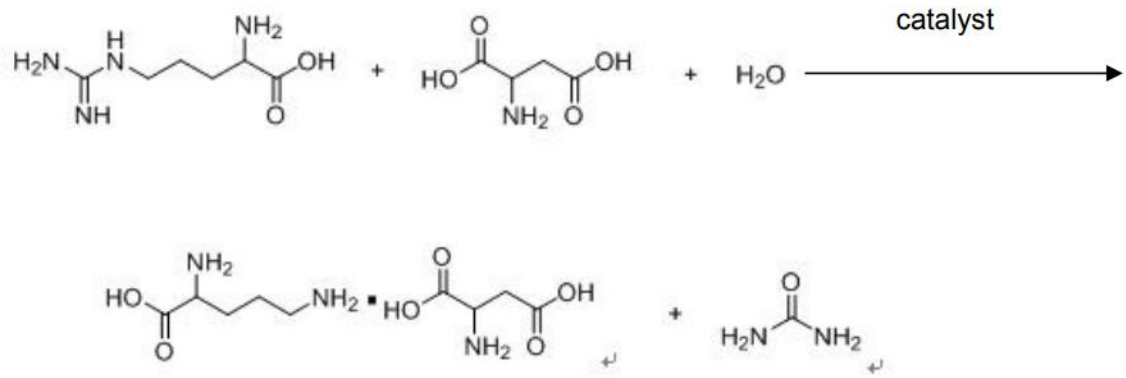
#### 3.2.S.2.2 제조공정 및 공정관리

1) 제조공정 기술



2) 합성 경로

엘-오르니틴-엘-아스파르트산의 합성 과정은 다음과 같다.




**3.2.S.2.3 원료관리**

Restricted Part로 제조사 (Jing Jing Pharmaceutical Co., Ltd)에서 식약처 전자메일로 송부할 예정입니다.

**3.2.S.2.4 주요공정 및 중간체 관리**

Restricted Part로 제조사(Jing Jing Pharmaceutical Co., Ltd)에서 식약처 전자메일로 송부할 예정입니다.

**3.2.S.2.5. 공정 밸리데이션 및 평가**

Restricted Part로 제조사(Jing Jing Pharmaceutical Co., Ltd)에서 식약처 전자메일로 송부할 예정입니다.

**3.2.S.2.6 제조공정 개발**

제조공정은 PV 배치 생산을 통해 성공적으로 재현했으며 독일약전(DAB) 기준에 적합한 제품을 생산할 수 있다.

### 3.2.S.6. 용기 및 포장

1) 포장정보

엘-오르니틴-엘-아스파르트산은 polyethylene 백에 1차 포장 후 fiber-drum에 외포장하여 출하된다.

- Specification of Inner Packing Material

| Item | Standard |
|---|---|
| Appearance | The surface should be smooth and uniform in color, and there should be no perforation, foreign matter, odor, or adhesion.<br>The heat-sealing part of the bag should be flat and free of false sealing. |
| identify | should be consistent with the control pattern |
| Specifications Dimensions | Lenght(mm) 900<br>Width(mm) 600<br>Thickness (mm) 0.08 |
| Microbial limit | The total number of aerobic bacteria≤1000cfu/ml<br>The total number of mold and yeast ≤ 100cfu/ml |

- Specification of Fiber drum

| Test item | Specification |
|---|---|
| Appearance | The paper barrel should be round and free of defects and cracks such as obvious out-of-roundness, concave deflation, skew, etc.<br>The barrel body is smooth, no mechanical damage, no wrinkle, no glue opening. Paint spreads evenly. No paint leakage, no bubbles, no obvious sagging.<br>Round curled edges without paper tongue.<br>Closing and rear lid and barrel body are well sealed, and the barrel body is rolled with imported cardboard paper.<br>The inside and outside of the barrel should be clean, free of impurities and oil stains. |
| Dimensions | Barrel body: 400mm±3mm<br>Inner height: 550mm±3mm<br>Outer height: 570mm±4mm<br>Weight: 3.15±0.3kg |

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## 5. 원료의약품의 시험성적서, 분석방법, 사용된 용매 등에 관한 자료

### 3.2.S.4. 원료의약품의 관리

#### 3.2.S.4.1 기준

엘-오르니틴-엘-아스파르트산은 DAB 기준을 따른다.

| Test | | Specification | Methods |
|---|---|---|---|
| Appearance | | White crystal or crystalline powder | DAB |
| Identi-fication | A.Optical Rotation,° | +26.5 ~ +29.0 ° | Ph. Eur. 2.2.7 |
| | B. IR | corresponds to standard | Ph. Eur.2.2.24 |
| | C. Ninhydrin reaction | Violet | DAB |
| | D. Mercuric acetate reaction | White Precipitation | DAB |
| | E. Molybdophosphoric acidreaction | Yellow Precipitation | DAB |
| Purity | 1) Clarity / Coloration | Clear, Colourless | Ph. Eur.2.2.1, 2.2.2(II) |
| | 2) pH | 6.0 ~ 7.0 | Ph. Eur. 2.2.3 |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Ph. Eur. 2.2.27 |
| | 4) Chloride | ≤ 300 ppm | Ph. Eur.2.2.4 |
| | 5) Sulfate | ≤ 200 ppm | Ph. Eur.2.4.13 |
| | 6) Ammonium | ≤ 400 ppm | DAB N 2.4.1 |
| | 7) Iron | ≤ 30 ppm | Ph. Eur.2.4.9 |
| | 8) Heavy metals | ≤ 10 ppm | Ph. Eur.2.4.8 |
| | 9) Water | ≤ 7.0 % | Ph. Eur.2.5.12 |
| | 10) Sulfated ash | ≤ 0.2 % | Ph. Eur. 2.4.14 |
| Assay | | 98.0 ~ 102.0 % | Ph. Eur. 2.2.20 |
| Residual solvent(Methanol) | | ≤ 3,000 ppm | In-house |

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### 3.2.S.4.2. 시험방법

| Gas chromatography | | Condition |
|---|---|---|
| Detector | | Flame ionization(FID) |
| Column | | DB-624 Capillary(G43), 0.25 mm x 30 m, 1.4μm |
| Temp. | Detector | 280 ℃ |
| | Oven | 40 ℃(5 min)→240 ℃(Rate 20℃/ min)(10 min) |
| Carrier gas | | nitrogen |
| Split Ratio | | 20 : 1 |
| Flows | | 1) Hydrogen : 40 mL/min, 2) Air : 400.0 mL/min |

| Head-space | Condition |
|---|---|
| Sample equilibration temperature | 80 ℃ |
| Quantitative loop temperature | 120 ℃ |
| Transmission line temperature | 120 ℃ |
| Equilibrating Time | 20 min |
| Injection Time | 1 min(mL) |
| GC cycle time | 25 min |

•Calculation

$$\text{Residue of MeOH (ppm)} = \frac{At \times Ws \times 1 \times 10^6}{As \times 1000 \times Wt} \times \frac{Ps}{100}$$

At : Peak area of residual solvent in the sample solution
As : Peak area of residual solvent in standard solution
1 : Dilution factor of sample
1000 : Dilution of standard solution
Wt : Weight of Sample (mg)
Ws : Weight of Standard (mg)
Ps : Purity of Standard

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### 3.2.S.4.3 시험방법 밸리데이션

분석방법은 DAB에 준거한다.

| Test Item | Criteria | Validation results | Result |
|---|---|---|---|
| System suitability test | The peak area measurement value RSD% (n=6) of repeated injection shall not exceed 10.0%; the number of theoretical plates (N) ≥ 3000 | Peak area repeatability RSD of 1.1%<br>The minimum number of theoretical plates is 17425 | Conform |
| Specificity | The blank solvent has no interference with methanol detection, and no other impurity peaks in the test solution interfere with each known impurity peak. | no interference | Conform |
| Detection of Limit | S/N is about 3, which can meet the testing requirements | The detection limit is 0.6010μg/ml, which is equivalent to 3ppm of the test sample | Conform |
| Detection of Quantitation | S/N is about 10, which can meet the testing requirements;<br>Take the limit of quantification solution for 6 consecutive injections, and calculate the RSD of the peak area ≤ 10.0% and the RSD of the retention time ≤ 10.0%. | The limit of quantification is 1.8030μg/ml, which is equivalent to the percentage content of the test product of 9ppm<br>The RSD for the limit of quantification precision was 1.8%<br>RSD for retention time is 0.1% | Conform |
| Linearity and range | R≤0.990;<br>The Y-axis intercept is within 25% of the 100% response value;<br>Response factor RSD≤10% | Linear equation: y =846.56x - 7.1573<br>R is 0.99996<br>The percentage of Y-intercept to 100% response value is 0.870%<br>Linear range 0.030080~1.20320mg/ml<br>Response factor RSD of 4.4. | Conform |
| Precision | Repeatability:<br>The RSD of the peak area for 6 consecutive injections of the reference solution is ≤10.0%; the RSD of the impurity content of the 6 samples of the test solution is ≤10.0%.<br>Intermediate precision:<br>Impurity content of the test solution | Repeatability:<br>The RSD of the reference solution is 1.1%<br>The RSD of the test solution is 0.7%<br><br>Intermediate precision:<br>The RSD of the test solution (n=6) is 1.2%<br>The RSD of the test solution (n=12) is | Conform |
| | RSD% (n=6) ≤ 10.0%, RSD% (n=12) ≤ 15.0% | 1.0% | |
| Accuracy test | According to the external standard method, the detected amount and recovery rate of each impurity were calculated. The average recovery rate is between 80% and 120%, and the relative standard deviation should not exceed 10.0% | 50% recovery was 102%, RSD (n=3) of 1.0%<br>100% recovery was 99%, RSD (n=3) of 0.6%<br>150% recovery was 99%, RSD (n=3) of 1.6%<br>The average recovery was 100%, and the RSD (n=9) was 2.0% | Conform |
| Durability | Under each condition, the RD of methanol content in the solution of the spiked test sample shall not exceed 15.0%) | When there is a slight change in the measurement conditions, the theoretical plate number (N) of the reference substance is more than 3000, and the RD is less than 10.0%, all of which meet the requirements, and the measurement results are within the acceptable range.<br>Including: different flow rates (1.315~1.715ml/min), different detector temperatures (275~285℃), different inlet temperatures (115~125℃), different headspace equilibration times (18~226min), Different headspace temperature (78 ~ 82 ℃). | Conform |

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### 3.2.S.4.4 배치 분석

1) Lot COA:

| | Batch Number | Batch Size | Manufacture Date | Analysis Date |
|---|---|---|---|---|
| PV1 | C552202010 | 400.84 kg | 2022.02.08 | 2022.02.10~2022.02.20 |
| PV2 | C552202011 | 400.84 kg | 2022.02.09 | 2022.02.10~2022.02.20 |
| PV3 | C552202012 | 400.84 kg | 2022.02.09 | 2022.02.11~2022.02.20 |

2) Result of Test

| Batch number | | | C552202010 | C552202011 | C552202012 |
|---|---|---|---|---|---|
| Manufacturing date | | | 2022.02.08 | 2022.02.09 | 2022.02.09 |
| Batch quantity | | | 400.84kg | 400.84kg | 400.84kg |
| Testing Item | | Standad | Result | Result | Result |
| Description | | White crystal or crystalline powder | White crystalline powder | White crystalline powder | White crystalline powder |
| pH | | 6.0 ~ 7.0 | 6.3 | 6.3 | 6.3 |
| Identification | IR | should be consistent with the standard infrared spectrum | Consistent with standard infrared spectrum | Consistent with standard infrared spectrum | Consistent with standard infrared spectrum |
| | Optical Rotation,° | +26.5 ~ +29.0 | 28.0 | 28.3 | 28.3 |
| Clarity of the solution | | ≤No. 1 Turbidity Standard | <No. 1 Turbidity Standard | <No. 1 Turbidity Standard | <No. 1 Turbidity Standard |
| color of solution | | ≤ B9 | <B9 | <B9 | <B9 |
| Wate % | | ≤ 7.0 | 0.81 | 0.66 | 0.77 |
| Residue on ignition | | ≤ 0.2 | 0.02 | 0.03 | 0.01 |
| Chloride,ppm | | ≤ 300 | < 300 | < 300 | < 300 |
| Sulfate(ppm) | | ≤ 200 | < 200 | < 200 | < 200 |
| Ammonium ,ppm | | ≤ 400 | < 400 | < 400 | < 400 |
| Heavy metal,ppm | | ≤ 10 | < 10 | < 10 | < 10 |
| Iron, ppm | | ≤ 30 | < 30 | < 30 | < 30 |
| Other Amino Acids,% | | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Compliance | Compliance | Compliance |
| Residual solvent methanol ppm | | ≤3000 | 91 | 95 | 89 |
| Assay, % | | 98.0 ~ 102.0 | 98.6 | 98.9 | 99.0 |

### 3.2.S.4.5 기준 설정근거

엘-오르니틴-엘-아스파르트산은 DAB 기준을 따르며, 잔류용매는 ICH Q3C를 따라 진행하였다. 일반 시험법은 DAB 및 EP을 따라 진행하였다.

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### 3.2.S.5 표준품 또는 표준물질

| Standard substance | Source | Specifications | Content | Application |
|---|---|---|---|---|
| L-Ornithine L-Aspartate | National Institutes for Food and Drug Control | 50 mg/bottle | 96.6% | For identification and content determination |

### 3.2.S.7 안정성

#### 3.2.S.7.1 안정성 요약과 결론

엘-오르니틴-엘-아스파르트산은 장기보존 안정성시험 및 가속 안정성시험을 실시하였다.

1) 실시한 안정성 시험 조건

| Division | Condition | Period | Methods |
|---|---|---|---|
| Long-term stability | 25±2℃,60±10%RH | 0,3,6,9,12, 18, 24,36 month | DAB |
| Accelerated stability | 40±2℃,75±5%RH | 0,1,2,3,6 month | DAB |

*According to ICH guideline ICH Topic Q1A(R2), ICH Topic Q1B)

Test items

| content | Test items |
|---|---|
| Long-term stability | Appearance、Water、Clarity / Coloration、Related substance、Assay |
| Accelerated stability | Appearance、Water、Clarity / Coloration、Related substance、Assay |

2) 사용한 Batch 정보

| Batch Number | Batch Size | Manufacture Date | Expiration Date |
|---|---|---|---|
| C552202010 | 400.84kg | 2022.02.08 | 2024.02.07 |
| C552202011 | 400.84kg | 2022.02.09 | 2024.02.08 |
| C552202012 | 400.84kg | 2022.02.09 | 2024.02.08 |

4) 안정성시험 항목과 시험방법

- 안정성시험 방법은 3.2.S.4에 따라 진행하였다.

5) 안정성시험 실시 결과

PV 로 제조된 LOA 3 배치(C5522010, C552202011, C55220202012)는 3 개월동안 가속안정성과 장기 안정성 테스트를 실시하였으며, 현재까지 유의미한 변화는 관찰되지 않았다.

한국의 경우 유효기간 3 년이 지났으며, 정상적인 저장 조건에서 엘-오르니틴-엘 -아스파르트산은 상온 ≤ 30 C)에서 안정하다.

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### 3.2.S.7.2. 허가 후 안정성시험 계획 및 이행서약

허가 후 최소 일년에 한번씩 장기 안정성시험 진행한다.

### 3.2.S.7.3. 안정성 자료

1) 가속시험 결과

**1.1) C552202010: 40±2℃, 75±5%RH(Accelerated)**

| Test | | Specification | Initial | 1 M | 3 M | 6M |
|---|---|---|---|---|---|---|
| | | | 2022.02.19 | 2022.03.21 | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | |
| Identifi-cation | A. Specific rotation | +26.5 ~ +29.0 ° | 28.0 | -- | | |
| | B. IR | Corresponding to STD | Conform | -- | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | 6.3 | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | |
| | 4) Chloride | ≤300 ppm | <300 | -- | | |
| | 5) Sulfate | ≤200 ppm | < 200 | -- | | |
| | 6) Ammonium | ≤400 ppm | <400 | -- | | |
| | 7) Iron | ≤30 ppm | < 30 | -- | | |
| | 8) Heavy metals | ≤ 10 ppm | < 10 | -- | | |
| | 9) Water | ≤7.0 % | 0.81 | 0.78 | | |
| | 10) Sulfated ash | ≤0.2 % | 0.02 | -- | | |
| Assay | | 98.0 ~ 102.0 % | 98.6 | 98.9 | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 91 | | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Accelerated term test's all test are observed no significant changes. | | | | | | |

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**1.2) C552202011: 40±2℃, 75±5%RH(Accelerated)**

| Test | | Specification | Initial | 1 M | 3 M | 6M |
|---|---|---|---|---|---|---|
| | | | 2022.02.19 | 2022.03.21 | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | |
| Identification | A. Specific rotation | +26.5 ~ +29.0 ° | 28.3 | -- | | |
| | B. IR | Corresponding to STD | Conform | -- | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | 6.2 | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | |
| | 4) Chloride | ≤300 ppm | <300 | -- | | |
| | 5) Sulfate | ≤200 ppm | < 200 | -- | | |
| | 6) Ammonium | ≤400 ppm | <400 | -- | | |
| | 7) Iron | ≤30 ppm | < 30 | -- | | |
| | 8) Heavy metals | ≤ 10 ppm | < 10 | -- | | |
| | 9) Water | ≤7.0 % | 0.66 | 0.81 | | |
| | 10) Sulfated ash | ≤0.2 % | 0.03 | -- | | |
| Assay | | 98.0 ~ 102.0 % | 98.9 | 98.6 | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 95 | -- | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Accelerated term test's all test are observed no significant changes. | | | | | | |

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**1.3) C552202012: 40±2℃, 75±5%RH(Accelerated)**

| Test | | Specification | Initial | 1 M | 3 M | 6M |
|---|---|---|---|---|---|---|
| | | | 2022.02.19 | 2022.03.21 | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | |
| Identification | A. Specific rotation | +26.5 ~ +29.0 ° | 28.3 | -- | | |
| | B. IR | Corresponding to STD | Conform | -- | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | 6.3 | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | |
| | 4) Chloride | ≤300 ppm | <300 | -- | | |
| | 5) Sulfate | ≤200 ppm | < 200 | -- | | |
| | 6) Ammonium | ≤400 ppm | <400 | -- | | |
| | 7) Iron | ≤30 ppm | < 30 | -- | | |
| | 8) Heavy metals | ≤ 10 ppm | < 10 | -- | | |
| | 9) Water | ≤7.0 % | 0.77 | 1.27 | | |
| | 10) Sulfated ash | ≤0.2 % | 0.01 | -- | | |
| Assay | | 98.0 ~ 102.0 % | 99.0 | 98.6 | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 89 | -- | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Accelerated term test's all test are observed no significant changes. | | | | | | |

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2) 장기시험 결과

**2.1) C552202010: 30±2℃,65±5%RH(long-term)**

| Test | | Specification | Initial | 3 M | 6 M | 9 M | 12 M | 18M | 24 M | 36 M |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 2022.02.10 | 2022.05.20 | | | | | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | | | | | |
| Identifi-cation | A. Specific rotation | +26.5 ~ +29.0 ° | 28.0 | -- | | | | | | |
| | B. IR | Corresponding to STD | Conform | -- | | | | | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | | | | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | -- | | | | | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | | | | | |
| | 4) Chloride | ≤300 ppm | <300 | -- | | | | | | |
| | 5) Sulfate | ≤200 ppm | < 200 | -- | | | | | | |
| | 6) Ammonium | ≤400 ppm | <400 | -- | | | | | | |
| | 7) Iron | ≤30 ppm | < 30 | -- | | | | | | |
| | 8) Heavy metals | ≤10 ppm | < 10 | -- | | | | | | |
| | 9) Water | ≤7.0 % | 0.81 | 1.20 | | | | | | |
| | 10) Sulfated ash | ≤0.2 % | 0.02 | -- | | | | | | |
| Assay | | 98.0 ~ 102.0 % | 98.6 | 99.4 | | | | | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 91 | -- | | | | | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Long-term test shall be conducted for 36 months in accordance with the stability test plan. | | | | | | | | | | |

**2.2) C552202011: 30±2℃,65±5%RH(long-term)**

| Test | | Specification | Initial | 3 M | 6 M | 9 M | 12 M | 18M | 24 M | 36 M |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 2022.02.10 | 2022.05.20 | | | | | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | | | | | |
| Identifi-cation | A. Specific rotation | +26.5 ~ +29.0 ° | 28.3 | -- | | | | | | |
| | B. IR | Corresponding to STD | Conform | -- | | | | | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | | | | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | -- | | | | | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | | | | | |
| | 4) Chloride | ≤300 ppm | <300 | -- | | | | | | |
| | 5) Sulfate | ≤200 ppm | < 200 | -- | | | | | | |
| | 6) Ammonium | ≤400 ppm | <400 | -- | | | | | | |
| | 7) Iron | ≤30 ppm | < 30 | -- | | | | | | |
| | 8) Heavy metals | ≤10 ppm | < 10 | -- | | | | | | |
| | 9) Water | ≤7.0 % | 0.66 | 1.19 | | | | | | |
| | 10) Sulfated ash | ≤0.2 % | 0.03 | -- | | | | | | |
| Assay | | 98.0 ~ 102.0 % | 98.9 | 99.8 | | | | | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 95 | -- | | | | | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Long-term test shall be conducted for 36 months in accordance with the stability test plan. | | | | | | | | | | |

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**2.3) C552202012: 30±2℃,65±5%RH(long-term)**

| Test | | Specification | Initial | 3 M | 6 M | 9 M | 12 M | 18M | 24 M | 36 M |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 2022.02.11 | 2022.05.20 | | | | | | |
| Appearance | | White crystalline powder or colorless crystals and well soluble in water | Conform | Conform | | | | | | |
| Identifi-cation | A. Specific rotation | +26.5 ~ +29.0 ° | 28.3 | -- | | | | | | |
| | B. IR | Corresponding to STD | Conform | -- | | | | | | |
| Purity | 1) Clarity/Coloration | Clear, Colourless | Conform | Conform | | | | | | |
| | 2) pH | 6.0 ~ 7.0 | 6.3 | -- | | | | | | |
| | 3) Related substance (TLC) | Spots other than the main spots in the test solution are not larger than the spots obtained in the standard solution | Conform | Conform | | | | | | |
| | 4) Chloride | ≤ 300 ppm | <300 | -- | | | | | | |
| | 5) Sulfate | ≤ 200 ppm | < 200 | -- | | | | | | |
| | 6) Ammonium | ≤ 400 ppm | <400 | -- | | | | | | |
| | 7) Iron | ≤ 30 ppm | < 30 | -- | | | | | | |
| | 8) Heavy metals | ≤ 10 ppm | < 10 | -- | | | | | | |
| | 9) Water | ≤ 7.0 % | 0.77 | 1.16 | | | | | | |
| | 10) Sulfated ash | ≤ 0.2 % | 0.01 | -- | | | | | | |
| Assay | | 98.0 ~ 102.0 % | 99.0 | 99.2 | | | | | | |
| Residual solvent (Methanol, In-house) | | ≤ 3,000 ppm | 89 | -- | | | | | | |
| shelf of life of L-Ornithine-L-Aspartate: 3years from the manufacturing date.<br>Long-term test shall be conducted for 36 months in accordance with the stability test plan. | | | | | | | | | | |