3.2.S.2.3 Material control

1) List of raw materials used in production process

Name	Application	Approved suppliers
Arginine	Raw material	CJ (Shenyang) Biotechnology Co., Ltd. Ajinomoto Co., Ltd. (Dealer: Shanghai Jinwang Pharmaceutical Technology Co., Ltd.) Jingjing Pharmaceutical Co., Ltd. Xingtai Food Additives Branch Hebei Amino Amino Acid Technology Co., Ltd.
Aspartate	Raw material	Changzhou YaBang Chemical Co., Ltd. Anhui Xuelang Biotech Co., Ltd.
Immobilized enzyme	catalyst	Hunan Fulaige Biotechnology Co., Ltd.
Purified water	solvent	Jingjing Pharmaceutical Co., Ltd.
Activated carbon	adsorbent	Shanghai Activated Carbon Co., Ltd. Nanping Yuanli Activated Carbon Co., Ltd.

2) Quality standards and testing methods of raw materials

2.1) Arginine

2.1.1) Quality standards of arginine

Item	Internal control standard
Properties	White crystal or crystalline powder
Specific rotation(^{o})	+26.9 ~ +27.9
Identification	The infrared absorption spectrum of the sample should be in consistent with the control one (spectrum set 1075).
pH	10.5 ~ 12.0
Chloride (%)	≤ 0.02
Sulfate (%)	≤ 0.02
Residue on ignition (%)	≤ 0.3
Loss on drying (%)	≤ 0.5
Arsenic salt (ppm)	≤ 1

Iron salt (ppm)	≤ 10
Heavy metal (ppm)	≤ 10
Transmittance (%)	≥ 98.0
Other Amino Acids (%)	≤ 0.4
Assay (%)	≥ 98.5
Purity (%)	≥ 98.0

1.1.2) Testing methods of arginine

1. Properties

Spread the arginine sample on clean A4 paper and observe it by eyes. The sample should be white, odorless, crystal or crystalline powder.

2. Specific rotation

Weigh two samples of 4.0g with a scale accurate to one ten-thousandth gram; place one of the sample in a 50ml volumetric flask, to which 6mol/L hydrochloric acid is added to dissolve the sample and make up to the volume; keep the flask in water bath for 20min at a temperature of 20°C, and conduct the measure according to “Standard Operating Procedures for WZZ-2B Digital Automatic Polarimeters” and a blank test is performed

Calculation formula:

$$[a]^{D}_{20}=\frac{(\alpha-\alpha_0)\times 100}{l\times m\times(1-X)\times 100/50}$$

Where:

α—measured optical rotation of the sample under test

α0—blank optical rotation

m —sample mass, g

l— length of the optical tube, dm

X—loss on drying of the sample, %

Judging criteria: +26.9º ~ +27.9º

3. Identification

3.1 Take appropriate amount of the product and arginine, to which 0.1mol/l hydrochloric acid is added respectively; dilute the solutions to make them containing about 10mg of hydrochloric acid per 1ml. The solutions should serve as the test solution and the reference solution. According to the chromatographic test under other amino acid terms, the position and color of the main spot of the test solution should be the same as that of the control solution.
3.2 According to General Rule 0402 (from the 4th volume of Chinese Pharmacopoeia (2015 edition), the potassium bromide pellet method should be adopted to peform the test. The infrared absorption spectrum of the sample should be in consistent with the control one (spectrum set 1075).

4. pH

Weigh 2.5g of the sample, and add 25ml of water to dissolve it; then measure the solution according to the "PB-10 Standard Operating Procedures of Precision pH Meter". Judging criteria: 10.5 ~ 12.0

5. Chloride

Sample tube: Weigh 0.3g of sample and place it in 50ml Nessler colorimetric tube; add water into the tube to make the solution up to 25ml; and add 10ml of dilute nitric acid into it; then add more water to the solution to make it up to 40ml; Shake it up, and add 1.0 ml of silver nitrate test solution into it, then dilute it with water to make 50 ml, and shake well.
Standard tube: absorb 6.0ml of standard sodium chloride solution, and place it in 50ml natron colorimetric tube; add water to dissolve it into 25ml; then add 10ml of dilute nitric acid and water to make it into 40ml, shake it well; add 1.0ml of silver nitrate test solution, and dilute it with water to make it into 50ml, then shake it well.
Place the two tubes in the dark for 5 min, then, under the clarifier, place them on a black background and look down from above the colorimetric tube to compare the resulting turbidity. The turbidity of the sample tube must be lower than that of the standard tube.
Judging criteria: ≤ 0.02%

6. Sulfate

Sample tube: Weigh 1.0g of sample, and place it in 50ml Nessler colorimetric tube; add water into the tube to make it up to 40ml and dissolve the sample with ultrasonic waves. add 2ml of dilute nitric acid into it, then shake it well; add 5ml of 25% cesium chloride into the solution

and shake it well; add purified water into the solution to make it up to 50ml and shake it well. Leave it for 10 minutes and shake it well.

Standard tube: Pipette 2.0m of standard potassium sulfate solution into seven 50ml Nessler colorimetric tubes respectively; add water into the tubes to make them to 40ml; add 2ml of dilute hydrochloric acid into the tubes and shake them well; then add 5ml of 25% of cerium chloride into them respectively and shake them well; add purified water into the solutions to make them to 50ml; shake them well; stand it for 10 minutes, then repeat the shake.

Under the clarifier, place the sample tube and the standard tube against the same black background; observed from the top of the colorimetric tube to perform the colorimetric analysis. the milky white turbidity produced by the sample tube should not be deeper than the standard tube.

Judging criteria: ≤ 0.02%

7. Residue on ignition

Precisely weigh 1.0g of the sample into a constant-weight crucible, add 1ml of sulfuric acid to wet the sample, burn it on an electric furnace until the sulfuric acid vapor is completely removed, then move to a high-temperature furnace and burn at 700℃ to completely ashed to constant weight.

Judging criteria: ≤ 0.3%.

8. Loss on drying

Weigh accurately 1.0g of sample into the constant-weight weighing bottle, and place it openly in the blast drying oven.

When the temperature rises to 105℃, start timing and dry it for 3h; then cover the weighing bottle, move it to a desiccator, and let it cool to the room temperature. Weigh the weighing bottle containing the sample precisely until a constant weight is achieved.

Calculation formula:

$$X = \frac{m-(m_1-m_0)}{m} \times 100\%$$

Where：

m_0-mass of the empty weighing bottle at a constant weight, g;

m-sample mass, g;

m_1-mass of the weighing bottle and sample at a constant weight, g;

9. Arsenic salt

(1) Sample bottle: Take 2.0g of sample, add 23ml of water to dissolve, and then add 5ml of hydrochloric acid.

(2) Standard bottle: Precisely measure 2.0ml of standard arsenic solution, add 5ml of hydrochloric acid and 21ml of water.

(3) Add 5 ml of potassium iodide test solution and 5 drops of acidic stannous chloride test solution to the two bottles respectively. After standing at room temperature for 10 minutes, add 2g of zinc particles. Immediately seal the installed airway C (with 60 mg of lead acetate cotton) on the bottle A, place the bottle A in a water bath at 25-40 ℃, react for 45 minutes, and take out the mercury bromide test paper. Spots in sample vials should not be deeper than those in standard vials.

standard one. Judging criteria: ≤ 1ppm

10. Iron salt

Sample tube: Weigh 1.0g of sample, and place it in 50ml Nessler colorimetric tube; add water into the tube to make the solution up to 25ml; add 4 ml of dilute hydrochloric acid and 50 mg of ammonium persulfate into it, then dilute with water to make 35 ml; then add 3 ml of 30% ammonium thiocyanate solution, and add water to make 50 ml, then shake it well.

Standard tube: absorb 1.0ml of standard iron solution, and place it in 50ml natron colorimetric tube and add water to make it to 25ml; then add 4ml of dilute hydrochloric acid and 50mg of ammonium persulfate and water to make it into 35ml; then add 3ml of 30% ammonium thiocyanate solution and water to make it into 50ml, then shake it well.

Place the two tubes against a white background immediately and look down from above the colorimetric tube to compare the resulting color. The color of sample tube must not be deeper than that of the standard tube.

Judging criteria: ≤ 10ppm

11. Heavy metals

Standard tube A: Take 2.0ml of standard lead solution into 25ml Nessler colorimetric tube, and add 2ml of acetate buffer (pH=3.5) into it; dilute with water to 25ml, and shake it up.

Sample tube B: Take 2.0g of sample into a 25ml Nessler colorimetric tube, and add 23ml of water to dissolve it; then add 2ml of acetate buffer (pH=3.5) and water to make it t25ml, then shake it well.

Control tube C: Take 2.0g of the sample into a 25ml Nessler colorimetric tube, and add water to dissolve it; then add 2ml of standard lead solution and 2ml of acetate buffer (pH=3.5) into it, and dilute with water to make 25ml, then shake it up.

Add 2ml of thioacetamide test solution to tube A, B and C respectively and shake them well. Leave the tubes for 2min, then place them against a white background. Observe from the top of the colorimetric tube and compare the colors displayed by tube A, B and C. The color of B shall not be deeper than that of A. The color of the C should be lighter than that of the A.

Judging criteria: ≤ 10ppm

12. Transmittance

Weigh 2.5g of the sample into a 25ml volumetric flask; dissolve it with water and dilute to the mark. Measure the light transmittance according to spectrophotometry by 1cm cuvette at 430 nm.

Judging criteria: ≥ 98.0%

Allowable deviation: Absolute difference of parallel samples ≤ 0.3%

13.Assay

Weigh accurately 0.08g of sample, and add 3ml of anhydrous formic acid to dissolve it; then add 50ml of glacial acetic acid, and titrate it with 0.1mol/L perchloric acid volumetric solution according to the Standard Operating Procedure of Metrohm 877 Titrino Plus, and correct the titration results with a blank test. Each 1 ml of perchloric acid titration solution (0.1mol/L) is equivalent to 8.710 mg of arginine.

Calculation formula:

$$Y = \frac{C \times (V - V_0) \times 8.710}{0.1 \times m \times (1 - X) \times 1000} \times 100\%$$

Where:

C-concentration of perchloric acid titration solution, mol / L;

V-volume of the perchloric acid titration solution consumed by the sample, ml;

V0- volume of the perchloric acid titration solution consumed by the blank, ml;

m- mass of the sample taken, g;

X-Loss on drying of the sample, % Judging criteria: based on dry product, content ≥ 98.5%

14.Purity (HPLC)

Liquid chromatography conditions

Chromatographic column: C18 column, 250×4.6mm 5μm

Mobile phase: 0.25mol/L sodium dihydrogen phosphate buffer (adjust with phosphoric acid pH3.40±0.02): water = 1:3

Detection wavelength: 205nm

Flow rate: 0.8ml/min Column temperature: 30℃

Sample solution: weigh accurately 25mg of sample after drying and place it into 25ml measuring flask, and dilute it to a constant volunme with mobile phase, then shake it well. Take 20 μl of the test solution and inject it into the liquid chromatograph, and record the chromatogram.

Judging criteria: ≥ 98.0%

Appendix 2: Arginine raw material inspection report

2.2）Aspartate

2.2.1) Quality Standard

Item	Internal control standard
Properties	White or off-white crystalline powder
Specific rotation (°)	+24.0 ~ +26.0
Identification	Consistent with standard infrared patterns
Acidity	2.5 ~ 3.5
Light transmittance (%)	≥ 98.0
Chloride (%)	≤ 0.02
Sulfate (%)	≤ 0.02
Ammonium salt (%)	≤ 0.04
Loss on drying (%)	≤ 0.2
Residue on ignition (%)	≤ 0.1
Iron salt (%)	≤ 0.001
Heavy metal (%)	≤ 0.001
Arsenic salt (%)	≤ 0.0001
Content (%)	99.0 ~ 100.5

2.2.2) Inspection method

1. Properties

Spread the aspartic acid sample on clean A4 paper and observe it by eyes. The sample Should be white or off-white crystalline powder

2. Specific rotation

Weigh two samples of 4.0g with a scale accurate to one ten-thousandth gram; place one of the sample in a 50ml volumetric flask,to which 6mol/L hydrochloric acid is added to dissolve the sample and make up to the volume; keep the flask in water bath for 20min at a temperature of 20±0.5°C, and conduct the measure according to “Standard Operating Procedures for SGWzz-2 Thermostatic Automatic Polarimeters”and a blank test is performed.

Calculation formula:

$$[a]^{D}_{20}= \frac{(\alpha-\alpha_0)\times 100}{l\times m\times(1-\mathrm{X})\times 100/50}$$

Where: α—measured optical rotation of the sample under test

α0—blank optical rotation

m —sample mass, g

l — length of the optical tube, dm

X—loss on drying of the sample, %

Judging criteria: +24.0o ~ +26.0o

3.Identify

Take an appropriate amount of this product and tablet with potassium bromide. Check the "Standard Operating Procedure of Infrared Spectrophotometer" according to law, and the infrared absorption spectrum of the sample is consistent with the spectrum set 913.

4. Acidity

Weigh 0.1g of the sample, and add 20ml of freshly boiled and purified water (within 4h) into it; stir it with a glass rod, then conduct measure according to “Standard Operating Procedure of PB-10 Precision pH Meter”.

Judging criteria: 2.5 ~ 3.5

5. Light transmittance

Weigh2.5g of the sample into a 25ml volumetric flask; dissolve it with 1 mol/L hydrochloric acid and dilute it to the mark. Measure the light transmittance according to spectrophotometry by 1cm cuvette at 430 nm. Judging criteria: ≥ 98.0%

6. Chloride

Sample tube: Weigh 0.3g of sample, and place it in 50ml Nessler colorimetric tube; add water into the tube to make the solution up to 25ml; and add 10ml of dilute nitric acid into it; then add more water to the solution to make it up to 40ml; Shake it up, and add 1.0 ml of silver nitrate test solution into it, then dilute it with water to make 50 ml, and shake well.

Standard tube: absorb 6.0ml of standard sodium chloride solution, and place it in 50ml natron colorimetric tube; add water to dissolve it into 25ml; then add 10ml of dilute nitric acid and water to make it into 40ml, shake it well; add 1.0ml of silver nitrate test solution, and dilute it with water to make it into 50ml, then shake it well.

Place the two tubes in the dark for 5 min, then, under the clarifier, place them on a black background and look down from above the colorimetric tube to compare the resulting turbidity. The turbidity of the sample tube must be lower than that of the standard tube.

Judging criteria: ≤ 0.02%

7. Sulfate

Sample tube: Weigh 1.0g of sample, and place it in 50ml Nessler colorimetric tube; add 4ml of dilute hydrochloric acid to it and shake it well. Should the solution be not clear, filter it with 0.22μm water membrane, and add water to make it 40ml; then add 5ml of 25% barium chloride and shake it well; then add purified water into the solution to make it up to 50ml and shake it well. Leave it for 10 minutes and shake it well.

Standard tube: Take 2.0ml of standard potassium sulfate solution into 50ml Nessler colorimetric tube, and dilute with water to 40ml, then add 5ml of 25% barium chloride solution and shake it well. Then add purified water to make it to 50ml and shake it well. Repeat the shake after 10minutes' of standing.

Under the clarifier, place the sample tube and the standard tube against the same black background; observe from the top of the colorimetric tube to perform the colorimetric analysis. It is normal when the solution is cloudy and muddy; it is abnormal when the solution is silver white and a redetermination is needed. The color of the sample tube shouldn't be deeper than that of the standard one.

Judging criteria: ≤ 0.02%

8. Ammonium salt

(1) Sample tube: Weigh 0.10g of sample, add 200ml of ammonia-free distilled water, and add 1g of magnesium oxide. Heating and distillation, the distillate was introduced into a 50ml Nessler colorimetric tube with 1 drop of dilute hydrochloric acid and 5ml of ammonia-free distilled water. The distillation was stopped when the distillate reached 40 ml. Add 5 drops of sodium hydroxide test solution, add ammonia-free distilled water to 50ml and shake well.

(2) Standard tube: add 4.0ml of standard ammonium chloride solution, 200ml of ammonia-free distilled water, and 1g of magnesium oxide. Heating and distillation, the distillate was introduced into a 50ml Nessler colorimetric tube with 1 drop of dilute hydrochloric acid and 5ml of ammonia-free distilled water. When the distillate reaches 40ml, stop the distillation, add 5 drops of sodium hydroxide test solution, add ammonia-free distilled water to 50ml and shake well.

(3) Add 2ml of alkaline mercury potassium iodide test solution to each of the sample tube and the standard tube, shake well, let stand for 15 minutes, put it on a white background, observe from top to bottom, compare the color, and it should not be darker.

Judging criteria: ≤ 0.04%

9. Loss on drying

Weigh accurately 1.0g of sample and place it in a weighing bottle at a constant weight; keep the bottle open and put it in a blast drying oven; When the temperature rises to 105℃, start timing and dry it for 3h; then cover the weighing bottle, move it to a desiccator, and let it cool to the room temperature. Weigh the weighing bottle containing the sample precisely until a constant weight is achieved.

Calculation formula:

$$X = \frac{m-(m_1-m_0)}{m} \times 100\%$$

Where：

mo-mass of the empty weighing bottle at a constant weight, g;

m-sample mass, g;

m1-mass of the weighing bottle and sample at a constant weight, g;

Judging criteria: ≤ 0.2%

10. Residue on ignition

Weigh precisely 1.0g of sample, and place it in a constant-weight crucible; place the crucible on the resistance furnace in a fume hood; slowly burn the crucible containing the sample (to avoid the sudden explosion or burning of the sample because of heat) until the sample is completely carbonized and no longer smoking. Allow it to cool to the room temperature. Add 1 ml of sulfuric acid to make the carbide completely wet and continue to heat it on the electric furnace until the removal of sulfuric acid vapor and the complete disappearance of the white smoke. Place the crucible in a box-type resistance furnace and ignite it at a temperature of 550 ° C until the full ashing of the sample. Stop the heating when the sample achieve a constant weight. Remove the crucible from the box, and cool it in the air for 1 ~ 2min, then place it in a suitable desiccator to cool it to room temperature, then accurately weigh the crucible.

Calculation formula:

$$X = \frac{m_1 - m_0}{m} \times 100\%$$

Where：

m-mass of the sample before ignition, g;

m0- mass of the crucible before ignition, g;

m1-mass of the crucible and residue after ignition, g;

Judging criteria: ≤ 0.1%

11.Heavy metals

(1) Tube A: Take the residue left under the residue on ignition of this product, add 0.5ml of nitric acid, evaporate to dryness, and let it cool. Add 2 ml of hydrochloric acid, evaporate to dryness on a water bath, and add 15 ml of water. Add ammonia test solution dropwise until it is neutral to the phenolphthalein indicator solution, add 2ml of acetate buffer (pH=3.5), dissolve with slight heat, transfer it to a Nessler colorimetric tube, add water to dilute to 25ml, and shake well.

(2) Tube B: Take the reagent for preparing the test solution. After evaporating to dryness in a porcelain dish, add 2ml of acetate buffer (pH=3.5) and 15ml of water. After dissolving with slight heat, transfer it into a Nessler colorimetric tube, add 1ml of standard lead solution, and then dilute it with an appropriate amount of water to make 25ml, and shake well.

(3) Add 2ml of thioacetamide test solution to tubes A and B respectively, shake well, and let stand for 2 minutes. Put it on the same white paper and see through it from top to bottom. The color displayed in tube A should not be darker compared to tube B.

Judging criteria: ≤ 0.001%

12. Arsenic salt

Sample bottle: Take 2.0g of sample to arsenic-containing Bottle A , and add 5ml of hydrochloric acid and 23ml of water to dissolve it; then add 5ml of potassium iodide test solution and 5 drops of acid stannous chloride test solution into it , then leave it at room temperature for 10min; add 2g of zinc particles into it , then densely plug the well-prepared airway tube C (containing 60 mg of lead acetate cotton) to Bottle A; place the bottle in a 25~40 ° C water bath for 45 minutes; then take the mercury bromide test paper out.

Standard bottle: Take 2.0ml of standard arsenic solution arsenic to Bottle A, then add 5ml of hydrochloric acid and 21ml of water to dissolve it; then add 5ml of potassium iodide test solution and 5 drops of acidic stannous chloride test solution into it, and leave it at room temperature for 10min; add 2g of zinc granules and densely plug the well-prepared airway tube C (containing 60 mg of lead acetate cotton) to Bottle A immediately. Place the bottle in a 25~40 ° Cwater bath for 45 minutes, then take the mercury bromide test paper out.

The arsenic spots produced by the sample should not be deeper than those of the standard one.

Judging criteria: ≤ 0.0001%

13.Iron salt

Sample tube: Weigh 1.0g of sample, and place it in 50ml Nessler colorimetric tube; add water into the tube to make the solution up to 25ml; add 4 ml of dilute hydrochloric acid and 50 mg of ammonium persulfate into it, then dilute with water to make 35 ml; then add 3 ml of 30% ammonium thiocyanate solution, and add water to make 50 ml, then shake it well.

Standard tube: absorb 1.0ml of standard iron solution, and place it in 50ml natron colorimetric tube and add water to make it to 25ml; then add 4ml of dilute hydrochloric acid and 50mg of ammonium persulfate and water to make it into 35ml; then add 3ml of 30% ammonium thiocyanate solution and water to make it into 50ml, then shake it well.

Place the two tubes against a white background immediately and look down from above the colorimetric tube to compare the resulting color. The color of sample tube must not be deeper than that of the standard tube.

Judging criteria: ≤ 10ppm

14. Content

Accurately weigh 80 mg of the sample, add 5 ml of anhydrous formic acid, and 30 ml of glacial acetic acid, and titrate with 0.1 mol/L perchloric acid according to the Standard Operating Procedure of Automatic Potentiometric Titrator, and correct the titration result with a blank test. Each 1ml of perchloric acid titration solution (0.1mol/L) is equivalent to 13.31mg of aspartic acid.

Calculation formula:

$$Y = \frac{C \times (V - V_0) \times 13.31}{0.1 \times m \times (1 - X) \times 1000} \times 100\%$$

Where:

C-concentration of perchloric acid titration solution, mol / L;

V-volume of the perchloric acid titration solution consumed by the sample, ml;

V0- volume of the perchloric acid titration solution consumed by the blank, ml;

m- mass of the sample taken, g;

X-Loss on drying of the sample, %

Judging criteria: based on dry product, content 99.0 ~ 100.5%

C Reagents, etc.

In addition, quality standards for excipients: activated carbon (for co-injection) and methanol have been established. See the table below for details

Appendix 3: Aspartic Acid raw material inspection report

2.3) Activated carbon Quality standard

Item	Internal control standard
Properties	This product is black powder; No odor, no taste, no sand
Identification	should present positive reaction
pH	should present neutral reaction
Chloride (%)	≤ 0.1
Sulfate (%)	≤ 0.05
Uncarbonized substances	Comply with the regulations
Sulfide	Comply with the regulations
Cyanide	Comply with the regulations

Solutes in ethanol (mg)	≤ 8
Fluorescent substance	Less than the absorbance of the control solution
Acid soluble substances （mg）	≤ 8
Loss on drying（%）	≤ 10.0
Residue on ignition（%）	≤ 3.0
Fe salt (%)	≤ 0.02
Zinc salt (%)	≤ 0.005
Heavy metal(ppm)	≤ 30
Adsorbent capacity	Comply with the regulations
Microbial limit(cfu/g)	The total number of aerobic bacteria is less than or equal to 1000 The total number of molds and yeasts is less than or equal to 100 E. coli shall not be detected Salmonella should not be detected10g
Bacterial endotoxin (EU/g)	< 2
Adsorption capacity of activated carbon to bacterial endotoxin (%)	> 99

Appendix 4: Activated carbon raw material inspection report

2.4) Purified water quality standard

Item	Pharmacopoeia of the People's Republic of China (2020 Edition)
Properties	This product is a colorless clear liquid; odorless
pH	Meets the requirments
Nitrate（%）	≤ 0.000006
Nitrite（%）	≤ 0.000002
Ammonia（%）	≤ 0.00003
Conductivity	Meets the requirments
Total organic carbon（mg/L）	≤ 0.50
Non-volatile matter（mg/100ml）	≤ 1

Heavy metal （%）	≤ 0.00001
Microbial limit(cfu/g)	≤ 100

3.2.S.2.4 Controls of Critical Steps and Intermediates

1) Process Control and Standards

No	Process	Parameter	Standard
1	convert	Temperature	-
2		pH	-
3	dry	Temperature	-

2) Intermediate quality standard

No	Name	Code	Test items	Standard
1	L-ornithine-L-aspartate Wet Powder	S55	loss on drying	≤ 50%
2	L-ornithine-L-aspartate Dry Powder	G55	loss on drying	≤ 7.0%

Test Method in Process

Weigh 10.0g of sample, measure it on a rapid moisture analyzer, dry it at 105℃ for 10 minutes until the moisture no longer drops, the scale moves statically, and read the recorded data.

3.2.S.2.5 Process Validation and/or Evaluation

1) Purpose

Process validation is the means of ensuring and providing documentary evidence that processes (within their specified design parameters) are capable of consistently producing a finished product of the required quality. The purpose is the documented demonstration that went into developing a process has led to a process that will consistently produce a given product.

The processes used for each step of L-Ornithine-L-Aspartate will consistently provide the process developing during a product’s lifetime. Also the quality will provide the desired degree of assurance as defined in the batch production records. We conducted for three batches in order to demonstrate validity of a given process. The critical steps and parameters were determined at study stage.