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.

2) Information of batch

Batch Number	Batch Size	Manufacture Date
C552202010	400.84kg	2022.02.08
C552202011	400.84 kg	2022.02.09
C552202012	400.84kg	2022.02.09

3) In-Process Control

No	Process name	Project
1	Convert	Temperature
2		pH
3	Separate wash	Dry weight loss
4	Dry	Temperature
		Dry weight loss

4) Yield

Item	Range	C552202010	C552202011	C552202012
Product(kg)	400~500 kg	400.84kg	400.84kg	400.84kg
Yield	80~100%	98.13%	98.60%	98.13%

5) Ressult of Process Validation

All three Production batches studied were in conformity with the specification (DAB). The Certificates of Analysis for the above-mentiones are provide in 3.2.S.4.4 batch analysis.

Test		Specification	C552202010 (PV1)	C552202011 (PV2)	C552202012 (PV3)
Appearance		White crystal or crystalline powder	Conform	Conform	Conform
	A. Specific rotation	+26.5 ~ +29.0 °	+28.0	+28.3	+28.3

Identifi-cation	B. IR	Corresponding to STD	Conform	Conform	Conform
Purity	1) Clarity / Coloration	Transparent	Conform	Conform	Conform
	2) pH	6.0 ~ 7.0	6.3	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	Conform
	4) Chloride	≤ 300 ppm	< 300	< 300	< 300
	5) Sulfate	≤ 200 ppm	< 200	< 200	< 200
	6) Ammonium	≤ 400 ppm	< 400	< 400	< 400
	7) Iron	≤ 30 ppm	< 30	< 30	< 30
	8) Heavy metals	≤ 10 ppm	< 10	< 10	< 10
	9) Water	≤ 7.0 %	0.81	0.66	0.77
	10) Sulfated ash	≤ 0.2 %	0.02	0.03	0.01
Assay		98.0 ~ 102.0 %	98.6	98.9	99.0
Residual solvent (Methanol, In-house)		≤ 3,000 ppm	91	95	89

Appendix5: Process Verification (C552202010) Finished Product Inspection Report

Appendix6: Process Verification (C552202011) Finished Product Inspection Report

Appendix7: Process Verification (C552202012) Finished Product Inspection Report

3.2.S.2.6 Manufacturing Process Development

Not applicable