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.