

L-Ornithine-L-Aspartate Stability data

2.1) C552202010: 25±2°C,60±5%RH(long-term)

[illegible]

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Bacterial endotoxin (EU/g)	<0.006EU/mg	<0.006EU/mg	/	/	/	/	/	< 0.006EU/m g	< 0.006EU/m g
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2.2) C552202011: 25±2℃,60±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	2022.08.20	2022.11.23	2023.02.22	2023.08.20	2024.02.21	2025.02.22
Appearance		White crystalline powder or colorless crystals and well soluble in water	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Identifi- cation	A. Specific rotation	+26.5 ~ +29.0 °	28.3	--	--	--	+28.0	--	+28.0	+28.0
	B. IR	Corresponding to STD	Conform	--	--	--	Conform	--	Conform	Conform
Purity	1) Clarity/Coloration	Clear, Colourless	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
	2) pH	6.0 ~ 7.0	6.3	--	--	--	6.2	--	6.2	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	Conform	Conform	Conform	Conform	Conform	Conform
	4) Chloride	≤ 300 ppm	<300	--	--	--	<300	--	<300	<300
	5) Sulfate	≤ 200 ppm	< 200	--	--	--	< 200	--	< 200	< 200
	6) Ammonium	≤ 400 ppm	<400	--	--	--	<400	--	<400	<400
	7) Iron	≤ 30 ppm	< 30	--	--	--	< 30	--	< 30	< 30
	8) Heavy metals	≤ 10 ppm	< 10	--	--	--	< 10	--	< 10	< 10
	9) Water	≤ 7.0 %	0.66	1.20	1.10	1.0	0.77	1.3	1.0	1.1

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	10) Sulfated ash	≤0.2 %	0.03	--	--	--	0.02	--	0.02	0.05
	11) Arsenic	≤ 2ppm	--	--	--	--	--	--	--	< 2
Assay		98.0 ~ 102.0 %	98.9	99.8	99.4	99.5	99.4	99.6	99.7	99.4
Residual solvent (Methanol, In-house)		≤ 3,000 ppm	95	--	--	--	91	--	90	88
Microbial limit	Total plate counts (cfu/g)	/	/	/	/	/	/	/	<1	<1
	Yeast and Mould (cfu/g)	/	/	/	/	/	/	/	<1	<1
	E.coli (cfu/g)	/	/	/	/	/	/	/	Absence	Absence
Bacterial endotoxin (EU/g)		<0.006EU/mg	< 0.006EU/mg	/	/	/	/	/	< 0.006EU/mg	< 0.006EU/mg

2.3) C552202012:25±2℃,60±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	2022.08.20	2022.11.23	2023.02.22	2023.08.20	2024.02.21	2025.02.22
Appearance		White crystalline powder or colorless crystals and well soluble in water	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Identification	A. Specific rotation	+26.5 ~ +29.0 °	28.3	--	--	--	+28.0	--	+27.9	+27.9
	B. IR	Corresponding to STD	Conform	--	--	--	Conform	--	Conform	Conform
Purity	1) Clarity/Coloration	Clear, Colourless	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
	2) pH	6.0 ~ 7.0	6.3	--	--	--	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	Conform	Conform	Conform	Conform	Conform
	4) Chloride	≤300 ppm	<300	--	--	--	<300	--	<300	<300
	5) Sulfate	≤200 ppm	< 200	--	--	--	< 200	--	< 200	< 200

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	6) Ammonium	≤400 ppm	<400	--	--	--	<400	--	<400	<400
	7) Iron	≤ 30 ppm	< 30	--	--	--	< 30	--	< 30	< 30
	8) Heavy metals	≤ 10 ppm	< 10	--	--	--	< 10	--	< 10	< 10
	9) Water	≤7.0 %	0.77	1.20	1.40	1.3	1.4	1.2	1.2	1.2
	10) Sulfated ash	≤0.2 %	0.01	--	--	--	0.05	--	0.02	0.03
	11)Arsenic	≤ 2ppm	--	--	--	--	--	--	--	< 2
Assay		98.0 ~ 102.0 %	99.0	99.2	99.2	99.7	99.8	99.4	99.4	99.3
Residual solvent (Methanol, In-house)		≤ 3,000 ppm	89	--	--	--	85	--	83	82
Microbial limit	Total plate counts (cfu/g)	/	/	/	/	/	/	/	1	<1
	Yeast and Mould (cfu/g)	/	/	/	/	/	/	/	<1	<1
	E.coli (cfu/g)	/	/	/	/	/	/	/	Absence	Absence
Bacterial endotoxin (EU/g)		<0.006EU/mg	< 0.006EU/mg	/	/	/	/	/	< 0.006EU/mg	< 0.006EU/mg