

STABILITY DATA Acetyl-L-Carnitine HCL

Sample name: Acetyl-L-Carnitine HCL			Batch No.: Production Date		ALC 19111306		Test date		Nov. 13, 2019	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%				End date		Nov. 12, 2021	
Item	Standard	0 month	3 rd month	6 th months	9 th months	12 th months	18 th months	24 th months		
Identification	IR positive	positive	positive	positive	positive	positive	positive	positive		
Appearance	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder, slightly Pseudo agglomerate	White crystalline powder, moderate Pseudo agglomerate		
Specific rotation	-27.0~ -29.0°	-27.77°	-27.75°	-27.76°	-27.76°	-27.74°	--27.75°	-27.75°		
PH	2.0~3.0	2.45	2.46	2.45	2.47	2.44	2.45	2.48		
Loss on drying	≤0.5%	0.15%	0.16%	0.17%	0.16%	0.17%	0.16%	0.15%		
Residue on ignition	≤0.5%	0.15%	0.16%	0.13%	0.14%	0.17%	0.16%	0.16%		
Assay	≥98.0%	99.26%	99.28%	99.25%	99.24%	99.24%	99.18%	99.15%		

The test started from Nov. 13, 2019. Test after 0 month, 3 month, 6 months, 9 months, 12 months, 18 months and 24 months.



Conclusion: Compared with the original result and found that the product is stable within the shelf life of 2 years.

Inspector:

何杰

Audit:



Sample name: Acetyl-L-Carnitine HCL			Batch No.: Production Date		ALC20101003		Test date		Oct. 10, 2020	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%			End date		Oct. 9, 2022		
Item	Standard	0 month	3 rd month	6 th months	9 th months	12 th months	18 th months	24 th months		
Identification	IR positive	positive	positive	positive	positive	positive	positive	positive	positive	
Appearance	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder, slightly Pseudo agglomerate	White crystalline powder, moderate Pseudo agglomerate		
Specific rotation	-27.0~ -29.0°	-27.76°	-27.75°	-27.77°	-27.76°	-27.75°	-27.78°	-27.75°		
PH	2.0~3.0	2.44	2.46	2.45	2.47	2.43	2.44	2.50		
Loss on drying	≤0.5%	0.16%	0.16%	0.15%	0.15%	0.16%	0.17%	0.15%		
Residue on ignition	≤0.5%	0.14%	0.15%	0.13%	0.14%	0.16%	0.15%	0.18%		
Assay	≥98.0%	99.25%	99.28%	99.26%	99.26%	99.24%	99.20%	99.18%		
<p>The test started from Oct. 10, 2020. Test after 0 month, 3 month, 6 months, 9 months, 12 months, 18 months and 24 months.</p> <p>Conclusion: Compared with the original result and found that the product is stable within the shelf life of 2 years.</p>										
Inspector: 						Audit: 				

Sample name: Acetyl-L-Carnitine HCL			Batch No.: Production Date		ALC21050810		Test date		May. 8, 2021	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%			End date		May. 7, 2023		
Item	Standard	0 month	3 rd month	6 th months	9 th months	12 th months	18 th months	24 th months		
Identification	IR positive	positive	positive	positive	positive	positive	positive	positive	positive	
Appearance	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder, slightly Pseudo agglomerate	White crystalline powder, moderate Pseudo agglomerate	
Specific rotation	-27.0~ -29.0°	-27.75°	-27.78°	-27.80°	-27.75°	-27.76°	-27.75°	-27.75°	-27.75°	
PH	2.0~3.0	2.45	2.44	2.48	2.48	2.55	2.60	2.65		
Loss on drying	≤0.5%	0.15%	0.15%	0.17%	0.16%	0.18%	0.15%	0.18%		
Residue on ignition	≤0.5%	0.18%	0.16%	0.15%	0.15%	0.18%	0.18%	0.16%		
Assay	≥98.0%	99.25%	99.26%	99.30%	99.35%	99.20%	99.18%	99.16%		
<p>The test started from May. 8,2021. Test after 0 month, 3 month, 6 months, 9 months, 12 months, 18 months and 24 months.</p> <p>Conclusion: Compared with the original result and found that the product is stable within the shelf life of 2 years.</p>										
Inspector: 何杰						Audit:				

