


STABILITY DATA L-Carnitine Fumarate

Sample name: L-Carnitine Fumarate			Batch No.: Production Date		LCF12061801		Test date JUN 18, 2012	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%				End date JUN 17, 2014	
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	-16.5~ -18.0°	-17.25°	-17.25°	-17.28°	-17.28°	-17.27°	-17.27°	-17.26°
PH	3.0~4.0	3.50	3.50	3.54	3.55	3.58	3.58	3.57
Loss on drying	≤0.5%	0.17%	0.18%	0.20%	0.21%	0.23%	0.24%	0.25%
Residue on ignition	≤0.5%	0.24%	0.26%	0.25%	0.24%	0.25%	0.26%	0.25%
Solubility	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification
L-Carnitine	58.5±2.0%	59.25%	59.25%	59.23%	59.24%	59.24%	59.20%	59.20%
L-Tartaric acid	41.5±2.0%	40.51%	40.51%	40.54%	40.54%	40.53%	40.55%	40.55%
Assay	≥98.0%	99.25%	99.26%	99.26%	99.25%	99.28%	99.27%	99.28%

The test started from July 18, 2010. 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: 


Audit: 


STABILITY DATA L-Carnitine Fumarate

Sample name: L-Carnitine Fumarate			Batch No.: Production Date		LCF13081501		Test date AUG 15, 2013	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%				End date AUG 14, 2015	
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	-16.5~ -18.0°	-17.35°	-17.33°	-17.33°	-17.34°	-17.36°	-17.35°	-17.36°
PH	3.0~4.0	3.56	3.54	3.54	3.55	3.57	3.57	3.57
Loss on drying	≤0.5%	0.27%	0.28%	0.25%	0.22%	0.23%	0.21%	0.25%
Residue on ignition	≤0.5%	0.24%	0.27%	0.25%	0.23%	0.25%	0.26%	0.27%
Solubility	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification
L-Carnitine	58.5±2.0%	57.25%	57.25%	57.23%	57.27%	57.34%	57.32%	57.32%
L-Tartaric acid	41.5±2.0%	42.55%	42.55%	42.52%	42.50%	42.53%	42.52%	42.52%
Assay	≥98.0%	99.25%	99.27%	99.27%	99.28%	99.28%	99.27%	99.28%

The test started from August 15, 2011. 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: 


Audit: 

STABILITY DATA L-Carnitine Fumarate

Sample name: L-Carnitine Fumarate			Batch No.: Production Date		LCF14061201		Test date JUN 12, 2014	
Storage Temperature: 25 ⁰ C ±1 ⁰ C			Humidity: 65%±10%			End date JUN 11, 2016		
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	-16.5~ -18.0°	-17.45°	-17.43°	-17.46°	-17.44°	-17.45°	-17.42°	-17.43°
PH	3.0~4.0	3.45	3.45	3.46	3.44	3.47	3.48	3.48
Loss on drying	≤0.5%	0.20%	0.21%	0.21%	0.22%	0.23%	0.22%	0.24%
Residue on ignition	≤0.5%	0.23%	0.25%	0.25%	0.22%	0.24%	0.26%	0.25%
Solubility	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification	Clarification
L-Carnitine	58.5±2.0%	57.55%	57.65%	57.63%	57.58%	57.56%	57.55%	57.61%
L-Tartaric acid	41.5±2.0%	42.15%	42.12%	42.28%	42.42%	42.43%	42.42%	42.40%
Assay	≥98.0%	99.33%	99.32%	99.30%	99.28%	99.26%	99.27%	99.26%

The test started from June 12, 2012. 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: 

Audit: 