黄冈华阳药业有限公司
Huanggang Huayang Pharmaceutical Co., Ltd.

STABILITY DATA L-Carnitine 50%

Sample Name	L-Carnitine 50%	Batch NO.	LBF101106	Production Date	Nov. 6, 2010	Test Date	Nov. 6, 2010
Storage Temperature		25±1℃	Humidity	65±10%	End Date	Nov. 5, 2012	

Item	standard	0 month	3rd month	6th month	9th month	12th month	18th month	24th month
Appearance	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder, slightly pseudo agglomerate	White or almost white powder, slightly pseudo agglomerate
Specific rotation	-14.0~-16.0°	-14.28°	-14.35°	-14.32°	-14.33°	-14.20°	-14.25°	-14.22°
pH	6.5~8.5	6.57	6.56	6.58	6.70	6.67	6.71	6.72
Water content	≤ 15% (%)	11.85	11.82	11.84	11.85	11.90	11.91	11.90
SiO_2 carrier	35%~45% (%)	36.50	36.53	36.52	36.55	36.49	36.47	36.51
Assay	L-Carnitine: ≥ 50% (%)	51.65	51.68	51.64	51.60	51.61	51.62	51.59
Chloride	≤ 0.4% (%)	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%

The test started from Nov. 6, 2010. Test after 0 month, 3 months, 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:	Auditor:

Add: 8 Wangu RD, Sanlifan Town, Luotian County, Hubei 438621, China
Tel: 86 713 5811498/5811489/5811558 Fax: 86 713 5811628
www. huayangbio.com Email: sales@huayangbio.com

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STABILITY DATA L-Carnitine 50%

Sample Name	L-Carnitine 50%	Batch NO.	LBF110603	Production Date	June 3, 2011	Test Date	June 3, 2011
Storage Temperature		25±1℃	Humidity	65±10%	End Date	June 2, 2013	

Item	standard	0 month	3rd month	6th month	9th month	12th month	18th month	24th month
Appearance	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder, slightly pseudo agglomerate	White or almost white powder, slightly pseudo agglomerate
Specific rotation	-14.0~-16.0°	-15.22°	-15.21°	-15.25°	-15.24°	-15.23°	-15.27°	-15.29°
pH	6.5~8.5	6.68	6.71	6.72	6.70	6.75	6.74	6.72
Water content	≤ 15% (%)	10.48	10.44	10.38	10.40	10.45	10.47	10.50
SiO_2 carrier	35%~45% (%)	37.25	37.23	37.26	37.28	37.31	37.32	37.30
Assay	L-Carnitine: ≥ 50% (%)	52.27	52.33	52.36	52.32	52.24	52.21	52.20
Chloride	≤ 0.4% (%)	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%

The test started from June 3, 2011. Test after 0 month, 3 months, 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:	Auditor:

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STABILITY DATA L-Carnitine 50%

Sample Name	L-Carnitine 50%	Batch NO.	LBF120506	Production Date	May 6, 2012	Test Date	May 6, 2012
Storage Temperature		25±1℃	Humidity	65±10%	End Date	May 5, 2014	

Item	standard	0 month	3rd month	6th month	9th month	12th month	18th month	24th month
Appearance	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder	White or almost white powder, slightly pseudo agglomerate	White or almost white powder, slightly pseudo agglomerate
Specific rotation	-14.0~-16.0°	-15.36°	-15.32°	-15.33°	-15.30°	-15.29°	-15.32°	-15.35°
pH	6.5~8.5	6.85	6.88	6.84	6.90	6.91	6.89	6.87
Water content	≤ 15% (%)	10.69	10.67	10.71	10.77	10.76	10.79	10.80
SiO_2 carrier	35%~45% (%)	35.88	35.90	35.87	35.92	35.95	35.93	36.20
Assay	L-Carnitine: ≥ 50% (%)	53.43	53.43	53.42	53.31	53.29	53.28	53.00
Chloride	≤ 0.4% (%)	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%	≤0.4%

The test started from May 6, 2012. Test after 0 month, 3 months, 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:	Auditor:

QC(2)

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www. huayangbio.com Email: sales@huayangbio.com