

Stability protocol

P QS-II 10.2.2 b

product: **L-Carnitine crystalline batch no. 038 03**

temperature: **25 ± 2 °C**

humidity: **60 ± 5 % r.H.**

test initiated on: **6.8.2003**

sample weight: **2 x 100 g + 1 x 200 g**

package type: **in close double PE bag, PE strap for tightening,
desiccant, 25 lt hardened paper drum with Al-foil
and with added 7 kg L-Carnitine crystalline**

Storage time (month)	Date of analysis	Appearance	Transparency (%)	Turbidity (FTU)	pH	Water content (w/w%)	L-Carnitine based on DM (w/w%)	γ- Butyrobetaine (w/w%)	Crotonobetaine (w/w%)	Betaine (w/w%)	Nor-carnitine (w/w%)	Trimethylamine (mg/kg)	Bio-burden (CFU/g)	Signature
	Limits	crystall powder	min. 85	max. 5.0	6.5-8.5	max. 4.0	99.0-101.0	max. 0.1	max. 0.1	max. 0.1	max. 0.1	max. 5.0	max. 50	
0	3.7.03	crystall powder	99.3	0.6	7.0	0.12	100.0	< 0.020	< 0.014	0.010	< 0.04	< 2.0	1	
3	6.11.03	crystall powder	99.2	0.6	7.0	0.18	100.7	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	0	
6	3.2.04	crystall powder	99.3	0.6	6.8	0.53	100.2	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	0	
9	7.5.04	crystall powder	98,7	0.6	6.9	0.62	100.0	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	0	
12	26.7.04	crystall powder	99.8	0.5	6.9	1.25	99.9	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	0	
18	6.2.05	crystall powder	99.6	0.6	6.7	2.48	99.5	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	1	
24	2.8.05	crystall powder	99,8	0,6	6,6	2,09	101,0	-	< 0.014	-	< 0.04	< 2.0	0	
36	4.-7.8. 2006	crystall powder	99,8	1,0	6,6	2,70	99,8	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	1	
48	2.-7.8. 2007	crystall powder	98,3	0,7	6,7	3,80	99,6	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	0	