

## Stability protocol

P QS-II 10.2.1 b

product: **L-Carnitine L-Tartrate batch no. 09202**

temperature:  **$40 \pm 2$  °C**

humidity:  **$75 \pm 5$  % r.H..**

test initiated on: **13.11. 2002**

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 8 kg L-Carnitine crystalline**

Storage time	Date of analysis	Appea- rance	Transpa- rency	Turbidity	pH	Water content	Content of L-Carnitine	$\gamma$ - Butyro- betaine	Crotono- betaine	Betaine	Nor- carnitine	Trimethyl- amine	Bio- burden	Signa- ture
(month)			(%)	(FTU)		(w/w%)	(w/w%)	(w/w%)	(w/w%)	(w/w%)	(w/w%)	(mg/kg)	(CFU/g)	
	Limits	crystall powder	min. 85	max. 5.0	3.0-4.5	max. 0.50	67.2-69.2	max. 0.15	max. 0.1	max. 0.1	max. 0.1	max. 5.0	max. 50	
0	5.11.02	crystall powder	99.8	0.2	3.6	0.10	68.1	< 0.020	< 0.014	< 0.01	< 0.01	< 2.0	0	
3	13.2.03	crystall powder	99.6	0.3	3.6	0.05	68.4	< 0.020	0.02	< 0.01	< 0.01	< 2.0	0	
6	13.5.03	crystall powder	99.9	0.3	3.6	0.13	67.9	< 0.020	0.03	< 0.01	< 0.03	< 2.0	0	
9	11.8.03	crystall powder	99.8	0.4	3.6	0.12	68.2	< 0.020	0.02	< 0.01	< 0.03	< 2.0	0	
12	13.11. 2003	crystall powder	99.8	0.4	3.6	0.09	68.1	< 0.020	0.02	< 0.01	< 0.03	< 2.0	0	
24	12.11. 2004	crystall powder	99.8	0.6	3.6	0.11	68.0	< 0.020	0.02	< 0.01	< 0.03	< 2.0	0	