Lonza

Stability protocol **P QS-II 10.2.2 d**

product: **L-Carnitine crystalline batch no. 47 04**

temperature: **40 ± 2 °C**
humidity: **75 ± 5 % r.H.**
test initiated on: **3.5.2004**

sample weight: **2 x 100 g + 1 x 200 g**
package type: **in close double PE bag, PE strap for tighting, 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	L-Carnitine based on DM	γ- Butyro-betaine	Crotono-betaine	Betaine	Nor-Carnitine	Trimethyl-amine	Total impurities (HPLC)	Bio-burden
(month)			(%)	(FTU)		(w/w%)	(w/w%)	(w/w%)	(w/w%)	(w/w%)	(w/w%)	(mg/kg)	(w/w%)	(CFU/g)
	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. 0.4	max. 50
0	28.4.04	crystall powder	99.7	0.2	7.2	0.06	99.6	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	< 0.08	0
6	3.11.04	crystall powder	99.7	0.3	6.6	1.58	100.1	< 0.020	< 0.014	< 0.010	< 0.04	< 2.0	< 0,08	0
9	3.2.05	crystall powder	99.9	0.5	6.9	2.79	100.4	< 0.020	< 0.014	0.01	< 0.04	< 2.0	< 0,08	0
12	3.5.05	crystall powder	99.5	0.7	6.5	3.81	99.8	< 0.020	< 0.014	< 0.01	< 0.04	< 2.0	< 0,08	0

Kouřim signature: