# Title: Acetyl L-Carnitine 500 mg, 100 Capsules

Allergy Research Group® / NutriCology®

Document No.: 70660CA Revision: 007

## **Certificate of Analysis**

Part Number	70660				
Lot Number	00412	00412			
<b>Product Count &amp; Form</b>	100 Vegetarian C	100 Vegetarian Capsules			
Packaging, Closure	225 cc bottle, desiccant, rayon/cotton				
Storage Condition	Room Temperatu	Room Temperature			
Shelf Life	24 months Expiration Date 03/22				
Label Number, Size	70660L, D				
Retain Sample	2 bottles per label (4 bottles total)				

### **ANALYSIS**

### **Physical**

Attribute	Method / SOP	Specification	Test Result
Product Color & Size	QC011	White, Size "00"	Complies
Product Weight	QC012	Meet USP <2091> 720 – 900 mg	Passes, 810 mg
Disintegration Time	QC018	Meet USP <2040>	Passes, 18:40 mins.

**Strength / Purity per Capsule** 

<b>Active Ingredient</b>	Label Claim	Specification	Test Result
Acetyl-L-Carnitine (as Hydrochloride)	500 mg	100 - 150% of LC by HPLC	660.1 mg
Other Ingredients: Hydroxynronyl methylgellulose migrocrystelline cellulose silicon dioxide I leucine			

<sup>\*</sup>Production and Process Control

### **Identification \ Chemical \ Heavy Metals**

Attribute	Method / SOP	Specification	Test Result
Identity	Bulk Certificate of Analysis Review	Approved	Approved
Identity	Near Infrared Spectroscopy	Matches Reference	Complies
Arsenic (inorganic)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	0.072 ppm
Cadmium	ICP-MS per USP <2232>	≤5 mcg/day Ψ	0.023 ppm
Mercury (total)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	BQL*
Lead	ICP-MS per USP <2232>	≤ 10 mcg/day Ψ	0.0108 ppm

<sup>\*</sup> BQL - Below Quantitative Level

### Microbiology

Attribute	Method / SOP	Specification	Test Result
Total Aerobic Count	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^3 \text{ CFU/g}$	$\leq 1 \times 10^3 \text{ CFU/g*}$
Total Yeast & Mold	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^2 \text{ CFU/g}$	$\leq 1 \times 10^2 \text{ CFU/g*}$
Coliform	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^2  \text{CFU/g}$	$\leq 1 \times 10^2 \text{ CFU/g*}$
Escherichia coli	USP/ AOAC/ FDA BAM	None Detected	None Detected*
Staphylococcus aureus	USP/ AOAC/ FDA BAM	None Detected	None Detected*
Salmonella	USP/ AOAC/ FDA BAM	None Detected	None Detected*

<sup>\*</sup>Production and Process Control

Casey Van Wagoner 2020.12.14 12:51:26 -07'00' Date: 14DEC2020



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40 West Louise Ave., Salt Lake City, UT 84115 Phone: (801) 485-1800 Fax: (801) 484-9211

Email: utlab@advancedlabsinc.com **FDA Registration #14353128308** 

# Test Certificate

Description: Acetyl-L-Carnitine Client: Allergy Research Group 40660/00412 Sample ID:

2300 N Loop Rd. Alameda, CA 94502

Lot No:

Location:

Received: 3/25/2020 3/31/2020 Completed:

Lab No: 191970-01

Analysis	Result	Per Unit	<b>Specifications</b>	Method
Total Aerobic Microbial Count	<10	CFU/g	<= 10,000 CFU/g	USP <2021>
Coliform	<10	CFU/g	<= 1,000 CFU/g	AOAC 991.14
E.Coli	Absent	per 10 grams	Absent	USP <2022>
Staphylococcus aureus	Absent	per 10 grams	Absent	USP <2022>
Salmonella	Absent	per 10 grams	Absent	USP <2022>
Total Yeast & Mold	<10	CFU/g	<= 1,000 CFU/g	USP <2021>
Yeast *	<10	CFU/g	<= 1,000 CFU/g	
Mold *	<10	CFU/g	<= 1,000  CFU/g	

<sup>\*</sup> For informational purposes only.

THESE RESULTS APPLY ONLY TO THE SAMPLE SUBMITTED AND NOT TO THE PRODUCT FROM WHICH IT WAS TAKEN. THESE RESULTS ARE PROVIDED ONLY FOR THE BENEFIT OF CLIENT, WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND, EXCEPT FOR THE EXPRESS LIMITED WARRANTY PROVIDED SOLELY TO CLIENT IN ADVANCED LABORATORIES' TERMS OF SERVICE.

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**Results Approved By:** 

Alisa Farnsworth-Quality Technician

Dated: 3/31/2020

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FDA Registration #14353128308

## Test Certificate

Description: Acetyl-L-Carnitine Client: Allergy Research Group Sample ID: 40660/00412 2300 N Loop Rd.

Sample ID: 40660/00412 2300 N Loop Rd.
Lot No: Alameda, CA 94502

Location:

Received: 3/25/2020 Completed: 4/1/2020

Lab No: 191973-01

Analysis	Result	Per Unit	<b>Specifications</b>	Method
† Acetyl L-Carnitine	660.1	mg/cap	>= 500 mg/cap	HPLC
Mercury	< 0.001	mcg/g	<= 0.5  mcg/g	ICP-MS USP <730>
Lead	0.108	mcg/g	$\leq 0.5 \text{ mcg/g}$	ICP-MS USP <730>
Arsenic	0.072	mcg/g	<= 0.5  mcg/g	ICP-MS USP <730>
Cadmium	0.023	mcg/g	$\leq 0.5 \text{ mcg/g}$	ICP-MS USP <730>

Acetyl L-Carnitine HCl analysis performed using HPLC by method adapted from Park KM, Lee MK, Park YH, Woo JS, Kim CK "HPLC of acetyl-L-carnitine in human plasma by derivatization with p-bromophenacyl bromide" as published in Journal Of Liquid Chromatography & Related Technologies 24 (4): 555-563 2001; utilizing sample derivatized with p-bromophenacyl bromide in the presence of 18-crown-6 followed by separation on a Waters Extera C18 column (150x3.5mm), 40°C, with 20mM Potassium phosphate, pH3.0/Acetonitrile (95:5) 1.5ml/min, detection by scanning photo diode array (200-400nm) with signal extraction at 260 nm.

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Results Approved By:

Alisa Farnsworth-Quality Technician

Dated: 4/1/2020

Tests marked with † were done at Atlas Bioscience Labs, LLC, a joint venture with Advanced Laboratories. - 1775 S. Pantano Rd - Ste #110, Tucson, AZ 85710

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