## Title: TMG Trimethylglycine, 100 Vegetarian Capsules

Allergy Research Group® / NutriCology®

Document No.: 73230CA Revision: 011

### **Certificate of Analysis**

Part Number	73230				
Lot Number	57430				
<b>Product Count &amp; Form</b>	100 Vegetarian Capsules				
Packaging, Closure	225 cc bottle, desiccant, rayon/cotton				
<b>Storage Condition</b>	Room Temperature				
Shelf Life	36 months Expiration Date 12/2022				
Label Number, Size	73230L, H				
Retain Sample	1 bottle per label (2 bottles total)				

#### **ANALYSIS**

#### **Physical**

Attribute	Method / SOP	Specification	Test Result
Product Color & Size	SOP 515	White, clear size "00"	Complies
Product Weight Variation	SOP 514	Meet USP <2091> 900- 1010 mg	Pass, 924.0 mg
Disintegration Time	SOP 522	Meet USP <2040>	Passes; 3 mins

<sup>†</sup> Per manufacturer's Certificate of Analysis

Purity/Strength per Capsule

<b>Active Ingredients</b>	<b>Label Claim</b>	Release Limits	Test Result
Betaine Anhydrous (Trimethylglycine)	750 mg	100 - 150% of LC by CE	782.4 mg

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

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

Attribute	Method / SOP	Specification	Test Result
Identity	Bulk Certificate of Analysis Review	Approved	Complies
Identity	Near Infrared Spectrometery	Matches Reference	Complies
Arsenic			BQL
(inorganic)	ICP-MS per USP <2232>	$\leq$ 15 µg/day $\Psi$	
Cadmium	ICP-MS per USP <2232>	$\leq$ 5 µg/day $\Psi$	BQL
Mercury	ICP-MS per USP <2232>	≤15 µg/day Ψ	BQL
Lead	ICP-MS per USP <2232>	≤10 μg/day Ψ	BQL

Ψ Permitted Daily Exposure, BQL - Below Quantification Limits

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Microbiology

Attribute	Method / SOP	Specification	Test Result
Total Aerobic Count	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^4  \text{CFU/g}$	< 10 CFU/g
Total Yeast & Mold	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^3  \text{CFU/g}$	< 10 CFU/g
Coliform	USP/ AOAC/ FDA BAM	$\leq 1 \times 10^2  \text{CFU/g}$	< 3 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

Approval:  Digitally signed by Kimberly Vennebus Date: 2020.04.07 15:20:44 -06'00'	Date: 07APR2020
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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: TMG Client: Allergy Research Group

 Sample ID:
 83230/57430
 2300 N Loop Rd.

 Lot No:
 Alameda, CA 94502

Location:

Received: 3/9/2020 Completed: 3/13/2020

Lab No: 190634-03

Analysis	Result	Per Unit	Specifications	Method
Total Aerobic Microbial Count	<10	CFU/g	<= 10,000 CFU/g	USP <2021>
Coliform	<3	MPN/g	<= 1,000  MPN/g	FDA BAM
E Coli	<3	MPN/g	Absent	FDA BAM
Salmonella	Absent	per 10 grams	Absent	USP <2022>
Staphylococcus aureus	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	

FDA BAM Method Utilized: 10g sample size

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: 3/13/2020

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## **Test Certificate**

Description: TMG Client: Allergy Research Group

Sample ID: 83230/57430 2300 N Loop Rd.
Lot No: Alameda, CA 94502

Location:

Received: 3/9/2020 Completed: 3/17/2020

Lab No: 190640-03

Analysis	Result	Per Unit	<b>Specifications</b>	Method
Mercury	0.003	μg/g	< 0.5 μg/g	ICP-MS USP <730>
Lead	0.009	$\mu g/g$	$< 0.5 \mu g/g$	ICP-MS USP <730>
Arsenic	0.073	$\mu g/g$	$< 0.5 \mu g/g$	ICP-MS USP <730>
Cadmium	< 0.001	$\mu g/g$	$< 0.5 \mu g/g$	ICP-MS USP <730>
† Trimethylglycine	782.4	mg/ Capsule	>= 750 mg/ Capsule	HPLC

FDA BAM Method Utilized: 10g sample size

Trimethylglycine analysis performed using HPLC following derivatization according to the AccQtag methodology (Waters, Inc.) using 20 mM HCl, Borate buffer, and AQC reagent in acetonitrile (1:3:1, v/v/v), followed by HPLC using Waters Extera C18 column (150x3.5mm, 3 $\mu$ m), 40°C, with isocratic mobile phase consisting of 20mM Potassium phosphate, pH3.0/Acetonitrile (95:5) 1.5ml/min with UV detection (254nm). Authentic chemical reference material obtained from Sigma-Aldrich.

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Results Approved By:

Alisa Farnsworth-Quality Technician

Dated: 3/17/2020

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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