

## Analytical Report

August 12, 2019

Tuyen Luong  
Allergy Research Group/NutriCology  
2300 North Loop Road  
Alameda, CA 94502

Page 1 of 1  
WO Number: W19H0261

Client: Allergy Research Group-QC  
Client #: A5537-T  
Sample Type: Tablet  
Collector: Client

Customer PO: LJ08072019  
Date Received: 8/8/2019  
Date Completed: 08/12/2019  
Discard Date: 08/26/2019

**CSL#: 19H0610 Melatonin 1.2mg - Lot#: 42231/ 20190709@2**

Parameter	Result	PQL	Method	Date	Analyst
Arsenic	<0.050 ug/g	0.050	ICP MS	08/12/19	RBP
Cadmium	<0.050 ug/g	0.050	ICP MS	08/12/19	RBP
Lead	<0.050 ug/g	0.050	ICP MS	08/09/19	JTP
Mercury	<0.050 ug/g	0.050	ICP MS	08/12/19	RBP

**CSL#: 19H0610**

Parameter	Result	Serving Size	Unit Weight	Specification
Arsenic	<0.05 ug/g	1 Tablet	0.31 g	<0.50 ug/g
Cadmium	<0.05 ug/g	1 Tablet	0.31 g	<0.50 ug/g
Lead	<0.05 ug/g	1 Tablet	0.31 g	<0.50 ug/g
Mercury	<0.05 ug/g	1 Tablet	0.31 g	<0.50 ug/g

Respectfully Submitted,  
Chemical Solutions, Ltd.

QA Representative

Notes:

CONFIDENTIAL REPORT. This report is confidential and is for the sole use of the addressee.  
This report can only be reproduced in full.  
The units for the PQL are the same as those shown for the result.



# Micro Quality Labs, Inc.

Specializing in Pharmaceutical, Dietary Supplements, Toys and Cosmetics Testing

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E-Mail: [Karine@MicroQualityLabs.com](mailto:Karine@MicroQualityLabs.com)

**Customer:** Allergy Research Group, LLC  
**Address:** 2300 North Loop Road  
Alameda, CA 94502


## ANALYTICAL/CHEMICAL CERTIFICATE OF ANALYSIS

**Sample Name:** MELATONIN 1.2MG  
**Product Code:** 42231  
**Batch/Lot:** 20190709@2  
**MQL Accession:** 190809-0155

**PO#:** LJ08072019  
**Sample Description:** FG  
**Rush:** N/A  
**Received Date:** 08/09/19

Test Requested:	Test Method:	Specification:	Results:
Melatonin	MQLTM-0491 By HPLC	NLT 1.2 mg / cap	1.1 mg / cap (**)


**Prepared By:**

  
Kendra Hensley/Document Control-Specialist

**AUG 16 2019**

08/16/19

**Reviewed By:**

  
Raffie Avakian/Quality Assurance Reviewer

**AUG 16 2019**

08/16/19

**Comment: (\*\*) OUT OF SPECIFICATION.**

*The aforementioned results on this report are representative of the samples submitted and may not be indicative of the entire manufacture, batch, and/or lot. Applicable current GMP's shall always be used when sampling. GLP's shall always be practiced by Micro Quality Labs to ensure the most accurate results.*

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**Project Description:** Product Testing (PO # LJ08072019)  
**Report Issued To:** Allergy Research Group  
2300 North Loop Rd.  
Alameda, CA 94502  
**Contact:** Janice Vu

### Certificate of Analysis

**AEMTEK #: 1908383**

**Sampling Date:** 2019-08-07  
**Sample Received:** 2019-08-08  
**Analysis Started:** 2019-08-08  
**Analysis Performed By:** AO, WY, JC  
**Report Issue Date:** 2019-08-11

Sample ID	Analyte	Aerobic Plate Count	Total Coliforms	Yeast	Mold	Escherichia coli	Salmonella	Staphylococcus aureus
1	Method Reporting Unit Method Detection Limit for Reporting Sample Description Lot #/Code Melatonin 1.2mg	AOAC OMA 990.12 CFU/g 10	AOAC OMA 991.14 CFU/g 10	AOAC OMA 2014.05 CFU/g 10	AOAC OMA 2014.05 CFU/g 10	USP 37 <62> (mod.) per 10g P/A	USP 37 <62> (mod.) per 10g P/A	USP 37 <62> (mod.) per 10g P/A
<b>RESULTS</b>								
		<10	<10	<10	<10	ND	ND	ND

**Terminology:**

CFU = Colony Forming Units  
< Indicates less than the reporting limit as noted  
ND = Not Detected, negative, absent. Sensitivity is about 1 organism per test portion.  
BAM = FDA Bacteriological Analytical Manual  
AOAC OMA = Official Methods of Analysis of the AOAC International, 18th ed.

MPN = Most Probable Number  
P/A = Presence/Absence  
CP Staph = Coagulase Positive Staphylococci (Staphylococcus aureus)  
CMMEF = Compendium of Methods for the Microbiological Examination of Foods, 4th ed.  
AOAC RI = AOAC Research Institute Performance Tested.

N/A = Not Applicable or not analyzed

*Lab 08/12/19*



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## Memo

**To: Tuyen Luong**

**From: Brett Kuenne, QA Manager**

**cc: Dave Hill**

**Date: 10/18/2018**

**Re: Overages in Green Mountain Pharmaceuticals Products sold to Allergy Research Group**

Tuyen-

This memo is in response to your request for Green Mountain Pharmaceuticals to add an additional 5% of API to the following products:

Pregnenolone 50 mg tablets  
Pregnenolone 100 mg tablets  
Pregnenolone 150 mg tablets  
DHEA 10 mg tablets  
DHEA 15 mg tablets  
DHEA 25 mg tablets  
DHEA 50 mg tablets  
Melatonin 1.2 mg tablets  
S-Acetyl-Glutathione 100 mg tablets  
S-Acetyl-Glutathione 300 mg tablets

We have evaluated your request; and will not be making any changes to our formulas for the above products. While 21CFR 101.36 states that 'reasonable excesses are allowed within current good manufacturing practice'; we feel that our current range of 90-110% of the stated amount for the above products meets this requirement. Please let me know if you have any further questions.

A handwritten signature in blue ink, appearing to read "Brett Kuenne", is written over a horizontal line.

Brett Kuenne, QA Manager

[brett@greenmountainpharma.com](mailto:brett@greenmountainpharma.com)

720-531-5379