

Micro Quality Labs, Inc.

Specializing in Pharmaceutical, Dietary Supplements, Toys and Cosmetic Testing 3125 N. Damon Way • Burbank, California 91505 (818) 845-0070 • Fax: (818) 845-0030 E-Mail: <u>Karine@MicroQualityLabs.com</u>



Customer: Address: Blue Diamond Herbs 8029 Fairview Rd. STE E Mint Hill, NC 28227

Received From:	Mint Hill, NC	
Received Date:	01/08/21	
Release Date:	01/15/21	
PO #	N/A	

MICROBIOLOGICAL CERTIFICATE OF ANALYSIS

Sample Name: RED HORN SULAWESI 50g Product Code: N/A Batch/Lot #: BDH106RHS MQL Accession #: 1051650

Description: RAW

Analyte:	Result:	Method:	Test Date:	Comment:	
ТРС	3.6x10 ³ cfu/gm	TM-01 (Modified USP61)	01/08/21	N/A	
Yeast/Mold	1.7x10 ³ cfu/gm	TM-01 (Modified USP61)	01/08/21	N/A	
Coliforms	10²cfu/gm	TM-01A (Modified USP62)	01/08/21	N/A	
E.coli	Absent	TM-01A (Modified USP62)	01/08/21	N/A	
Pseudomonas spp.	Absent	TM-01A (Modified USP62)	01/08/21	N/A	
S.aureus	Absent	TM-01A (Modified USP62)	01/08/21	N/A	
Salmonella/Shigella	Absent	TM-01A (Modified USP62)	01/08/21	N/A	

All Products were tested in accordance with the USP Standard for Total Plate Count and Enrichment. Additional guidance was referenced by CTFA *Microbiological Guidelines*.

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JAN 1 5 2021

Prepared By: Monique Mendoza/ Document Control Specialist

Reviewed By: Ani Zohrabyan/Microbiologist

Date:

Micro Quality Laboratories, Inc. (MQL), is an A2LA ISO 17025 accredited testing laboratory (Certificate Number 3034.01). The requirements of ISO 17025 were followed for the test, results and preparation of this certificate of analysis. MQL's scope of accreditation may be found on A2LA or MQL websites.

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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Customer: Address:

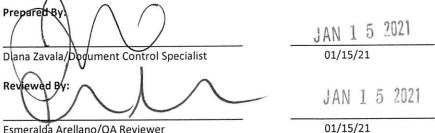
Blue Diamond Herbs 8029 Fairview Rd. STE E Mint Hill, NC 28227

ANALYTICAL/CHEMICAL CERTIFICATE OF ANALYSIS

Sample Name: RED HORN SULAWESI POWDER Product Code: N/A Batch/Lot: BDH106RHS MQL Accession: 210111-0037

PO#: N/A Sample Description: RAW Rush: N/A Received Date: 01/11/21

Test Requested:	Test Method:	Specification:	Results:		
Lead	MQLTM-0278	N/A	0.115 ppm		
	By ICP-MS				
Arsenic	MQLTM-0278	N/A	0.035 ppm		
	By ICP-MS		00 - 24		
Cadmium	MQLTM-0278	N/A	0.020 ppm		
	By ICP-MS				
Mercury	MQLTM-0278	N/A	0.013 ppm		
	By ICP-MS				



Esmeralda Arellano/QA Reviewer

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Form# 03B.2 Analytical / Chemical Certificate of Analysis, Revised 07-05-2016 DCR2016-0062

United States Pharmacopeia (USP) Limit for Nutritional Supplements:

- Arsenic 3.000 ppm / 3000.000 ppb
- Cadmium 3.000 ppm / 3000.000 ppb
- Lead 10.000 ppm / 10000.000 ppb
- Mercury 3.000 ppm / 3000.000 ppb

California Proposition 65 Daily Limits for Heavy Metals:

- Arsenic 10 ppm / 10,000.000 ppb
- Cadmium 4.1 ppm / 4,100.000 ppb
- Lead 0.5 ppm / 500.000 ppb**
- Methyl Mercury 0.3 ppm / 300.000 ppb

For labels with a single daily dose of 500mg, the PPM in products cannot be higher than:

- Arsenic = 20.000 ppm / 20,000.000 ppb
- Cadmium = 8.000 ppm / 8,000.000 ppb
- Lead = 0.900 ppm / 900.000 ppb
- Mercury = 0.600 ppm / 600.000 ppb

FDA Tolerable Daily Diet Lead intake:

- Children <6 years old = 6.000 ppm / 6000.000 ppb
- Pregnant women = 25.000 ppm / 25000.000 ppb
- Adults = 75.000 ppm / 75000.000 ppb



Recommended Microbial Limits for Botanical Ingredients (in colony-forming units (cfu)/g)

Organization	AHPA	NSF/ANSI	USP	WHO	EHIA	EP	AHPA	USP
Plant material	Dried, unprocessed herbs for use as ingredients in dietary supplements	Botanical ingredient, non-extract	Dried or powdered botanicals	Untreated crude intended for further processing	NA	NA	Powdered botanical extracts and soft extracts	Powdered botanical extracts
Total aerobic microbial count	10 ⁷	107	10 ⁵	NA or 10 ⁵ -10 ⁷ as per specific monographs	NA.	NA	104	104
Total combined yeast & mold count	10 ⁵	10 ⁵	10 ³	10 ⁵ (mold propagules); Occasionally 10 ⁴ for specific monographs	NA	NA	10 ³	10 ³
Enterobacteria count (bile- tolerant Gram-negative bacteria)	10 ⁴ (Total coliforms)	104	10 ³	10 ³	NA	NA	10 ² (Total coliformis)	NA
Escherichia coli	Not detected in 10 g*	10 ^{2**}	Absence in 10 g	104	NA	NA	Not detected in 10 g*	Absence in 10 g
Salmonella spp.	Not detected in 25 g*	Not detected in 10 g	Absence in 10 g	NA or absent	NA	NA	Not detected in 25 g*	Absence in 10 g
Staphylococcus aureus	NA	Not detected in 10 g	NA	NA or absent	NA	NA	NA	NA

AHPA – American Herbal Products Association, Guidance, 8630 Fenton St. #918, Silver Spring, MD 20910; 301-588-1171. EHIA – European Herbal Infusions Association EP – European Pharmacopoeia NSF/ANSI – NSF International Standard/American National Standard for Dietary Supplements 173 – 2006

USP - United States Pharmacopeial Convention, USP-NF 35-30, 2012

WHO - World Health Organization, Quality control methods for medicinal plant materials, Geneva, 1998

NA - Not Assigned

*Sample size may vary depending on the method used.

**If the presence of Escherichia coli is confirmed, then testing shall be performed based on the USFDA Bacteriological Analytical Manual in Chapter 4A to determine whether the colonies are pathogenic enterovirulent Escherichia coli (EEC), not limited to 0157:H7. There is a zero tolerance for the presence of EEC.

(a) (i) for dried, unprocessed herbs for use as ingredients in dietary supplements, and (ii) for herbal supplements in solid form consisting of dried, unprocessed herbs:

- Total aerobic plate count: 10⁷ colony forming units/gram
- Total yeasts and molds: 10⁵ colony forming units/gram
- Total coliforms: 10⁴ colony forming units/gram
- Salmonella spp.: not detected in 25 grams
- Escherichia coli: not detected in 10 grams
- Total aflatoxins (B1 + B2 + G1 + G2): 20 µg/kg (ppb)
- Aflatoxin B1: 5 µg/kg (ppb)