



Double Wood LLC
 3510 Scotts LN STE 219
 Philadelphia, PA 19129-1573

CERTIFICATE OF ANALYSIS

Product Name: Sulbutiamine
 4/19/2021

Lot# 2103102

Prepared For Double Wood LLC

Description

Code No	VGL-1408C
Control No./Lot	2103-102
Batch Size	270,000 Capsules
Date Of Manufacture	April, 2021
Date Of Expiration	April, 2023
Description	#0 Clear Gelatin Capsule filled with white Powder Blend
Average Fill Weight (10 Capsules)	3.50 gm ± 5%
Average Filled Capsule Weight (10 Capsules)	4.50 gm ± 5%
Disintegration Time (USP:<2040>)	Passes As Per USP<2040>Current
Weight Variation	Passes As Per USP<2091>Current

ASSAY: AS PER 1 CAPSULE

<u>ACTIVE INGREDIENTS</u>	<u>Label claim/capsule</u>	<u>Result</u>	<u>Method</u>
Sulbutiamine	200 mg	200 mg	PPCS*

*In accordance with 21 CFR 111.75 c or d ingredient test method is substantiated through Quantitative Analysis, testing, and/or examination; in-process testing, examination, and/or monitoring, and other aspects of the established Production and Process Control System (PPCS)

Other Ingredients: Gelatin (Capsule) and rice flour
 Input as per batch record at the time of manufacture

MICROBIOLOGICAL CONTAMINANTS

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT/Method</u>
TOTAL BACTERIAL COUNT	NMT 1,000 cfu/g	Pass-NSMB9-01Biolumix
TOTAL YEAST & MOLD (Y&M)	NMT 100 cfu/g	Pass-NSMB9-01Biolumix
SALMONELLA SP.	Negative	Pass-NSMB9-01Biolumix
E.Coli	Negative	Pass-NSMB9-01Biolumix

HEAVY METAL TEST

<u>Test</u>	<u>Specification</u>	<u>Result</u>	<u>Method</u>
Lead (Pb)	NMT 0.5 mcg/1 capsule	0.007 mcg/1 Capsule	ICP-MS
Mercury (Hg)	NMT 2.0 mcg/1 capsule	0.010 mcg/1 Capsule	ICP-MS
Arsenic (As)	NMT 10 mcg/1 capsule	0.033 mcg/1 Capsule	ICP-MS
Cadmium (Cd)	NMT 4.1 mcg/1 capsule	0.014 mcg/1 Capsule	ICP-MS

QUALITY CONTROL DEPARTMENT

Vita-gen Labs

Date

4/19/21