



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

Product Name: TUDCA (tauroursodeoxycholic acid)

Lot# 21032103

Date: 4/29/2021

Prepared for: Double Wood LLC

Description

Code No	VGL-2159C
Control No./Lot	21032103
Batch Size	900,000 Capsules
Date Of Manufacture	April, 2021
Date of Expiration	April, 2023
Description	#1 Clear gelatin capsule filled with white powder blend
Average Fill Weight (10 capsules)	2.50 gm ± 5%
Average Filled Weight (10 capsules)	3.50 gm ± 5%
Disintegration Time (USP:<2040>)	Passes As Per USP<2040>Current
Weight Variation	Passes As Per USP<2091>Current

ASSAY: AS PER 2 Capsules

<u>ACTIVE INGREDIENTS</u>	<u>Label claim/2 capsules</u>	<u>Result</u>	<u>Method</u>
Tauroursodeoxycholic Acid (TUDCA)	500 mg	500 mg	PPCS*

Other Ingredients: Gelatin (Capsule), Rice Flour
 Input as per batch record at the time of manufacture

MICROBIOLOGICAL CONTAMINANTS

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>	<u>METHOD</u>
TOTAL BACTERIAL COUNT	NMT 10,000 cfu/g	<5 cfu/g	USP 61
TOTAL YEAST & MOLD (Y&M)	NMT 1000 cfu/g	<7 cfu/g	USP 61
SALMONELLA SP.	Negative	Not detected	USP 62
E.Coli	Negative	Not detected	USP 62
S. Aureus	Negative	Not detected	USP 62

HEAVY METAL TEST

<u>Test</u>	<u>Specification</u>	<u>Result</u>	<u>Method</u>
Lead (Pb)	NMT 0.5 mcg/Daily Dose	0.020 mcg/2 capsule	ICP-MS
Mercury (Hg)	NMT 2.0 mcg/Daily Dose	Not Detected	ICP-MS
Arsenic (As)	NMT 10 mcg/Daily Dose	0.010 mcg/2 capsule	ICP-MS
Cadmium (Cd)	NMT 4.1 mcg/Daily Dose	0.024 mcg/2 capsule	ICP-MS

*In Accordance with 21 CFR § 11.75 result is substantiated through component testing and/or examination: in-process testing, examination, and/or monitoring; and other aspects of the established Production and Process Control System (PPCS)

QUALITY CONTROL DEPARTMENT

Vita-gen Labs

Date

4/29/21