

DATE: **10/23/2023**

CERTIFICATE OF ANALYSIS

Product: **OPTI-PURE CAPS**
Product code : **18483**
Prepared For: **NUETHIX FORMULATIONS**

Lot No: **2307207**
Serving Size : **3 Caps**
Manufacture Date: **09/2023**

PHYSICAL CHARACTERISTICS

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>	<u>METHOD</u>
Average Capsule Weight	798mg – 882mg	840 mg	Balance Reading
Capsule Size	"00"	"00"	Organoleptic
Disintegration	≤ 30 Min	11 Min	USP <2040>
Capsule Color	Natural/Natural	Natural/Natural	Organoleptic
Capsule Type	Gelatin	Gelatin	Chemical Test
Blend Color	Light Yellow to Green Yellow w/Spots	Light Yellow w/Spots	Organoleptic

AMOUNT PER SERVING

INGREDIENT

Vitamin A (As Retinyl Palmitate)	448mcg - 963.2mcg	672mcg	PPCS [‡]
Vitamin A (As Beta Carotene)	57mcg - 122.55mcg	85.5mcg	PPCS [‡]
Vitamin C (As Magnesium Ascorbate)	180mg - 207mg	198mg	PPCS [‡]
Vitamin E (As D-Alpha Tocopheryl Succinate)	69mg - 134.55mg	89.7mg	PPCS [‡]
Vitamin B1 (As Thiamine HCl)	8.3mg - 14.94mg	10.41mg	HPLC
Vitamin B2 (Riboflavin)	8.3mg - 14.94mg	11.46mg	HPLC
Vitamin B3 (Niacin)	10mg - 13.5mg	13mg	PPCS [‡]
Vitamin B6 (As Pyridoxal-5-Phosphate)	5mg - 6.75mg	6.5mg	PPCS [‡]
Vitamin B6 (As Pyridoxine HCl)	5mg - 9mg	5.76mg	HPLC
Folate (As L-5-Methyltetrahydrofolate Calcium) (Biofolate®)	340mcg - 640mcg DFE DFE	510mcg	PPCS [‡]
Vitamin B12 (As Methylcobalamin) On Dicalcium Phosphate	0.4mcg - 0.8mcg	0.6mcg	PPCS [‡]
Biotin On Dicalcium Phosphate	0.66mcg - 1.32mcg	0.99mcg	PPCS [‡]
Pantothenic Acid (As Calcium-D-Pantothenate)	33.3mg - 56.61mg	39.96mg	PPCS [‡]
Magnesium (As Magnesium Ascorbate, Magnesium Citrate & Magnesium Malate)	50mg - 66.2mg	56.58mg	ICP-OES
Zinc (As Zinc Picolinate)	2mg - 2.6mg	2.475mg	ICP-OES
Selenium (As L-Selenomethionine)	0.33mcg - 0.56mcg	0.363mcg	PPCS [‡]
Manganese (As Traacs® Manganese Bislycinate Chelate)	495mcg - 668.25mcg	612.0mcg	ICP-OES
Molybdenum (As TRAACS® Molybdenum Glycinate Chelate)	51mcg - 86.7mcg	56.1mcg	PPCS [‡]
Calcium (As Calcium-D-Glucarate)	33mg - 47.43mg	33.78mg	ICP-OES
Milk Thistle (Silybum Marianum) Seed Extract 80% Silymarins	100mg - 140mg	105mg	PPCS [‡]
Alpha Lipoic Acid	100mg - 125mg	110.94mg	HPLC

‡In accordance with 21 CFR § 111.75 (c) or (d) ingredient is exempt from testing. 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).

N-Acetyl-L-Cysteine	100mg - 125mg	105mg	PPCS [‡]
DIM (Diindolylmethane)	80mg - 100mg	84mg	PPCS [‡]
L-Methionine	66.7mg - 83.38mg	70.04mg	PPCS [‡]
Glycine	66.7mg - 83.38mg	70.04mg	PPCS [‡]
L-Glutamic Acid	66.7mg - 73.37mg	70.04mg	PPCS [‡]
Taurine	66.7mg - 73.37mg	70.04mg	PPCS [‡]
L-Glutamine	66.7mg - 73.37mg	70.04mg	PPCS [‡]
Choline (As Choline Bitartrate)	26.68mg - 29.35mg	28.01mg	PPCS [‡]
Quercetin Dihydrate	66.7mg - 93.38mg	70.03mg	PPCS [‡]
Inositol	33.3mg - 41.63mg	35.18mg	PPCS [‡]
L-Ornithine HCl	33.3mg - 41.63mg	35.18mg	PPCS [‡]
Broccoli Sprout Extract 0.4%	33.3mg - 46.62mg	35.18mg	PPCS [‡]
Sulforaphane			
L-Glutathione	16.7mg - 20.88mg	17.54mg	PPCS [‡]
L-Serine	16.7mg - 18.37mg	17.54mg	PPCS [‡]
L-Histidine HCl	16.7mg - 18.37mg	17.54mg	PPCS [‡]
L-Carnitine (As L-Carnitine Tartrate)	16.7mg - 18.37mg	17.54mg	PPCS [‡]
Coenzyme Q10	8.3mg - 10.38mg	8.72mg	PPCS [‡]
Grape Seed Extract 95% Polyphenols	3.3mg - 4.62mg	3.47mg	PPCS [‡]
Superoxide Dismutase (SOD)	33mcg - 37.95mcg	36.3mcg	PPCS [‡]
Catalase	15mcg - 27.75mcg	16.5mcg	PPCS [‡]

CONTAMINANTS

MICROBIOLOGICAL

Total Aerobic Plate Count	<10 ⁴ cfu/g	100 cfu/g	USP<61>
Total Yeast and Mold (Y&M)	<10 ³ cfu/g	<10 cfu/g	USP<61>
Enterobacteriaceae	<10 ² cfu/g	<10 cfu/g	USP<62>
Salmonella spp.	Absent	Absent	USP<62>
E. Coli	Absent	Absent	USP<62>
Staphylococcus aureus	Absent	Absent	USP<62>

HEAVY METALS:

Mercury (2µg/day)	≤ 0.8354 ppm	0.0098 ppm	ICP/MS
Lead (8.8µg/day)	≤ 3.6759 ppm	0.0118 ppm	ICP/MS
Arsenic (10µg/day)	≤ 4.1771 ppm	0.0370 ppm	ICP/MS
Cadmium (4.1µg/day)	≤ 1.7126 ppm	0.0466 ppm	ICP/MS

GLUTEN

NMT 20 ppm	< 4 ppm	ELISA
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B-LACTOGLOBULIN

Not Detected (LOQ 5.0 ppm)	< 5ppm	ELISA
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CASEIN

Not Detected (LOQ 2.5 ppm)	< 2.5ppm	ELISA
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QUALITY CONTROL
BACTOLAC PHARMACEUTICAL, INC.

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