

Title: **Optivite® P.M.T.**

Biomicotek® / Optimox®

Document No.: 00103CA

Revision: 003

Certificate of Analysis

Part Number	00103		
Lot Number	K9151		
Product Count & Form	180 Tablets		
Packaging, Closure	275 cc bottle, Child Resistant Cap 45mm, desiccant, rayon/cotton		
Storage Condition	Room Temperature		
Shelf Life	24 months		
Label Number, Size	00103L, I		
Manufacture Date	02APR2020	Expiration Date	APR2022
Retain Sample	1 bottle (stored at ARG)		

ANALYSIS

Physical

Attribute	Method / SOP	Specification	Test Result
Product Color, Size	QC011	Yellow (Y/VP), Size T3 Tablet	Complies
Product Weight Variation	QC012	Meets USP <2091>: 1050 – 1150 mg	1102 mg
Disintegration time	ARG SOP 522	Meets USP <2040>: NLT 50 min., NMT 180 min	Pass [†]

† Tested by FTI

Purity / Strength per Six (6) Tablets

Ingredients	Label Claim (6)	Specification	Test Result
Vitamin A (as retinyl palmitate and 60% as beta carotene)	12,500 IU	100- 150% LC by HPLC	100- 150% LC by HPLC*
Vitamin C	1,500 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Vitamin D (as cholecalciferol)	100 IU	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Vitamin E (as d-alpha tocopheryl succinate)	100 IU	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Thiamin (as thiamine mononitrate)	25 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Riboflavin	25 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Niacin (as niacinamide)	25 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Vitamin B6 (as pyridoxine HCl)	300 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Folic Acid	200 mcg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Vitamin B12 (as hydroxocobalamin)	60 mcg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Biotin	60 mcg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Pantothenic Acid (from Calcium Pantothenate)	25 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Iron (as amino acid chelate)	15 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Iodine (as hydrolyzed protein complex)	75 mcg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Caclium (as amino acid chelate)	125 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Magnesium (as amino acid chelate)	250 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Zinc (as amino acid chelate)	25 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*

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Ingredients	Label Claim (6)	Specification	Test Result
Selenium (as hydrolyzed protein complex)	100 mcg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Copper (as amino acid chelate)	0.5 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Manganese (as amino acid chelate)	10 mg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Chromium (as hydrolyzed protein complex)	100 mcg	100 - 150% LC by ICP-OES	100 - 150% LC by ICP-OES*
Choline (from choline bitartrate)	313 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Citrus Bioflavonoids	250 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Betaine HCl	100 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Pancreatin 4x	93 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*
Inositol	24 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
p-Aminobenzoic Acid (PABA)	25 mg	100- 150% LC by HPLC	100- 150% LC by HPLC*
Rutin	25 mg	100 - 150% LC by HPLC	100 - 150% LC by HPLC*

Other Ingredients: Stearate acid, carnauba wax, hydroxypropyl methylcellulose, silica, magnesium stearate, pharmaceutical glaze, titanium oxide, and natural flavors.

*Production and Process Control

Identification \ Chemical \ Heavy Metals


Attribute	Method / SOP	Specification	Test Result
Identity	Bulk Certificate of Analysis Review	Approved	Approved
Identity	Near Infrared Spectroscopy	Matches reference	Matches reference
Arsenic (inorganic)	ICP-MS per USP <2232>	≤ 15 mcg/day	≤ 15 mcg/day*
Cadmium	ICP-MS per USP <2232>	≤ 5 mcg/day	≤ 5 mcg/day*
Mercury (total)	ICP-MS per USP <2232>	≤ 15 mcg/day	≤ 15 mcg/day*
Lead	ICP-MS per USP <2232>	≤ 10 mcg/day	≤ 10 mcg/day*

*Production and Process Control, BQL – Below Quantitative Level; †Issued MRB

Microbiology

Attribute	Method / SOP	Specification	Test Result
Total Aerobic Count	USP/ AOAC/ FDA BAM	≤ 1 x 10 ³ CFU/g	≤ 1 x 10 ³ CFU/g*
Total Yeast & Mold	USP/ AOAC/ FDA BAM	≤ 1 x 10 ² CFU/g	≤ 1 x 10 ² CFU/g*
Coliform	USP/ AOAC/ FDA BAM	≤ 1 x 10 ² CFU/g	≤ 1 x 10 ² CFU/g*
Escherichia coli	USP/ AOAC/ FDA BAM	None Detected	None Detected*
Staphylococcus aureus	USP/ AOAC/ FDA BAM	None Detected	None Detected*
Salmonella	USP/ AOAC/ FDA BAM	None Detected	None Detected*

*Production and Process Control, † Per FTI test data

Approval: 	Digitally signed by Kimberly Vennebush Date: 2020.07.21 15:13:00 -06'00'	Date: 21JUL2020
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If you liked our service, please tell a friend. If you didn't, please tell us!

Test Certificate

Description: Optivite Tablets
Sample ID: 00103
Lot No: K9151
Location:
Received: 5/5/2020
Completed: 5/11/2020Client: Allergy Research Group
2300 S Main St
Salt Lake City, UT 84115

Lab No: 195374-01

Analysis	Result	Per Unit	Specifications	Method
Total Aerobic Microbial Count	< 10	CFU/g	<= 1,000 CFU/g	USP <2021>
Coliform	< 10	CFU/g	<= 100 CFU/g	AOAC 991.14
E.Coli	Absent	per 10 grams	Absent	USP <2022>
Staphylococcus aureus	Absent	per 10 grams	Absent	USP <2022>
Salmonella	Absent	per 10 grams	Absent	USP <2022>
Total Yeast & Mold	< 10	CFU/g	<= 100 CFU/g	USP <2021>
Yeast *	< 10	CFU/g	<= 100 CFU/g	USP <2021>
Mold *	< 10	CFU/g	<= 100 CFU/g	USP <2021>

* For informational purposes only.

THESE RESULTS APPLY ONLY TO THE SAMPLE SUBMITTED AND NOT TO THE PRODUCT FROM WHICH IT WAS TAKEN. THESE RESULTS ARE PROVIDED ONLY FOR THE BENEFIT OF CLIENT, WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND, EXCEPT FOR THE EXPRESS LIMITED WARRANTY PROVIDED SOLELY TO CLIENT IN ADVANCED LABORATORIES' TERMS OF SERVICE.

THIS CERTIFICATE SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT WRITTEN APPROVAL FROM ADVANCED LABORATORIES.

Results Approved By:


Kristina Noll - Quality Technician

Dated:

5/11/2020

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Test Certificate

 Description: Optivite Tablets
 Sample ID: 00103
 Lot No: K9151
 Location:
 Received: 5/5/2020
 Completed: 5/13/2020

 Client: Allergy Research Group
 2300 S Main St
 Salt Lake City, UT 84115

Lab No: 195375-01

Analysis	Result	Per Unit	Specifications	Method
Copper	0.601	mg/6 tablets	> 0.5 mg/6 tablets	ICP-OES USP <730>
Mercury	<0.001	µg/g	< 0.5 µg/g	ICP-MS USP <730>
Lead	0.068	µg/g	< 0.5 µg/g	ICP-MS USP <730>
Arsenic	<0.001	µg/g	< 0.5 µg/g	ICP-MS USP <730>
Cadmium	0.056	µg/g	< 0.5 µg/g	ICP-MS USP <730>
Iron	18.4	mg/6 tablets	> 15 mg/6 tablets	ICP-OES USP <730>
† Vitamin D3 (Cholecalciferol)	161.0	IU/6 tablets	> 100 IU/6 tablets	HPLC
Zinc	29.0	mg/6 tablets	> 25 mg/6 tablets	ICP-OES USP <730>

Vitamin D3 (Cholecalciferol) analysis performed using HPLC by method adapted from Wang, L.H., Huang, S.H., ""Determination of vitamins A, D, E, and K in Human and Bovine Serum, and Beta-Carotene and Vitamin A Palmitate in Cosmetic and Pharmaceutical Products, by Isocratic HPLC,"" as published in Chromatographia, 55(5-6): 289-296, 2002; utilizing a Hypersil C-18 column (25 cm x 4.6 mm), with detection performed by scanning PDA (200-400nm) with signal extraction at 254nm for quantification. Authentic chemical reference material obtained from Sigma-Aldrich

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 Results Approved By: 
 Kristina Noll - Quality Technician

Dated: 5/13/2020

Tests marked with † were done at Atlas Bioscience Labs, LLC, a joint venture with Advanced Laboratories. -
 1775 S. Pantano Rd - Ste #110, Tucson, AZ 85710

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