



UNIPHARM

UNIPHARM, INC.

75 Progress Lane

Waterbury, CT 06705

www.unipharmus.com

FDA Drug Registration # 3009928224

FDA Food Registration# 16963275420

CT Dept of Consumer Protection FME.0000146

U-QCA-010-002, Rev 13

CERTIFICATE OF PRODUCT CONFORMANCE

Product Name: Vitrum Plus	Date(s) Packaged: 02-DEC-2023, 04-DEC-2023, 05-DEC-2023
Product Material Number: 43965/9010-06UA	Units Packaged: 16,407
Product Batch Number: WN164	Product Specification: 9010-06UA, Rev 4
Bulk Lot: 2307022	Date of Manufacturing: 22/09/2023
PO Number: 4500087450	Date of Expiry: 09/2025
Package Size and Count: 60 Count Bottles	Bulk Material Release Authorization Provided by Unipharm on 27-NOV-2023

PHYSICAL CHECKS		
Item	Requirement	Result
Tablet Count	60 per unit	60 per unit
Product Description	White Film Coated Tablet with Bisect on one side and "VITRUM" on the other	Acceptable
Seal Integrity	Fully sealed, no burns, no odor	Acceptable
Torque	4-12 in. lbs.	7-11 in. lbs.
Batch Number Imprint	Correct and legible	Acceptable
Bottle Label Version	300822V1.2	300822V1.2
Bottle Label Date Imprint(s)	Correct and legible	Acceptable
Insert Presence	Present	Acceptable
Insert Version	300822V1.2	300822V1.2
IFC Date Imprint(s)	Correct and legible	Acceptable
IFC Version	300822V1.2	300822V1.2
Shipper Closure	Carton fully sealed, no damage	Acceptable
Shipper Label Printing	(9010-06UA.002) Correct and legible	Acceptable

Comments: Saleable Units= 16,404

This is to certify that this Product batch was packaged in accordance with the current Quality Agreement and packaging service agreement between Acino Pharma AG and Unipharm, Inc. and in full compliance with 21 CFR 111. Physical Check/Laboratory Analysis (Micro tests*) is performed for packaged product as per established program. I hereby certify that the given information is authentic and accurate.

Generated By: Megha Patel Document Control Specialist, Unipharm, Inc. Waterbury, CT Date: 12/07/2023

Megha Patel

Verified By: [Signature] Quality Manager, Unipharm, Inc. Waterbury, CT Date: 12/07/2023

Mohamed Sami

Dr. Olanid V11.86
big 02.02.24 [Signature]



EAGLE NUTRITIONALS

111 Commerce Road
Carlstadt, NJ 07072

485 Washington Avenue
Carlstadt, NJ 07072

Main: (201) 964-1441 Fax: (201) 964-1442 Email: eaglenutri@msn.com

CA
11/27/23

Certificate of Analysis

Product Name:	VITRUM PLUS	Code Number:	8339-F
Lot/ Batch Number:	2307022	Dosage Form:	Film Coated Tablet
Delivery Quantity:	983,751	Package By Date:	22-Feb-2024
Manufacturing Date:	22-Sep-2023	Finished Good Expiration Date:	SEP 2025

Test Items	Specification	Test Method	Result
Identification	TiO ₂ Free, White Film Coated Tablet with Bisect on one Side and "VITRUM" on the Other	Organoleptic	PASS
Average Weight	1484.00 mg/Tablet ± 5 % (between 1409.8 mg and 1558.2 mg)	Lab.023	1487 mg
Uniformity of Mass	18 of 20 Tablets between 1409.8 mg and 1558.2 mg Remaining 2 Tablets between 1335.6 mg and 1632.4 mg	Lab.023	1436 mg – 1522 mg ----
Hardness	NLT 10 Kp	Lab.013	25.8 Kp – 30.7 Kp
Disintegration	NMT 60 Minutes	Lab.012	45 Minutes

Ingredients	Strength/Potency	Result	Actual %	Limits	Date Tested
Vitamin A Acetate	1.72 mg	2.51 mg	145.9 %	90%-150%	10/05/23
Vitamin E Acetate	20.1 mg	22.8 mg	113.4 %	90%-150%	10/06/23
Vitamin C	60.0 mg	68.7 mg	114.5 %	90%-150%	10/17/23
Folic Acid	0.40 mg	0.45 mg	112.5 %	90%-150%	09/27/23
Vitamin B1 (Thiamine Nitrate)	1.50 mg	1.70 mg	113.3 %	90%-150%	09/27/23
Vitamin B2 (Riboflavin)	1.70 mg	2.30 mg	135.3 %	90%-150%	09/27/23
Vitamin B3 (Niacinamide)	20.0 mg	21.4 mg	107.0 %	90%-150%	09/27/23
Vitamin B6 (Pyridoxine HCL)	2.0 mg	2.2 mg	110.0 %	90%-150%	09/27/23
Cyanocobalamin (Vitamin B12)	0.0060 mg	0.0079 mg	131.7 %	90%-150%	10/03/23
Cholecalciferol (Vitamin D3)	0.010 mg	0.013 mg	130.0 %	90%-150%	10/05/23
D-Biotin	0.030 mg	0.043 mg	143.3 %	90%-150%	10/04/23

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Ingredients	Strength/Potency	Result	Actual %	Limits	Date Tested
Pantothenic Acid (Calcium Pantothenate)	10.0 mg	13.1 mg	131.0 %	90%-150%	09/28/23
Iodine	0.150 mg	0.176 mg	117.3 %	90%-160%	09/27/23
Calcium	162.0 mg	170.0 mg	104.9 %	90%-125%	10/09/23
Phosphorus	125.0 mg	127.0 mg	101.6 %	90%-125%	10/09/23
Iron	16.00 mg	17.60 mg	110.0 %	90%-125%	10/09/23
Manganese	2.50 mg	2.95 mg	118.0 %	90%-125%	10/09/23
Potassium	40.0 mg	43.0 mg	107.5 %	90%-125%	10/16/23
Chlorine	36.3 mg	33.6 mg	92.6 %	90%-125%	10/09/23
Copper	2.0 mg	2.3 mg	115.0 %	90%-125%	10/09/23
Zinc	15.0 mg	15.2 mg	101.3 %	90%-125%	10/09/23
Magnesium	100.0 mg	95.5 mg	95.5 %	90%-125%	10/09/23
Phylloquinone (Vitamin K1)	0.025 mg	0.031 mg	124.0 %	90%-160%	10/18/23
Selenium	0.025 mg	0.030 mg	120.0 %	90%-160%	10/09/23
Molybdenum	0.025 mg	0.024 mg	96.0 %	90%-160%	10/09/23
Chromium	0.025 mg	0.036 mg	144.0 %	90%-160%	10/09/23
Vanadium	0.010 mg	0.013 mg	130.0 %	90%-160%	10/09/23

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Heavy Metals Testing:				
Test Items	Specification	Result	Date Tested	Method Reference
Lead	NMT 5.0 mg/kg	<i>Not a routine test. Manufacturer guarantees the parameter results are within the declared limits</i>		
Arsenic	NMT 3.0 mg/kg			
Cadmium	NMT 1.0 mg/kg			
Mercury	NMT 1.0 mg/kg			

Microbiological Testing:				
Test Items	Specification	Result	Date Tested	Method Reference
Total amount of aerobic and anaerobic microorganisms	NMT 50,000 cfu/g	10 cfu/g	10/19/23	<2021> Microbial Enumeration Tests
Enterobacteriaceae (Coliforms) per 0.1 g	Not Allowed	Absent in 0.1 g	10/19/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
E. coli per 1.0 g of product	Not Allowed	Absent in 1.0 g	10/19/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
Pathogenic microorganisms, including salmonellae per 10.0 g	Not Allowed	Absent in 10.0 g	10/19/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
Total Plate Count (Yeast and Mold)	NMT 100 cfu/g	<10 cfu/g	10/23/23	<2021> Microbial Enumeration Tests

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Pesticides Testing:				
Test Items	Specification	Result	Date Tested	Method Reference
Heptachlor	Not Allowed	Not a routine test. Manufacturer guarantees the parameter results are within the declared limits		
Aldrin	Not Allowed			

DEVIATIONS	N/A
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PREPARED BY:

Cindy Saigon
Quality Control Technician

DATE:

11/10/23

CERTIFIED BY:

David Rodriguez
Quality Assurance Manager

DATE:

11/10/23

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