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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 14

CERTIFICATE OF PRODUCT CONFORMANCE

Product Name: Vitrum Century Plus	Date(s) Packaged: 18-DEC-2023, 19-DEC-2023
Product Material Number: 43864/9050-03UA	Units Packaged: 16,083
Product Batch Number: WN169	Product Specification: 9050-03UA, Rev 4
Bulk Lot: 2307019	Date of Manufacturing: 10-OCT-2023
PO Number: 4500089685	Date of Expiry: 10/2025
Package Size and Count: 30 Count Bottles	Bulk Material Release Authorization Provided by UNIPHARM on 15/12/2023

PHYSICAL CHECKS		
Item	Requirement	Result
Tablet Count	30 per unit	30 per unit
Product Description	White Film Coated Tablet with Bisect on One Side	Acceptable
Seal Integrity	Fully sealed, no burns, no odor	Acceptable
Torque	4-12 in. lbs.	5-10 in. lbs.
Batch Number Imprint	Correct and legible	Acceptable
Bottle Label Version	020922V1.2	020922V1.2
Bottle Label Date Imprint(s)	Correct and legible	Acceptable
Shrink Band Integrity	Container enclosed, smooth appearance	Acceptable
IFC Date Imprint(s)	Correct and legible	Acceptable
Insert Presence	Present	Acceptable
Insert Version	020922V1.2	020922V1.2
IFC Version	020922V1.2	020922V1.2
Shipper Closure	Carton fully sealed, no damage	Acceptable
Shipper Label Printing	Version 9050-03UA.002, Correct and legible	Acceptable

Comments: Saleable Units=16,077

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: 01/19/2024
Megha Patel

Verified By: Mohamed Sami, Quality Manager, Unipharm, Inc. Waterbury, CT Date: 01/19/2024
Mohamed Sami

Box 04 N 05 18 beg 180920 ef

EAGLE NUTRITIONALS

111 Commerce Road 485 Washington Avenue
Carlstadt, NJ 07072 Carlstadt, NJ 07072

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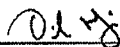
CA
12/15/23

Certificate of Conformance Product Release Authorization

Product Name:	VITRUM CENTURY PLUS	Code Number:	8338-F
Lot/ Batch Number:	2307019	Delivery Quantity:	486,221
Manufacture Date:	10-Oct-2023	Expiration Date:	OCT 2025

This is to certify that this product batch was manufactured and released in accordance with all applicable legal requirements of the final market including, but not limited to FDA 21 CFR 110, 111, 117, local legal requirements and the Product Specifications. I hereby certify that the given information is authentic and accurate.

CERTIFIED BY:



David Rodriguez
Quality Assurance Manager

DATE:

12/07/23

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12/15/23

Certificate of Analysis

Product Name:	VITRUM CENTURY PLUS	Code Number:	8338-F
Lot/ Batch Number:	2307019	Dosage Form:	Film Coated Tablet
Delivery Quantity:	486,221	Package By Date:	10-Mar-2024
Manufacturing Date:	10-Oct-2023	Finished Good Expiration Date:	OCT 2025

Test Items	Specification	Test Method	Result
Identification	TiO ₂ Free, White Film Coated Tablet with Bisect on One Side	Organoleptic	PASS
Average Weight	1490.00 mg/Tablet ± 5 % (between 1415.5 mg and 1564.5 mg)	Lab.023	1521 mg
Uniformity of Mass	18 of 20 Tablets between 1415.5 mg and 1564.5 mg Remaining 2 Tablets between 1341 mg and 1639 mg	Lab.023	1502 mg – 1546 mg -----
Hardness	NLT 10 Kp	Lab.013	31.3 Kp – 35.4 Kp
Disintegration	NMT 60 Minutes	Lab.012	33 Minutes

Ingredients	Strength/Potency	Result	Actual %	Limits	Date Tested
Vitamin A Acetate	1.888 mg	2.144 mg	113.6 %	90%-150%	10/13/23
Beta Carotene	0.112 mg	0.124 mg	110.7 %	90%-150%	11/06/23
Vitamin E Acetate	30.1 mg	32.8 mg	109.0 %	90%-130%	10/16/23
Vitamin C (Ascorbic Acid)	60.0 mg	70.1 mg	116.8 %	90%-150%	11/16/23
Folic Acid	0.20 mg	0.26 mg	130.0 %	90%-150%	11/14/23
Vitamin B1 (Thiamine Hydrochloride)	1.50 mg	1.66 mg	110.7 %	90%-150%	10/13/23
Vitamin B2 (Riboflavin)	1.70 mg	1.87 mg	110.0 %	90%-150%	10/13/23
Vitamin B3 (Niacinamide)	20.0 mg	21.8 mg	109.0 %	90%-150%	10/13/23
Vitamin B6 (Pyridoxine HCl)	3.0 mg	3.2 mg	106.7 %	90%-150%	10/13/23
Cyanocobalamin (Vitamin B12)	0.0060 mg	0.0076 mg	126.7 %	90%-150%	10/13/23
Cholecalciferol (Vitamin D3)	0.010 mg	0.013 mg	130.0 %	90%-150%	10/30/23
D-Biotin	0.030 mg	0.040 mg	133.3 %	90%-150%	10/13/23

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Ingredients	Strength/Potency	Result	Actual %	Limits	Date Tested
Pantothenic Acid (Calcium D-Pantothenate)	10.0 mg	13.1 mg	131.0 %	90%-150%	10/12/23
Iodine (Potassium Iodide)	0.150 mg	0.141 mg	94.0 %	90%-160%	10/18/23
Calcium (Calcium Carbonate & Ca (HPO ₄).2H ₂ O)	200.0 mg	212.0 mg	106.0 %	90%-125%	10/19/23
Phosphorus	48.0 mg	56.2 mg	117.1 %	90%-125%	10/19/23
Iron (Ferrous Fumarate)	9.0 mg	8.7 mg	96.7 %	90%-125%	10/19/23
Manganese (Manganese Sulfate Monohydrate)	2.50 mg	2.45 mg	98.0 %	90%-125%	10/19/23
Potassium	80.0 mg	75.0 mg	93.8 %	90%-125%	10/19/23
Chlorine	72.0 mg	76.7 mg	106.5 %	90%-125%	10/19/23
Copper (Copper Oxide)	2.00 mg	1.90 mg	95.0 %	90%-125%	10/19/23
Zinc (Zinc Oxide)	15.0 mg	14.3 mg	95.3 %	90%-125%	10/19/23
Magnesium (Magnesium Oxide)	100.0 mg	96.6 mg	96.6 %	90%-125%	10/19/23
Phylloquinone (Vitamin K1)	0.010 mg	0.012 mg	120.0 %	90%-160%	11/06/23
Selenium (Sodium Selenate)	0.020 mg	0.024 mg	120.0 %	90%-160%	10/19/23
Molybdenum (Sodium Molybdate)	0.0250 mg	0.0348 mg	139.2 %	90%-160%	10/19/23
Chromium (Chromium Chloride)	0.100 mg	0.132 mg	132.0 %	90%-160%	10/19/23
Vanadium (Sodium Metavanadate)	0.010 mg	0.016 mg	160.0 %	90%-160%	10/19/23
Boron (Sodium Borate)	0.150 mg	0.161 mg	107.3 %	90%-160%	10/19/23

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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	11/16/23	<2021> Microbial Enumeration Tests
Enterobacteriaceae (Coliforms) per 0.1 g	Not Allowed	Absent in 0.1 g	11/16/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
E. coli per 1.0 g of product	Not Allowed	Absent in 1.0 g	11/16/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
Pathogenic microorganisms, including salmonellae per 10.0 g	Not Allowed	Absent in 10.0 g	11/16/23	<2022> Microbiological Procedures for Absence of Specified Micro Organisms
Total Plate Count (Yeast and Mold)	NMT 100 cfu/g	5 cfu/g	11/20/23	<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: CS
Cindy Saigon
Quality Control Technician

CERTIFIED BY: DR
David Rodriguez
Quality Assurance Manager

DATE: 12/07/23

DATE: 12/07/23