



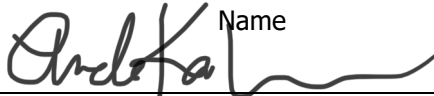
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**CERTIFICATE OF ANALYSIS**

<b>Product Name:</b> Proferrin® Forte 90 Count Bottles	<b>Lot Number:</b> N22080223
<b>Type:</b> Dietary Supplement	<b>Manufacturing Date:</b> August 2022
<b>Country of Origin:</b> United States	<b>Shelf Life Date:</b> February 2025

<u>Identity</u>	<u>Specification</u>	<u>Results</u>	<u>Method</u>
Tablet Appearance	Black core, red coated 0.346" X 0.747" oval shaped tablet, plain on both sides	Conforms	Visual
Identity	FT-IR spectra conforms to reference material directly or by library match	Pass	FT-IR
<u>Label Claim</u>	<u>Specification</u>	<u>Results</u>	<u>Method</u>
Assay – Iron	Average of 10 tablets is 100% to 125% of 12 mg label claim	Av. 12.8 mg/tablet, 107% label claim	Inductively Coupled Plasma Spectrometry
Quantity and Content Uniformity	10 of 10 tablets are 100% to 125% of label claim, RSD ≤ 6.0 ≤ 1 tablet of 30 outside 100% to 125% range, RSD ≤ 7.8	Pass	Inductively Coupled Plasma Spectrometry
Assay – Iron	100% to 160% of 1000 mg label claim	1122 mg/tablet, 112% label claim	Inductively Coupled Plasma Spectrometry
<u>Physical Properties</u>	<u>Specification</u>	<u>Results</u>	<u>Method</u>
Friability – Uncoated Tablets	1.0% maximum with no caps or breaks	0.1%	SOP 350-75-00003
Tablet Breaking Force (Hardness) Uncoated Tablets	15-22 kp	20.80 kp	SOP 350-75-00009
Average Tablet Weight	As Reported	1063 mg	SOP 350-75-00003
Tablet Weight Variation	≤ 2 tablets of 20 may differ from the avg. weight by ± 5% 0 tablets of 20 may differ from avg. weight by ± 10%	Pass	USP<2091>
Disintegration – Uncoated Tablets	Not more than 30 minutes	Pass	USP<2040>
<u>Chemical Analysis</u>	<u>Specification</u>	<u>Results</u>	<u>Method</u>
Arsenic (As)	< 10.0 µg/day (<3.04 ppm)	<0.010 ppm	ICP/MS
Cadmium (Cd)	< 4.1 µg/day (<1.25 ppm)	<0.005 ppm	ICP/MS
Lead (Pb)	< 0.5 µg/day (<0.15 ppm)	0.0680 ppm	ICP/MS
Total Mercury (Hg)	< 0.3 µg/day (<0.09 ppm)	<0.005 ppm	ICP/MS
<u>Microbiology</u>	<u>Specification</u>	<u>Results</u>	<u>Method</u>
Total Aerobic Plate Count	NMT 1,000 CFU/g	< 1,000 CFU/g	030-85-00042
Yeast and Mold	NMT 100 CFU/g	< 100 CFU/g	030-85-00042
<i>E. Coli</i>	Absent	Absent	030-85-00042
<i>Salmonella Typhimurium</i>	Absent	Absent	030-85-00042
<i>Staphylococcus aureus</i>	Absent	Absent	030-85-00042
<i>Listeria</i>	Negative (org/25 g)	Negative (org/25 g)	RapidChek/AOAC RI 020401
<i>Streptococcus</i>	Not Detected (CFU/g)	Not Detected (ND) CFU/g	MEF Chapter 10
<i>Enterobacteriaceae</i>	Not Detected (CFU/g)	Not Detected (ND) CFU/g	030-85-00042
<i>Bacillus</i>	Not Detected (CFU/g)	Not Detected (ND) CFU/g	MEF Chapter 14

**Amanda Kashenberg**

Name  
  
 Authorized Signature

**Director of Scientific & Regulatory Affairs**

Title  
 26-Sep-22  
 Date