

**Product:** apo-Transferrin Human Powder

**Catalog #: 800-130P**

**Lot #: H17Y13K**

**Origin: United States (100%)**

**Manufacture Date: May 2019**

**Expiration Date: May 2024**

TEST	METHODOLOGY	SPECIFICATION	RESULTS
<b>Biological Testing</b>			
Bioburden		<10 cfu/mL	Pass
Endotoxin	LAL	≤1 EU/mg	< 0.05 EU/mg
<b>Microbiological Testing</b>			
Mycoplasma		Not Detected	Not Detected
<b>Viral Testing</b>			
HBsAg		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
ALT		Pass	Pass
Syphilis		Negative	Negative
HBV-NAT		Non-Reactive	Non-Reactive
HIV-NAT		Non-Reactive	Non-Reactive
HAV-NAT		Non-Reactive	Non-Reactive
HCV-NAT		Non-Reactive	Non-Reactive
Parvo B19-NAT		Non-Reactive	Non-Reactive
<b>Physical Testing</b>			
Appearance		Report	White Crystalline Powder
pH @ RT, 3% Solution		6.5-8.0	7.13
Moisture		≤5.0%	0.85%
Solubility	Readily Soluble at 1% in De-ionized water		Pass
Optical density		Report	11.26
<b>Biochemical Testing</b>			
Purity	Cellulose Acetate Electrophoresis	≥98% of total protein	Pass
Protein Analysis		>98%	103.2%
SDS-Polyacrylamide Gel		Conforms	Pass
Iron Estimated ICP		< 50ppm	9 ppm



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*Results shown were obtained by carefully performed methods believed to be reliable. However, since some results may vary for specific tests depending upon methodology and other variables, it is suggested that tests for which results are particularly important be repeated by the user of this product.*

*All human blood products are collected from stringently screened donors at FDA-licensed collection centers in the United States. All donors are tested and found to be negative for Indirect Antiglobulin*

*Single homogenous batch, heat treated at 62±2°C for 10 hours and lyophilized from approximately 0.02M NH4HCO3. May contain traces of buffre salts. Dispensed by fry weight.*

*Store at 2-8 °C. Allow temperature to equilibrate to room temperature prior to use.*

*[Signature]* 25sep2019

Created By/ Date

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Verified By/Date