



Monobind Inc.

The World Resource for Diagnostic Products

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Certificate of Analysis

Product: Human Serum Albumin Lyophilized Low Folate and Low Vitamin B₁₂ –
Reagent Grade
Item number: HA0DLB
Lot number: 089RM-01G09
Batch Size: 150Kg
Pack in: As request
Date of Manufacture: July 16, 2009
Date of Expiration: July 2019 at -20°C
Storage Condition: -20°C
Fractionation Method: Cohn-Oncley Cold Alcohol Procedure
Countries of Plasma Origin: US FDA Licensed Facilities

CAUTION: This material not for use in product subject to license under section 351 of the US Public Health Safety Acts.

Test	Result	Methodology
Appearance	Cream powder	Visual
Optical density	0.031 Od	@540 nm
pH	7.0	pH meter
Solubility	13 minutes	Manual stirring
Total protein	4.8 g/dL	Biuret
Purity	98%	Protein electrophoresis
Folate	<0.34 ng/mL	Centaur
Vitamin B ₁₂	73 pg/mL	Centaur
Calcium	<5 mg/dL	Arsenazo III
Chloride	12.6 mEq/L	ISE
Potassium	0.09 mEq/L	ISE
Sodium	24.7 mEq/L	ISE
Ash	2.5%	550°C, 3 hours incineration
Microbial	0 cfu/mL	Pour plate, 30-35°C, 48 hours
Moisture	1.8%	Karl Fisher

- Each plasma unit used in the preparation of human albumin was tested and found negative for the following by FDA licensed reagents.
- Each donation is tested and found negative or non-reactive to the following.
 - HIV I & II Antibodies.
 - HCV Antibodies.
 - HBsAg
 - Syphilis
 - HIV and HCV by NAT
- Results base on 5% solution.

Authorized by: Ashatola 07-16-2009
Quality Control Department



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ISO 13485 & 9001 Certified Company