

## Certificate of Analysis

**Product:** Human Serum Albumin Lyophilized High Purity – Reagent Grade  
**Item number:** HA0DH  
**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-Onclcy 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	0.032 Od	@540 nm
pH	6.9	pH meter
Solubility	12 minutes	Manual stirring
Total protein	4.9 g/dL	Biuret
Purity	99.4%	Protein electrophoresis
Calcium	<5 mg/dL	Arsenazo III
Chloride	5.7 mEq/L	ISE
Potassium	0.09 mEq/L	ISE
Sodium	9.6 mEq/L	ISE
Ash	0.9%	550°C, 3 hours incineration
Microbial	0 cfu/mL	Pour plate, 30-35°C, 48 hours
Moisture	0.96%	Karl Fisher

1. Each plasma unit used in the preparation of human albumin was tested and found negative for the following by FDA licensed reagents.
2. 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
3. Results base on 5% solution.

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

