

Title:	TECHNICAL DATASHEET		
Review Date:	10-JAN-2025	Signature:	All
Date of Issue:	10-JAN-2023	Approved by:	Dr. Iman Kamranfar
Document ID:	TDS-HSA-001-1KG	Version:	001

Human Serum Albumin

Treatment	Lyophilized coarse powder
Product Code	HSA-001-1KG
Origins	USA
Pack Size	1 kg*
Shelf Life	5 Years from DOM
Storage Temperature	2 – 8 °C
Shipping Temperature	ambient

QC Specifications

Physical and Chemical Analysis	Specifications	Units
Appearance	Powder	n/a
Protein Composition (Albumin Purity)	> 92.0	% (w/w)
Potassium	Test & Report	mEq/L
Sodium	Test & Report	mEq/L
рH	Test & Report	n/a
Endotoxin	Test & Report	EU/mg
Moisture	Test & Report	% (w/w)

^{*}Other pack sizes are available on request.

Individual donor units used in the preparation of this product are tested and must be found negative by tests for antibodies to HIV 1/2, HCV and non-reactive for HBsAg. Pooled samples must be found non-reactive for HIV-1 RNA, HBV DNA and HCV RNA by Nucleic Acid Test. All testing performed with kits approved by the FDA. Each donor is tested and must be found negative for syphilis according to FDA guidelines.

All donor units are collected at FDA approved donor centres located in the United States.

The pool of source plasma for fractionation from which the product comes from, is tested and must be found non-reactive for virological markers HBsAg, anti HIV-1/ HIV-2 and anti HCV using validated serological tests, and for HCV RNA, HIV-1 RNA and HBV DNA using validated techniques.

ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS.

Product Use: NOT FOR USE IN HUMANS OR CLINICAL DIAGNOSIS. THESE PRODUCTS ARE INTENDED FOR RESEARCH OR DIAGNOSTIC MANUFACTURING USE ONLY.