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	Title:	**TECHNICAL DATASHEET**		

Human Serum Albumin Solution 10% in DPBS, Suitable for Cell Culture

Treatment	Sterile-filtered, Suitable for cell culture, Serum-free, Xenobiotic-free, does not contain stabilizer or preservative
Product Code	HSA-001-100ML
Raw Material Origin	USA
Manufactured in	Germany
Pack Size	100 mL
Shelf Life	3 Years from DOM
Storage Temperature	≤ -15°C, away from direct light
Shipping Temperature	Dry Ice

Key Features and Benefits

- Sterile, ready-to-use solution
- Consistent lot-to-lot performance
- Low endotoxin and bioburden levels
- Free from additives and preservatives
- Supports serum-free culture systems
- Manufactured under traceable, quality-controlled processes

General Information

Human Serum Albumin (HSA) 10% Solution – Cell Culture Grade is a sterile, high-purity protein solution derived from human plasma collected from approved and fully screened donors. The product is formulated at 10% (w/v) albumin in a physiologically buffered aqueous solution and sterile-filtered through a pharmaceutical-grade single-use filtration line to ensure freedom from microbial contamination.

This HSA is specifically prepared for in vitro and bioprocessing applications, providing a consistent, safe, and reliable source of human albumin for research and manufacturing processes. It is free from additives, preservatives, and stabilizers that could interfere with cell growth, making it ideal for serum-free and chemically defined media systems.

Human serum albumin acts as a carrier and stabilizer protein, protecting labile molecules and cells from mechanical stress, oxidation, and adsorption losses.

Applications

- **Cell culture supplementation:**
  Provides protein and osmotic balance in serum-free and chemically defined media for mammalian and stem cell culture.

- **Cryopreservation and cell storage:**
  Enhances cell viability and recovery during freezing, thawing, and transport by reducing shear and osmotic stress.

- **Bioprocessing and upstream manufacturing:**
  Used as a stabilizer or carrier protein in recombinant protein and viral vector production systems.

- **Reagent and enzyme stabilization:**
  Prevents denaturation and surface adsorption in diagnostic and analytical reagent formulations.

- **Drug and nanoparticle formulation research:**
  Serves as a model protein or excipient for binding, transport, and stabilization studies.

QC Specifications

Physical and Chemical Analysis	Specifications	Units
Appearance	Off-White to yellowish clear solution	n/a
Used HSA Protein: Purity	≥96.0	% (w/w)
Used HSA Protein: Moisture	≤ 5.0	% (w/w)
Used HSA Protein: Bioburden	< 100	CFU/mL
Used HSA Protein: Chloride	Test and Report	mEq/L
Used HSA Protein: Sodium	Test and Report	mEq/L
Used HSA Protein: Solubility (10% at Room Temperature)	Clear Pale Yellow Solution	n/a
pH	6.5 – 7.5	n/a
Osmolality	Test and report	mOsm/kg
Endotoxin	< 1.0 EU/mL	< 1.0 EU/mL

Sterility			
Aerobic Bacteria	Internally Validated	Not detected	n/a
Anaerobic Bacteria	Internally Validated	Not detected	n/a
Fungi (Yeast & Mold)	Internally Validated	Not detected	n/a
Mycoplasma	qPCR	Not detected	n/a

Virology

Donor units used in the manufacture of this product were collected at FDA licensed facilities. Each donor unit was tested by an FDA approved method for the presence of antibody to HIV 1/2, antibody to HCV, HIV-Ag and/or HIV NAT, as well as for HBsAg and found to be negative.

The pool of source plasma for fractionation from which the product comes from has been tested and 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.

Caution: ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS. Not for use in humans or clinical diagnosis. These products are intended for research or manufacturing only. Test methods and techniques may produce variable results and are for informational use only; therefore, the user should evaluate material for suitability in a given system.

Intended Use: FOR CELL CULTURE, RESEARCH, AND FURTHER MANUFACTURING USE ONLY.
NOT FOR HUMAN OR ANIMAL THERAPEUTICS AND INJECTIONS.