PRODUCT PAGE

Human Serum Albumin (HSA) 25% Solution

Vials (100 mL) Cat. # AK8228-0100 | Bags (100 mL) Cat. # AR1037-0100

Product Description:

Akron's Human Serum Albumin (HSA) 25% Solution is manufactured, tested, and released following relevant cGMP guidelines for blood-derived ancillary materials and supported by a Type II Master File (MF) on file with the FDA which can be referenced during your drug or biologic application process. Akron's HSA 25% Solution is specifically formulated for cell and gene therapy commercial manufacturing.

Akron's HSA 25% Solution uses raw material sourced from US donors, collected in FDA-licensed facilities adhering to all donor screening and virus testing legislation set forth in US 21 CFR 610. Redundant pathogen testing occurs during the manufacturing process to ensure safety. Sterile filtration and aseptic filling are performed in-house with Endotoxin and Sterility testing performed per USP/EP and Mycoplasma testing performed per EP on the final product. Akron's HSA 25% Solution does not contain stabilizers typically found in other pharmaceutical albumin solutions because these substances (caprylate & acetyltryptophanate) have been shown to interfere with relevant cell culture. Their exclusion allows for an HSA supplement that promotes optimal cell culture performance for the human cell therapy industry.

Albumin is the most abundant protein in blood plasma and has historically been used in cell culture for its ability to support mammalian cell growth. Albumin is known to carry many important substances including lipids, amino acids, hormones, peptides, metals, and other undefined low molecular weight molecules. It also offers antioxidant protection to cells and participates in the transport and signal mechanics of hormones and growth factors. Akron's cGMP-compliant HSA 25% Solution can be used in a wide range of applications such as cell culture supplementation, assay standardization, protein stabilization, and product formulation.

Advantages:

Raw Material

- Human Plasma from US-licensed plasma donation centers
- Donor screening and virus testing per 21 CFR 610.40
- cGMP Raw Material – Cohn Fraction V

Manufacturing

- Type II eCTD DMF (#019354) on file with FDA
- Formulated with WFI (water for injection)
- Does not contain stabilizers Caprylate or N-Acetyl-L-Tryptophanate
- No animal-derived materials are used in the manufacture of this product
- Sterile microfiltration followed by aseptic filling

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Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO 13485:2016, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products
- High Purity, Low Endotoxin - Endotoxin, and Sterility testing per USP/EP; Mycoplasma testing per EP

Release Testing:

- Appearance
- pH
- Osmolality
- Concentration
- Purity
- Mycoplasma
- Bacterial Endotoxins
- Sterility

Stability:

- 24-month stability (vials)
- Store at 2-8 °C
- Transport with cold packs

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

Related Products:

Catalog Number	Product Name	Size
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)	100 mL
AR1010-0100	Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated	100 mL
AK9930-0001	Human Fibronectin Solution, Virus Inactivated	1 mg
AR1011-0100	Human Serum Albumin (HSA) 25% Solution Research	100 mL

For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.