PRODUCT PAGE

# Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)™



## Product Description:

Akron's Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)™ is manufactured, tested, and released following relevant cGMP guidelines for blood-derived ancillary materials. The HSA substance is 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% CSS is specifically formulated for sterile closed-system cell and gene therapy commercial manufacturing.

HSA 25% CSS 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. Akron's HSA 25% CSS 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. Akron's cGMP-compliant HSA 25% CSS can be used in a wide range of applications such as cell culture supplementation, assay standardization, protein stabilization, and product formulation.

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.

The HSA 25% CSS product is packaged in a sterile single-use bag with weldable tubing, allowing for easy incorporation into modern closed-system cell culture bioprocessing protocols. HSA 25% CSS increases safety and ease of use by allowing for the introduction of supplement material into culture media in a fully contained manner. The final product undergoes Endotoxin, Mycoplasma, and Sterility testing.

## Advantages:

### Raw Material

- US donor raw material sourced from FDA-licensed donation centers
- Donor screening and virus testing per 21 CFR 610.40
- cGMP Raw Material Intermediate – Cohn Fraction V

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## Manufacturing

- 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

## Packaging

- Sterile bag chamber – Ethylene-vinyl acetate (EVA) for inert biocompatibility and increased flexibility
- Weldable polyvinyl chloride (PVC) 6" outlet tubing (2.5 mm ID x 4.1 mm OD) with female Luer adapter
- End of inlet tubing sealed using controlled radiofrequency or heat
- Two twist-off spike ports allowing for various attachments and adapters to fit your purpose
- Tubes and ports are welded into the bag chamber eliminating potential failure points
- All primary packaging is plasticizer free
- Primary packaging materials extensively validated, controlled, and qualified to ensure a consistent experience
- Shipped in validated CSafe Parcel insulated shipper for consistent delivery

## 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

## Release Testing:

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

## Stability:

- Under long-term stability
- Store at 2-8 °C
- Transport with cold packs

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## 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 |
|---|---|---|
| AR1048-0100 | Human AB Serum CSS, Converted from Octaplas® | 100 mL |
| AR1045-0010 | Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions (CSS)™ | 1 MIU |
| AK9930-0001 | Human Fibronectin Solution, Virus Inactivated | 1 mg |
| AK8228-0100 | Human Serum Albumin 25% Solution | 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 |

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