Excipient Albumin

CSL Behring Human Serum Albumin

For more information, contact CSL Behring
USA: (610) 878-4000 | 1020 First Avenue | King of Prussia, PA 19406-0901
Switzerland: +41 31 344 44 44 | Wandorfstrasse 10 | CH-3000 Bern 22

excipients@cslbehring.com | www.HSAExcipient.com
Why use excipient human serum albumin (HSA)?

CSL Behring excipient grade HSA batches are manufactured specifically to be used for the pharmaceutical, biopharmaceutical, and medical device markets.
- 100% human origin - contains no genetically modified proteins

With a multitude of pharmaceutical and biotechnology uses, HSA can¹:
- Stabilize product potency during manufacturing, shipping, and storage
- Provide you with an excipient that occurs naturally in the body and is well tolerated
- Act as a carrier molecule/scaffold in drug delivery to transport therapeutic peptides and proteins
- Serve as a coating on medical devices
- Be used as a component in nanoparticle albumin-bound formulations
- Be used as a medium component for:
  - Cell culture
  - Cryopreservation
  - Stem cell expansion

Albumin – the body’s main defense regulation protein:
- The major oncotic protein
- Essential transport medium for substances such as hormones, metabolites and drugs
- Anti-oxidant properties

---

Why choose CSL Behring?

We take responsibility for our HSA from plasma collection to product release

At CSL Behring, we’re dedicated to meeting or exceeding the most stringent international standards for plasma-product safety in accordance with guidelines from worldwide regulatory agencies. Our dedication to collecting safe plasma and producing the highest quality products via CSL’s Integrated Safety System is well known in the industry and includes:

- CSL Behring-owned collection centers
- Strict donor selection and donor screening
- Extensive plasma testing and inventory hold before release for manufacturing
  - 5-NAT/PCR testing
- CSL Behring-owned fractionation manufacturing facilities
- Proven virus inactivation and removal in the HSA manufacturing process
- Pharmacovigilance

Safety and Quality

- Single donations, mini pools and final product are tested for the detection of human pathogenic viruses.
- Mandatory serologic and laboratory screens are carried out on donated plasma including tests for HIV-1, HIV-2, hepatitis B and C and parvovirus B19, in addition, liver function tests are performed.
- During more than a 50 year history* of marketing CSL Behring Albumin, there is no case of transmission of viral disease or CJD.

* 50 years include the total experience of Albumin production in Bern, Switzerland.

3. CSL Behring pharmacovigilance, data on file.
We’re dedicated to providing a consistent and reliable supply of HSA

- CSL commitments to delivering the volume of HSA that you need for your project
- Specific resources that are experts in the utilization of excipient HSA
- All of our plasma, for excipient purposes, is drawn in select FDA- and GHA-approved centers
- CSL’s manufacturing process enhances batch-to-batch consistency

Overview of HSA Manufacturing
CSL Behring’s HSA excipient product, regulatory and quality practices are second to none

Clearing regulatory hurdles can be a great challenge both in terms of time and financial investment. To save you time and money, CSL Behring’s experts can provide assistance to facilitate registration of pharmaceutical or biological products and medical devices that contain HSA:

- 25% HSA specification designated for global RA Bodies acceptation
- Dedicated and highly experienced regulatory and quality teams support excipient HSA customers through all stages of clinical development and product registration worldwide
- Our HSA is registered in numerous countries around the world; letters of access can be provided to health authorities on behalf of our customers
- Additional up-to-date technical documentation can be provided to local health authorities to meet regulatory requirements
- Batches are manufactured at CSL’s state-of-the-art fractionation facilities in Bern, Switzerland, and meets USP, EU and JP specifications
- Each plasma pool and final product batch is sent to an Official Medicines Control Laboratory (OMCL) for testing and release; OMCL certification can be provided for each batch that is delivered
- Vendor questionnaires can be completed and site audits may be scheduled, as per contractual agreement
- Additional documentation can be provided as needed
- Exclusively manufactured from 5 Virus Marker tested U.S. Source Plasma, drawn in select FDA-and EU-approved centers belonging to CSL Behring
- Triple testing/comprehensive batch documentation: USP/EU/JP CoA’s, Swissmedic batch release certificate (OCABR), Summary Production and Control Protocols, Testing Declaration, etc.
- Letter of Authorization (LOA) to existing HSA licenses or alternatively submission of abbreviated excipient HSA dossier
- PMF full access for EU markets and reference to Swiss/EU PMF approval for Emerging Markets
CSL Behring performs tri-testing to meet the needs of a globalizing marketplace

CSL Behring performs tri-testing for excipient HSA lots in order to confirm their compliance with the regulations of US, European Union, and Japanese markets. Tri-testing includes all tests that are required by the FDA, EMEA, and PMDA. Because tri-testing helps meet the specific pharmacopeia requirements of the governing bodies, manufacturers will benefit from streamlined product sales in these areas.

For excipient HSA, **Certificates of Analysis** for each of these 3 regions can be provided, each one stating the performed tests with their requirements and results.

**CSL Behring Albumin Licenses Worldwide**
At CSL Behring, we partner with you to ensure your ongoing success.

But don’t just take our word for it—see what some of our customers have said:

“CSL Behring is a superb collaborative partner…”

“The difference in customer service is phenomenal…”

“CSL Behring Customer Support is easy to work with and fully available…”

On a scale of 1 to 10, the customer service provided by CSL Behring was “a 25.”

For more information about our excipient albumin, please contact CSL Behring at excipients@CSLBehring.com