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RECOMBINANT HUMAN SERUM ALBUMIN GMP grade

Multifunctional Recombinant Excipient for Advanced Biopharmaceutical Manufacturing



- **Manufactured in GMP-Certified Facilities**
- **Low Aggregate Content**
- **Animal-Origin-Free Recombinant Production**
- **Consistent Batch-to-Batch Performance**
- **Designed for Sensitive Biopharmaceutical Formulations**

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A Defined Recombinant Alternative to Plasma-Derived Albumin

Advanced therapy manufacturing requires raw materials that combine **consistency, scalability and long-term supply security.** Recombinant human serum albumin provides a defined, animal-origin-free alternative to plasma-derived albumin.

Plasma-derived Albumin	Canvax rHSA
Blood-derived source	Recombinant production
Donor-dependent supply	Controlled manufacturing
Variable biological material	Defined composition
Supply constrained by plasma availability	Scalable production
Batch variability	Consistent batch-to-batch performance
Animal-derived sourcing concerns	Animal-origin-free

Canvax rHSA Highlights

- Recombinant human serum albumin produced in *Pichia pastoris*
- Manufactured in GMP-certified facilities
- Available for bulk supply and GMP programs
- Animal-origin-free with supporting quality documentation
- Flexible formats and supply strategies aligned with customer workflows

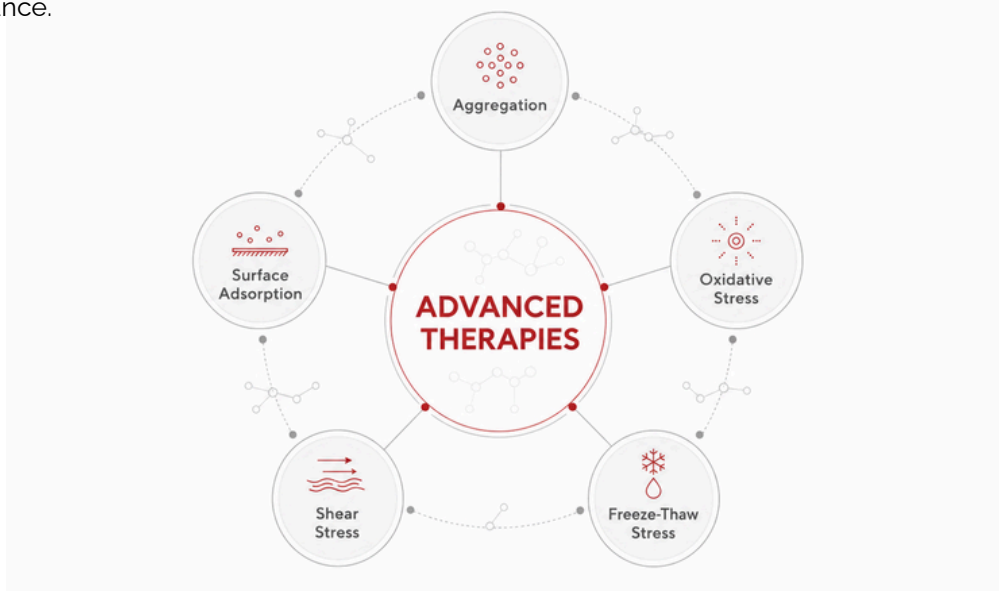
Designed to support advanced therapy programs from development through GMP manufacturing.

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Advanced therapies are inherently fragile

Cell therapies, viral vectors, vaccines and recombinant biologics are exposed to multiple sources of stress throughout development, manufacturing, storage and administration.

These challenges can compromise product quality, reduce recovery yields and impact therapeutic performance.



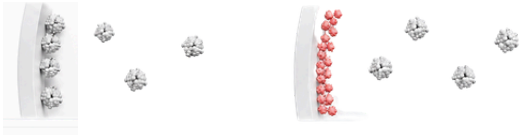
Recombinant HSA is widely used as a stabilizing excipient in sensitive biopharmaceutical workflows.

How rHSA Supports Sensitive Biologics

Recombinant human serum albumin is widely used as a functional excipient in sensitive biopharmaceutical formulations, where it can contribute to product stability throughout manufacturing, storage and handling.

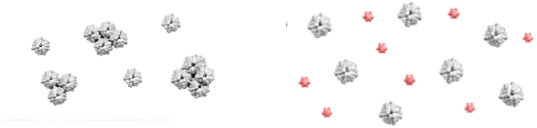
Reduces Surface Adsorption

Sensitive biologics can be lost through interaction with tubing, filters, vessels, bags and container surfaces.
rHSA can help minimize non-specific adsorption by providing a protective protein environment within the formulation.



Controls Aggregation

Protein and particle aggregation can negatively impact stability, activity and product quality.
Albumin can contribute to formulation stability by limiting unwanted intermolecular and surface interactions.



Provides Oxidative Protection

Sensitive biologics may be exposed to oxidative conditions that can affect structural integrity and functionality.
Albumin can contribute to a protective formulation environment against oxidative stress during processing and storage.



Sensitive Biologic Canvas rHSA Oxidative species

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Applications in Advanced Biopharmaceutical Manufacturing

Whether used in cell therapy, viral vectors, vaccines or protein therapeutics, Canvax rHSA can be supplied in formats aligned with customer-specific development and manufacturing workflows.

Cell Therapy

- Cell washing buffers
- Cryopreservation media
- Cell processing workflows

One excipient.
Multiple applications.



Viral Vectors

- Viral vector stabilization
- Downstream processing
- Filtration and storage

Vaccines

- Vaccine stabilization
- Cold-chain robustness
- Formulation support during storage

Flexible formats and supply options aligned with your workflow.

Protein & Ab Therapeutics

- Aggregation management
- Surface protection
- Formulation stability

Your workflow. Your requirements. Your rHSA solution.

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Why Canvax rHSA

Canvax supports **customer qualification, supplier approval and audit processes** through GMP-certified manufacturing facilities, established quality systems and comprehensive technical documentation.

GMP Manufacturing Facilities



GMP-certified facilities designed for the manufacture of biopharmaceutical products, operating under ISO 9001 and ISO 13485 quality systems.

Analytical Characterization



Analytical characterization including identity, purity, aggregate profile and endotoxin assessment, supporting robust quality control and batch-to-batch consistency.

Bulk Supply and Scalability



Manufacturing capacity to support bulk supply requirements, from development-scale batches to larger volumes aligned with program needs.

Supply Chain Reliability



Integrated manufacturing and quality systems designed to support consistent supply, change control and long-term program continuity.

Fill & Finish and Packaging



Fill and finish capabilities for client-specific formats, supporting controlled dispensing, packaging and labeling under qualified conditions.

Customer Audits & Quality Systems



Experience supporting customer audits, supplier qualification activities and quality documentation requests for regulated manufacturing environments.

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Quality and Analytical Characterization

Designed to support robust formulation and manufacturing workflows

The analytical framework for Canvax recombinant human serum albumin is designed to assess critical quality attributes including identity, purity, concentration, aggregate profile and product integrity, supporting consistent quality and GMP manufacturing requirements.

Need more info? Request Quality Documents

Interested in evaluating the product? Request an R&D sample

Parameter	Typical Specification
Protein Content	190–210 mg/mL
Purity	≥ 99%
HMW Aggregates	≤1.0%
Fragments	≤1.0%
Host Cell Proteins	≤1 µg/g protein
Endotoxin	≤0.5 EU/mL
Sterility	Meets USP <71>
Appearance	Clear, straw-to-amber, free from visible particles
Caprylate	14.4–17.6 mM

Additional characterization may include peptide mapping, molecular mass analysis, residual host-cell DNA, mycoplasma, sodium, potassium, osmolality, process-related impurities and other product-specific quality attributes according to customer requirements and intended use.