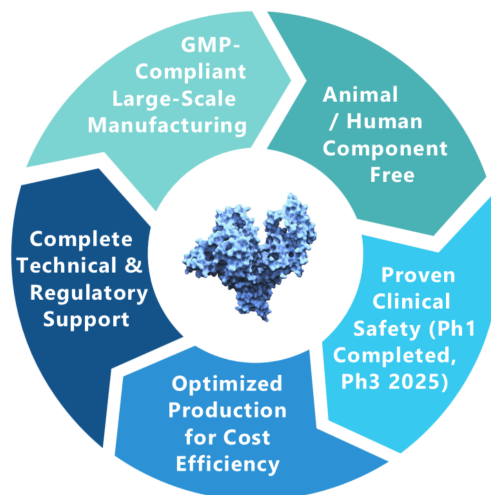


## Elevate your Innovations with



### The new Standard of Excellence

Manufactured using recombinant technology in state-of-the-art, cGMP-compliant facilities, sRbumin<sup>®</sup> is a high-purity recombinant human albumin engineered to address the need for high-quality excipients and ancillary materials.



- Advanced Therapies**  
(Cell & Gene Therapy and Tissue Engineering Products)
- Drug Formulation, Drug Delivery**  
(Biologics and Small Molecules)
- Medical Technologies**  
(Implantable Medical Devices, Medical Equipment, IVD)
- Vaccines**  
(Manufacturing and Formulation)
- In Vitro Fertilization, Cryopreservation**  
(Protection of Cells)

### For various Technical Applications and Therapeutic Modalities

sRbumin<sup>®</sup> has been meticulously designed to support a diverse array of applications and technical uses, ensuring your innovations reach their full potential.

This makes sRbumin<sup>®</sup> ideal for research & development, drug formulation and delivery, the manufacturing and formulation of advanced therapies and vaccines, the coating of medical devices, and more.

### Product Attributes

<b>Purity</b>	≥ 99%	<b>Presentation</b>	Liquid 20% (w/v) (20, 50, 100 mL) or lyophilized; bulk quantities available
<b>Animal / human component free</b>	Yes	<b>Expression system</b>	<i>Pichia pastoris</i> ( <i>Komagatella phaffii</i> )
<b>cGMP</b>	Yes	<b>Regulatory documentation</b>	Access to DMF filed with U.S. FDA available
<b>Shelf-life</b>	36 months		

### Comprehensive Customer Support

**1) Comprehensive technical support**

Troubleshooting along with expert consultations on e.g., application-specific optimizations, design of experiment, scale-up strategies

**3) Custom filling and packaging**

From small volumes to bulk filling sizes to meet your requirements at every stage of development

**5) Complimentary conjugation development services\***

Complimentary custom conjugation development\* and optimization of conjugation chemistry and conditions\* (\*conditions apply)

**2) Comprehensive quality and regulatory documentation support**

Access to comprehensive quality and regulatory documentation, including drug master file (DMF) support, regulatory approvals and GMP compliance certifications

**4) Albumin fusion protein development**

Support for the development and manufacturing of rHSA fusion proteins

**6) Complimentary custom formulation development services\***

Complimentary formulation development or optimization services\* and access to our team of formulation scientists for consultation\* (\*conditions apply)

## Frequently Asked Questions & Answers

### Product & Purchasing

1. *How can I purchase sRbumin<sup>®</sup>?*

You may purchase sRbumin<sup>®</sup> directly from Shilpa Biologicals. Please contact our sales team at [www.srbumin.com](http://www.srbumin.com) for pricing, availability, and sample requests.

2. *What packaging sizes and presentations are available?*

sRbumin<sup>®</sup> is offered as a 20% (w/v) solution in volumes of 20 mL, 50 mL, and 100 mL, as well as bulk quantities. Lyophilized sRbumin<sup>®</sup> and custom packaging are available upon request.

3. *What is the shelf life of sRbumin<sup>®</sup>?*

Our sRbumin<sup>®</sup> liquid presentation has a long shelf life of 36 months (from the date of manufacturing) when stored at 2–8°C (protect from light; do not freeze).

### Manufacturing

1. *How is sRbumin<sup>®</sup> produced and is it free of animal and human components?*

sRbumin<sup>®</sup> is a recombinant human albumin (rHA) that is produced using a yeast-based expression system ensuring high batch-to-batch consistency and remarkable purity. sRbumin<sup>®</sup> is 100% free from animal and human components.

2. *How does sRbumin<sup>®</sup> compare to plasma-derived albumin?*

sRbumin<sup>®</sup> is free from the risk of blood-borne pathogens while delivering outstanding purity and unparalleled batch-to-batch consistency, compared with plasma-derived albumin. Our recombinant manufacturing process and large manufacturing capacity (in the range of metric tons) enables us to offer a dependable supply to our customers from R&D and clinical scale to commercial production.

### Regulatory, Quality & Clinical Safety

1. *What quality standards does sRbumin<sup>®</sup> meet?*

sRbumin<sup>®</sup> is manufactured in accordance with GMP requirements and undergoes stringent quality control for purity, sterility, and consistency.

2. *What type of regulatory and quality documentation can you provide?*

Shilpa Biologicals can provide access to a Type II Drug Master File (DMF) filed with the U.S. FDA, along with quality documentation, including a certificate of analysis (CoA) and a certificate of origin (CoO). A quality agreement can be readily implemented upon request.

3. *Has sRbumin<sup>®</sup> demonstrated clinical safety?*

sRbumin<sup>®</sup> has successfully demonstrated clinical safety in a Phase 1 clinical trial for direct therapeutic use. sRbumin<sup>®</sup> can be readily used as an excipient or ancillary material for various technical applications and therapeutic modalities from R&D to commercial products.



sRbumin<sup>®</sup> human recombinant albumin is a product by Shilpa Biologicals, manufactured at our sites in India and sold worldwide.

For more information and to contact us please visit:

**[www.srbumin.com](http://www.srbumin.com)**

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