# Exbumin® Recombinant HSA Reconstitution

*Marcus Curl, Vice President of Product Applications*
*InVitria, Inc., USA*

## APPLICATION BENEFITS

- ***Recombinant, blood-free, and animal-origin-free HSA***
- ***Used as an excipient in approved injectable therapeutics***
- ***Enhances viral stability for vaccines and gene therapies***
- ***Stabilizes cells and tissues in cell therapy and regenerative medicine***
- ***Supports tissue viability during cryopreservation and storage***
- ***Manufactured animal-free at the tertiary level per GMP***

## INVITRIA SOLUTIONS

Exbumin - Recombinant Human Serum Albumin

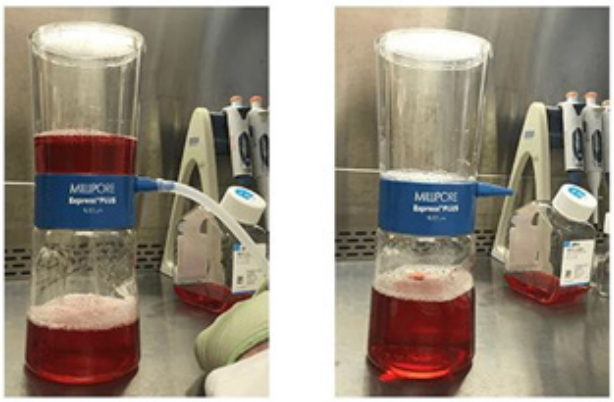



## EXECUTIVE SUMMARY

Exbumin is InVitria's recombinant, animal-origin-free human serum albumin manufactured under GMP in an ISO 9001:2015–certified facility. Unlike serum-derived albumin, which introduces risks of variability and adventitious agents, Exbumin provides a safe, consistent, and scalable alternative. It is the first recombinant albumin approved for use as an excipient in injectable therapeutics and has been used in hundreds of thousands of doses. Exbumin improves viral stability in vaccines and gene therapies, maintains tissue viability during cryopreservation and storage, and stabilizes cells and tissues in regenerative medicine applications. This application note provides a step-by-step process for preparing Exbumin as a sterile 10% liquid stock solution for in vitro workflows and formulation use.

**Key Highlights**

- Simple, reproducible reconstitution protocol
- Stabilizes cells and tissues in biomanufacturing workflows
- Reduced variability vs. serum-derived albumin
- Enhances viral stability in vaccines and gene therapies
- Animal-origin-free and GMP-grade recombinant albumin



*Sterile filtration ensures Exbumin is ready for consistent, animal-origin-free workflows.*

## INTRODUCTION

Human serum albumin (HSA) is a multifunctional protein that plays key roles in supporting cell growth and stability. It protects cells from oxidative stress through antioxidant activity, delivers energy via fatty acid transport, and stabilizes essential metal ions required for cellular processes (Francis, 2010; He & Carter, 1992; Taverna et al., 2013). These properties make albumin a valuable excipient in therapeutic formulations and a critical supplement in advanced cell culture applications.

Traditionally, HSA for use in research and manufacturing has been sourced from human plasma. While effective, plasma-derived albumin presents significant limitations, including batch-to-batch variability, the risk of adventitious agents, and supply chain constraints (Blázquez-Prunera et al., 2017; Chisini et al., 2017; van der Valk et al., 2010). These challenges create regulatory and operational hurdles for manufacturers developing scalable and reproducible workflows.

Recombinant albumins address these limitations by offering a consistent, animal-origin-free, and scalable alternative. Exbumin is InVitria's recombinant HSA produced under GMP in an ISO 9001:2015–certified facility. It has been incorporated into FDA- and EMA-approved products, including licensed vaccines, and has demonstrated safety and consistency across hundreds of thousands of clinical doses.

Beyond its regulatory and clinical acceptance, Exbumin provides stabilization benefits across a range of applications. It enhances viral stability in vaccines and gene therapies, maintains tissue viability during cryopreservation and storage, and supports the stabilization of cells and tissues used in regenerative medicine and cell therapy manufacturing.

This application note outlines a step-by-step protocol for preparing Exbumin as a sterile, 10% stock solution suitable for use in biomanufacturing, cryopreservation, regenerative medicine, and vaccine formulation workflows.

## MATERIALS & METHODS

### Materials

**Recombinant Human Serum Albumin**

- Exbumin (InVitria 777HSA097)

**Reconstitution Supplies**

- 125 mL sterile PETG media bottle (ThermoFisher 2019-0125)
- Cell culture–grade DPBS, PBS, or basal media (e.g., DMEM/F-12, DMEM, MEM, RPMI)

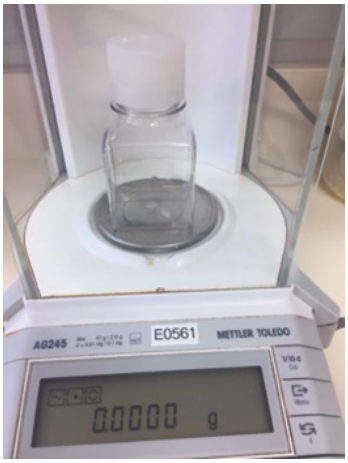
**Filtration System**

- 500 mL 0.2 µm vacuum filtration system (Millipore SCGPU05RE)

### Exbumin Reconstitution Protocol

**Step 1 - Weigh bottle**

- Begin with an empty 125 mL sterile PETG media bottle.
- Record its weight.




**Step 2 - Add Exbumin powder**

- Under a laminar flow hood, add 10 g Exbumin to the bottle.



- Weigh again to confirm the actual powder weight added.



- Use this recorded weight to calculate the final resuspension volume.

## Example Calculation

$$\text{Resuspension Volume (mL)} = \frac{\text{Exbumin weighed (mg)}}{\text{100 mg/mL}}$$

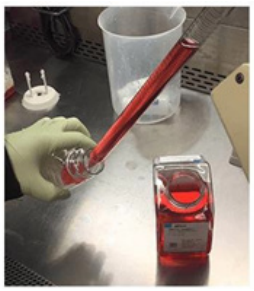
$$\text{Resuspension Volume (mL)} = \frac{\text{10828.6 (mg)}}{\text{100 mg/mL (10\%)}}$$

**Target Resuspension Volume (mL) = 108.3 mL**

### Step 3 - Add buffer

- Add ~70% of the calculated buffer volume (DPBS, PBS, or basal media) to the 125 mL bottle.
  ***Caution:*** *Do not add full buffer volume yet — allow for powder displacement.*

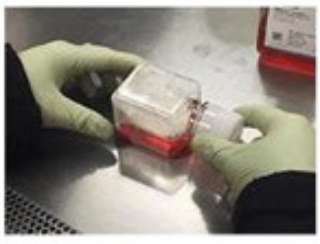




### Step 4 - Dissolve the powder

- Cap the bottle and gently tip the bottle on its side so the powder falls into the buffer.
  ***Caution:*** *Do not shake or vortex. Gently roll to wet all powder with liquid.*





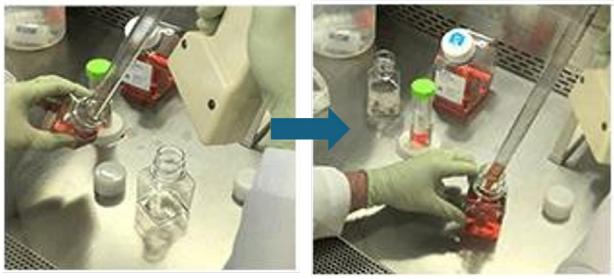
- Return the container upright and allow the albumin to dissolve, undisturbed at 4°C for at least 12 hours, protected from light.





### Step 5 - Adjust to final volume

- Once the powder is fully dissolved, bring the solution up to the calculated final volume with additional buffer.



- Transfer ~50 mL of the solution into a fresh sterile 125 mL bottle.
- Move the remaining solution into the same bottle and record the total volume.
- Add the difference between the measured volume and the target volume using buffer.

### Step 6 - Sterile filter

- Filter the reconstituted solution through a 0.2 µm vacuum-driven disposable filtration system.





- Collect sterile stock in a clean, labeled container.
- Store under sterile conditions until use.

**Note (Manual Filtration Option):**

For manual filtration, use a 25 mm 0.8 µm filter (Pall 4188), followed by a 0.2 µm 30 mm PES low–protein-binding filter (Celltreat 229747), with a sterile Luer-lock syringe (Medline SYR103010H).

## CONCLUSION

This application note provides a clear and reproducible method for preparing Exbumin as a sterile 10% stock solution. By following this protocol, researchers and manufacturers can reliably incorporate Exbumin into workflows requiring stability and consistency. Exbumin enhances viral stability in vaccines and gene therapies, maintains tissue viability during cryopreservation and storage, and stabilizes cells and tissues in regenerative medicine and cell therapy. Its scalability, safety, and excipient-grade quality make Exbumin a trusted choice for both biomanufacturing and therapeutic formulation applications.

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## ORDERING INFORMATION

| Description | Order Info |
|---|---|
| ***Exbumin - Recombinant Human Serum Albumin***<br>***Animal-Origin-Free \| GMP-Produced*** | 777HSA097 |
| Exbumin - Recombinant Human Serum Albumin, 10 g Bottles | 777HSA097-10g |
| Exbumin - Recombinant Human Serum Albumin, 100 g Bottles | 777HSA097-100g |
| Exbumin - Recombinant Human Serum Albumin, 1 Kg Bottles | 777HSA097-1Kg |

## ABOUT INVITRIA

InVitria is a global leader in developing and manufacturing high-performance, animal-origin-free cell culture supplements and recombinant proteins. Our products eliminate human and animal serum-derived components to improve consistency, reduce regulatory burden, and accelerate the approval of life-changing therapies. Trusted in clinical and commercial production of cell and gene therapies, vaccines, regenerative medicine, and medical devices, InVitria supports cGMP and ISO-compliant manufacturing aligned with FDA and EMA expectations. Scalable to meet growing global demand, our chemically defined solutions enable safer, more efficient biomanufacturing.

InVitria
Performance. Defined.

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**InVitria, Inc.**
2718 Industrial Drive
Junction City, KS 66441 USA
Phone: 800-916-8311
Fax: 785-238-5688
Email: info@invitria.com
www.invitria.com