Exbumin®

Recombinant Human Serum Albumin (rHSA), Excipient Grade Animal-Origin-Free

Exbumin



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1. PRODUCT DESCRIPTION

Exbumin® is a high-purity, chemically defined, animal-origin-free recombinant human serum albumin (rHSA) supplied as a sterile lyophilized powder. Manufactured in a non-mammalian expression system, it offers a consistent and scalable alternative to plasma-derived albumins for use in regulated biopharmaceutical workflows.

Designed for formulation and stabilization of cells, viruses, and therapeutic proteins, Exbumin supports biologic development across cell and gene therapy, vaccine, and protein drug platforms. Its validated performance in injectable-grade products includes enhancing final product yield, maintaining biological activity, and improving stability in both upstream and final formulation settings.

This product is regulatory-friendly and eliminates risks associated with animal- or serum-derived components. Like all InVitria products, it is made in an ISO 9001–certified, cGMP-compliant U.S. facility that is certified animal-origin-free (AOF), with documented controls preventing the use or presence of animal-derived materials.

2. PRODUCT INFORMATION

GMP Part Number	777HSA097
Product Type	Excipient-grade recombinant human albumin
Format	Lyophilized powder
Purity	≥ 98.0%
Packaging	10 g, 100 g, & 1 kg bottles
Endotoxin Level	≤ 0.100 EU/mg
pH	6.50 - 7.50
Source	Recombinant
Shelf Life	4 years
Storage	-20°C
Manufacturing Site	• Animal-origin-free facility • ISO 9001–certified • cGMP-compliant

GUIDELINES FOR USE

3. APPLICATIONS

- Stabilization of live, attenuated, or inactivated viral vaccines
- Maintains tissue and cell viability during long-term cryopreservation and storage
- Final excipient in approved injectable biologics around the world
- Improves virus yield during downstream manufacturing

4. PREPARATION & USE

Format: This product is supplied as a lyophilized powder.

Reconstitution: For 100 mL of a 10% w/v stock solution, add 10 g pre-weighed Exbumin to 125 mL sterile PETG bottle. Add approximately 70 mL of cold, sterile DPBS, PBS, or basal media. Gently mix to dissolve, avoid vortexing or vigorous mixing. Allow to dissolve fully at 4°C for at least 12 hours, protected from light. Once no visible particles remain, bring to final volume (100 mL) using the same buffer or media

Mixing: Gently invert or tilt bottle until homogenous; **DO NOT SHAKE OR VORTEX.**

Filtration: Sterile filter the reconstituted solution using a 0.2 µm low-protein-binding filter.

Note: *This product is lyophilized and not classified as sterile. To ensure sterility, reconstitute under aseptic conditions and sterile filter using a 0.2 µm low-protein-binding filter before use in sterile workflows.*

Recommended usage:

- *Excipient applications:*
  - Viral vector & vaccine stabilization: 1–10 mg/mL
  - Cell therapy cryopreservation: 50–100 mg/mL
  - Cell therapy infusion (fill-finish): 10–50 mg/mL
  - Therapeutic protein formulation: 0.5–5 mg/mL, depending on protein sensitivity and adsorption risk
- *Upstream applications:*
  - Cell culture supplementation: 0.1–2 g/L
  - Virus production (culture phase): 0.5–1.5 g/L *—Adjust based on virus system and production platform*
- **Optimization**: Due to its high purity and consistent activity, Exbumin often performs at lower concentrations than serum-derived HSA. Start at equivalent mass (mg/mL) and titrate to the minimal effective dose.

5. STORAGE & STABILITY

- **Shelf life:** Up to 4 years when unopened and stored at −20°C.
- **Reconstituted solutions:** Store at 2–8°C protected from light for up to 4 weeks.
- Keep tightly sealed to prevent contamination and moisture uptake.
- **AVOID:**
  - Repeated freeze–thaw cycles
  - Prolonged exposure to temperatures >25°C
  - Direct sunlight or UV exposure
  - Vigorous agitation (shaking, vortexing, etc.)
  - Contact with oxidizing agents
  - Opening outside a sterile environment

6. REGULATORY NOTES

- Animal-origin-free (AOF)
- Chemically defined
- Manufactured in a cGMP-compliant, ISO 9001-certified facility
- Manufactured in the USA for reliable sourcing and regulatory alignment
- Ethically sourced & sustainable

7. ADDITIONAL RESOURCES

- Website - Exbumin
- Data Sheet - Exbumin
- SDS - Exbumin
- Guidelines for Use - Exbumin
- Application Note - Exbumin - Reconstitution
- Video - rHSA Reconstitution Video Protocol
- Application Note - Exbumin – Stabilizing Virus with Albumin to Improve Yield Application Note
- Application Note - T Cell Cryopreservation Using Exbumin, Recombinant Human Serum Albumin, and Reduced DMSO

8. ORDERING INFORMATION

Exbumin	***Product #***
GMP-10 g bottles	777HSA097-10g
GMP-100 g bottles	777HSA097-100g
GMP-1 kg bottles	777HSA097-1kg

Performance. Defined.

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