# CreaCyte® rHSA by InVitria

## as Excipient

### REGULATORY-APPROVED rHSA FOR BIOPHARMACEUTICAL FORMULATION

CreaCyte® rHSA as Excipient (Exbumin® by InVitria) is a high-purity recombinant human serum albumin (rHSA) designed to enhance performance in biopharmaceutical drug formulation. This chemically defined albumin can be used as an injectable excipient to enhance the stability of therapeutic proteins, improve viral stability for vaccines and gene therapies, stabilize cells and tissues in cell therapy and regenerative medicine applications, and maintain tissue viability in cryopreservation and storage.

### DESCRIPTION

- ≥ 98 % recombinant human serum albumin
- Highly pure excipient with consistent quality
- Used in the formulation of FDA, EMA and PMDA-approved biopharmaceuticals
- Flexibility for inclusion level
- Animal-component free
- Produced under cGMP in an ISO-certified facility in the USA

### APPLICATIONS

- Therapeutic Protein Stabilization
- Cell & Gene Therapy
- Vaccines
- Regenerative Medicine
- Medical Devices
- Tissue & Cell Storage

### PRODUCT PROPERTIES

| | |
|---|---|
| Format | Lyophilized powder |
| Shelf Life | 4 years |
| Regulatory Compliance | cGMP, ISO 9001 |
| Packaging | 10 g and 100 g bottles |
| Storage | –20 °C |

- **Optimized for final formulation –** Improved stability, shelf-life and thermal logistics for biopharmaceutical drug products
- **Enhanced downstream processing –** Increased virus yield and recovery in purification workflows
- **Versatile excipient –** Supports protein and viral stability (e.g., AAV, LV) as well as cell and tissue viability and preservation
- **No adventitious agent testing –** Animal-free rHSA eliminates raw material screening and viral testing

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## RECOMBINANT HSA AS PREMIUM EXCIPIENT IN INJECTABLE BIOPHARMACEUTICALS

CreaCyte® rHSA as Excipient (Exbumin® by InVitria) is produced in a scalable, non-mammalian recombinant expression system. It is blood-free and animal-component free. Due to its recombinant DNA This manufacturing method ensures an animal-component-free HSA, without donor-to-donor variability or risk of human or bovine adventitious agent contamination compared to blood-derived products.

Regulatory agencies such as the FDA (Food and Drug Administration – USA), EMA (European Medicines Agency – European Union) and PMDA (Pharmaceuticals and Medical Devices Agency – Japan) have approved the use of CreaCyte® rHSA as Excipient in final formulations of injectable biopharmaceuticals. This highly pure excipient has been shown to be safe in more than 250,000 human injections.

CreaCyte® rHSA as Excipient supports stability of biopharmaceuticals such as therapeutic proteins, vaccines, gene therapies and cell therapies in final formulation and during manufacturing. For example, in the case of virus-based therapies, it can be used as a media component to improve viral titer during inoculation and as an excipient added to final formulations to enhance viral stability prior to injection.

## RECOMMENDATIONS FOR USE

**Excipient in Final Formulations**

CreaCyte® rHSA as Excipient inclusion at 1 – 50 mg/mL is reported to be effective in final formulation excipient use. Optimal inclusion levels depend on characteristics of the formulation and manufacturing process and need to be empirically determined in each case.

CreaCyte® rHSA as Excipient is soluble in water and common buffers such as DPBS and PBS at a wide range of concentrations. Below are suggested inclusion ranges based on the type of application.

**Virus Stabilization during Manufacturing**

CreaCyte® rHSA as Excipient inclusion at 2 – 30 mg/mL is found to be effective for virus stabilization during viral production. However, different virus types and cellular substrates have optimal inclusion levels to enhance virus titer and should be empirically determined. Once the cells have reached the desired confluency, initiate virus production by transfecting with plasmid DNA or infection with the virus to be expanded. Once the transfection media has been removed, use a virus production media of choice containing 2 – 30 mg/mL CreaCyte® rHSA as Excipient. Perform the virus production run and harvest with CreaCyte® rHSA incorporated with virus product.

| Final Formulation Applications | Inclusion (mg/mL) |
|---|---|
| Therapeutic protein formulation | 1 – 10 [1] |
| Cell therapy formulation | 20 – 50 [2 – 3] |
| DNA virus formulation | 10 – 50 [4] |
| RNA virus formulation | 2 – 30 [5 – 6] |

## RECONSTITUTION PROTOCOL

This document provides a step-by-step overview for preparing CreaCyte® rHSA for use as a 10 % stock liquid solution for in vitro workflows and formulation use.

## MATERIALS

- CreaCyte® rHSA as Excipient
- Cell culture grade DPBS, PBS, or basal media such as DMEM F/12, DMEM, MEM, RPMI
- 125 mL sterile PETG media bottle
- 500 mL, 0.2 µm vacuum filtration system

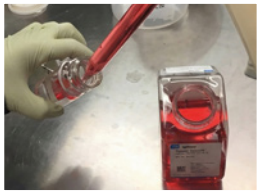
1. Weigh an empty, 125 mL sterile PETG media bottle.

2. Under a laminar flow hood, add 10 g CreaCyte® rHSA as Excipient to the bottle. Weigh the bottle containing the powder to determine the actual weight added.

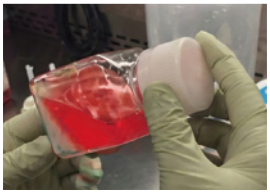

3. Calculate the volume required to produce a 10 % concentrated solution. See exemplary calculations on the right-hand side.

Example: Resuspension volume (mL)
= Weight of CreaCyte® rHSA (mg) / 100 (mg/mL)
= 10828.6 / 100
= 108.3 mL

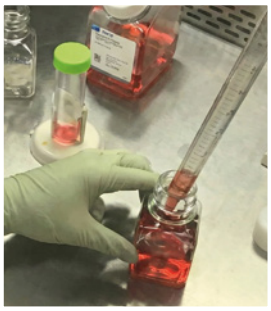
4. Gently reconstitute the powder in cell culture grade DPBS, PBS, or the selected basal media by adding 70 % of the calculated final volume directly to the 125 mL bottle. Do not add the full final volume of buffer at this stage. An allowance must be made to account for volume displacement caused by the powder.



5. Cap the 125 mL bottle and gently turn it on its side to allow the powdered albumin to fall into the buffer. Avoid the formation of bubbles during this step. Return the container upright and allow the albumin to dissolve, undisturbed (no shaking) at 4°C in the dark for a minimum of 4 hours and preferably overnight.



6. Once all the powder albumin has dissolved, bring the volume up to the calculated target by adding additional reconstitution liquid. To achieve this easily, use a 50 mL pipette to move exactly 50 mL of the reconstituted albumin powder to a fresh 125 mL bottle. Using the same pipette, remove the remaining liquid from the original bottle, noting the volume. Finally, pipet the difference between the target volume and the volume as measured by pipetting and add this volume of reconstitution liquid to the new bottle.



7. Sterilize the stock solution by filtering through an 0.2 µm vacuum-driven disposable filtration system. Collect sterile stock in a clean, labeled container. Store under sterile conditions until use.

8. Optional: For manual filtration, we recommend using a 25 mm, 0.8 µm filter, followed by a 30 mm, 0.2 µm PES low-protein-binding filter, using a sterile Luer-lock syringe.



## REFERENCES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