CreaCyte® rHSA by InVitria

for Cell Culture Media

OPTIMIZED rHSA FOR SUPERIOR CELL CULTURE PERFORMANCE

CreaCyte® rHSA for Cell Culture Media (Cellastim® S by InVitria) is a high-performance recombinant human serum albumin (rHSA) designed to replace both human and bovine serum albumin in cell culture. This chemically defined albumin enhances cell growth, viability, and productivity while eliminating risks associated with plasma-derived albumins. It is ideal for stem cell expansion, virus propagation, and biologics manufacturing.

DESCRIPTION

- > 96.0 % recombinant human serum albumin
- Enhanced with lipids for cellular support
- Low endotoxin levels (< 1 EU / mg)
- Broad cell line compatibility
- Animal-component free
- Produced under cGMP in an ISO-certified facility in the USA

APPLICATIONS

- Cell & Gene Therapy
- Regenerative Medicine
- Vaccines
- Medical Devices
- Tissue & Cell Storage
- Diagnostics & Reagents

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 cell culture** – Supports high-density growth in primary cell, stem cells, CHO, HEK, and VERO cells
- **No adventitious agent testing** – Animal-free rHSA eliminates raw material screening and viral testing
- **Lipid-rich** – Provides critical fatty acids for cell culture performance
- **Clinically proven** – Used in GMP biologics manufacturing, including approved products
- **Lower inclusion needed** – Requires less rHSA than bovine or human serum albumin

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HSA PLAYS A KEY ROLE IN BIOPHARMA CELL CULTURE

Human serum albumin (HSA) has been identified as a powerful tool for the expansion of many cell types in vitro[1]. It is a multifaceted protein capable of binding many different types of molecules[2]. HSA therefore plays diverse roles in cell biology, acting as an antioxidant to improve health of cells by binding to reactive oxygen species, as an energy-delivery system by chaperoning fatty acids in the bloodstream, and as a mediator for solubilization and stabilization of metal ions required for cellular processes[2,3]. These functions make HSA supplementation of cell culture media an integral step in facilitating cell proliferation.

As cell-based immunotherapies, gene therapy, and stem-cell therapy continue to show promise in the lab and in the clinic[4–6], the availability of safe and consistently high-performing HSA grows in importance for the future of these technologies[7]. HSA used in the culture of mesenchymal stem cells (MSCs), hematopoietic stem cells (HSCs), T Cells, HEK293, VERO, MDCK, BHK-21, and many other key cell types is traditionally sourced directly from human serum[1,8].

However, media supplementation with serum-derived or other animal-derived supplements can introduce adventitious pathogenic agents, create variability in bioprocesses, and present the risk of a supply-chain bottleneck. Accordingly, chemically defined media supplemented with recombinant and well-characterized alternatives to animal-derived components are increasingly being used as a viable strategy for improving consistency and enabling scalability for cell-based therapies[7,9].

RECOMBINANT HSA ENHANCES CELL CULTURE PERFORMANCE

CreaCyte® rHSA for Cell Culture Media (Cellastim® S by InVitria) is produced in a scalable, non-mammalian recombinant expression system. It is naturally free of prion agents (bovine spongiform encephalopathy and other transmissible spongiform encephalopathy agents) and carries less potential risk from other mammalian adventitious agents compared to serum-derived components. In addition to improved safety, it has shown consistent performance in supporting the culture of T-Lymphocytes, HEK293, MSC, HSC, and VERO, among other cell types[10,11].

CreaCyte® rHSA for Cell Culture Media has been designed to enhance cell doubling times, deliver essential lipids, provide micronutrients and antioxidants, and reduce oxidative stress in cell culture applications. It has the identical amino acid sequence as the major HSA isoform found in human serum. It is lipid-enhanced (1.4 % by weight) for excellent, consistent growth and directed differentiation of a wide variety of human cell types, including T-Lymphocytes, HEK293, hybridoma/NS0, CHO, fibroblasts, mesenchymal stem cells, hematopoietic stem cells, and virus production in VERO/MDCK cell culture. Every lot is tested with multiple T-lymphocyte cells from donors to ensure consistency and performance.

Using CreaCyte® rHSA as a recombinant and scalable source of albumin in cell culture is an enabling tool for large-scale manufacture of cell-based and gene therapies.

RECOMMENDATIONS FOR USE

The optimum concentration of albumin for cell culture applications varies with the type of cell and the composition of the medium. Albumin is typically used at concentrations of 0.5 to 2 g/L in media formulations. Concentrated liquid stocks can be prepared by dissolving CreaCyte® rHSA in basal media, cell culture grade PBS or water.

To learn more about recommended inclusion concentrations for your cell type, please contact our biopharma experts.

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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 cell culture applications.

MATERIALS

- CreaCyte® rHSA for Cell Culture Media
- 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

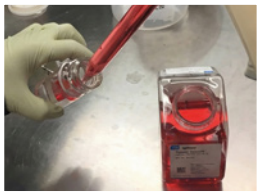
1. Weigh an empty, 125 mL sterile PETG media bottle.

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

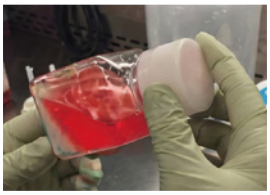
3. Calculate the volume required to produce a 10 % concentrated solution. See exemplary calculations on the right-hand side.

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

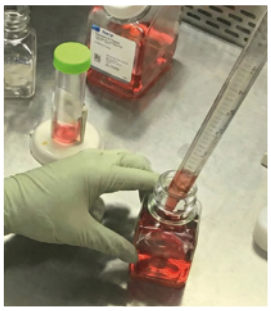
4. Gently reconstitute the powder in cell culture grade DPBS, PBS, or the selected basal media by adding 70 % of the calculated final volume directly to the 125 mL bottle. Do not add the full final volume of buffer at this stage. An allowance must be made to account for volume displacement caused by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

1. Francis GL. Albumin and mammalian cell culture: implications for biotechnology applications. Cytotechnology. 2010;62(1):1-1
2. He XM, Carter DC. Atomic structure and chemistry of human serum albumin. Nature. 1992;358(6383):209-215
3. Taverna M, Marie AL, Mira JP, Guidet B. Specific antioxidant properties of human serum albumin. Ann Intensive Care. 2013;3(1):4
4. Maude SL, Teachey DT, Porter DL, Grupp SA. CD19-targeted chimeric antigen receptor T-cell therapy for acute lymphoblastic leukemia. Blood. 2015;125(26):4017- 4023.
5. Trounson A, Thakar RG, Lomax G, Gibbons D. Clinical trials for stem cell therapies. BMC Med. 2011;9:52.
6. Cavazzana-Calvo M, Hacein-Bey S, de Saint Basile G et al. Gene therapy of human severe combined immunodeficiency (SCID)-X1 disease. Science. 2000;288(5466):669- 672.
7. van der Valk J, Brunner D, De Smet K et al. Optimization of chemically defined cell culture media–replacing fetal bovine serum in mammalian in vitro methods. Toxicol In Vitro. 2010;24(4):1053-1063
8. Blázquez-Prunera A, Díez JM, Gajardo R, Grancha S. Human mesenchymal stem cells maintain their phenotype, multipotentiality, and genetic stability when cultured using a defined xeno-free human plasma fraction. Stem Cell Res Ther. 2017;8(1):103
9. Chisini LA, Conde MCM, Grazioli G et al. Venous Blood Derivatives as FBS-Substitutes for Mesenchymal Stem Cells: A Systematic Scoping Review. Braz Dent J. 2017;28(6):657-668
10. Alfano RW. Albumin in cell culture media—an examination of quality and function. In: Brieva T, Miller W, Mason C, eds. Scale-up and manufacturing of cell-based therapies V. ECI Symposium Series; 2017
11. Pennybaker A, Alfano R. Utilization of recombinant albumins in the expansion of human T lymphocytes. Cell Gene Ther Insights. 2018;4(4):231-239.

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