

Recombumin®

Recombinant Human Albumin

Product Information

The Recombumin® product portfolio consists of commercially available, high-quality, animal and human-origin-free recombinant human albumins. Recombumin® is a multi-functional excipient, ancillary and raw material, and its stabilizing properties have been validated through long-established use in multiple marketed life science products.

Sartorius' highly pure, safe, and consistent Recombumin® recombinant albumins are the purest form of albumin available, offering batch-to-batch consistency and the highest levels of antioxidant capacity. Sartorius' Recombumin® supports advanced therapy development at every stage of their journey from research and development to in-human application.



Features and Benefits

- Reduces surface adsorption, forming a one molecule thick monolayer on hydrophobic and hydrophilic surfaces.
- Prevents aggregation, dispersing evenly in solution to minimise instability.
- Scavenges free radicals protecting against oxidative stress
- Recombumin® supports an optimal micro-environment for sustained cell viability, acting as a pH buffer and nutrient source
- Recombumin® supports cell viability during and post-cryopreservation.
- Recombumin® is a wholly human and animal-origin-free product alleviates logistical challenges

Application

Close to 40 years of experience and process evolution have created Sartorius' market leading recombinant human albumin (rHA), Recombumin®. Dosed over 200 million times and utilized in a range of drug products, Recombumin® supports over 45% of the top 20 blue-chip pharmaceutical companies to deliver innovative drugs, vaccines, and therapies across the world.

Recombumin®, a multifunctional excipient, readily adsorbs to both hydrophobic and hydrophilic surfaces in a single monolayer, preventing non-specific adsorption of advanced biopharmaceuticals during manufacture, formulation, and storage. Only 1-2 mg Recombumin® is needed to coat 1m² of surface. Through multiple mechanisms, Recombumin® prevents aggregation and particle formation. By dispersing uniformly in a solution, it affords an insulating quality that minimizes physical drug instability. Given its natural free thiol group, Recombumin® protects advanced therapies and biotherapeutics by from oxidation scavenging free radicals to protect the final product against oxidation.

Stability and consistency are fundamental to the success of therapies as they move beyond pre-clinical testing. Adsorption, aggregation, and oxidative stress present challenges to multiple treatment modalities, and Recombumin® overcomes these challenges, supporting the commercial deployment of treatments into the marketplace. The Recombumin® portfolio's drug master files and regulatory packages are also supported by non-clinical and clinical safety data. Extensive real-world evidence from clinical and marketed therapeutics using Recombumin® are true testament to the quality, consistency, and performance of Sartorius' recombinant human albumin portfolio.

Relevant Applications

- Cell Therapy
- Gene Therapy
- Gene Modified Cell Therapy
- Vaccines
- Viral Based Therapies
- Medical Devices
- Diagnostics and Reagents

Features of the Standard Product



Only USP-NF compliant rHA - purest albumin available



Stable with a 5-year shelf life (when stored at 2-8 °C)



Proven batch-to-batch consistency



ICH Q7 cGMP



Chemically Defined



Non-Animal Origin



For research or further manufacture use



Available in 50 mL vials or 1 L bioprocess bags (depending on product line)



Liquid Product



Extensive DMFs in key markets

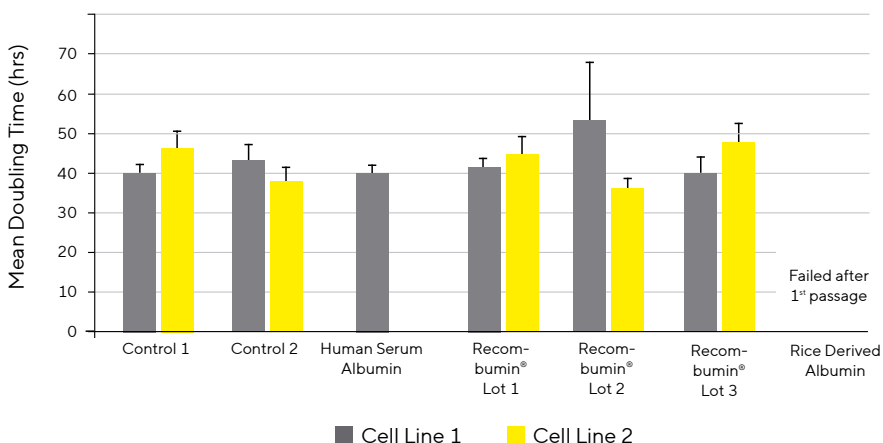
Simplifying Your Decision

	Upstream Processing	Downstream Processing	Cryopreservation	Final Formulation
Cell Therapy	Cell banking, separation, expansion, differentiation	Prevent against cell stress and absorption during separation and processing	Support cell storage and post thaw cell viability	Excipient: protect cells from stress
Gene Modified Cell Therapy	Patient and donor bio-processing, expansion, proliferation	Improve viral transduction. Prevent against cell stress and absorption during separation and processing	Support cell storage and post thaw cell viability	Excipient: protect cells from stress
Gene Therapy	Optimize viral vector manufacture including transfection, prevent viral particle aggregation, protect from shear stress	Prevent against vector aggregation and absorption during processing	Support storage and post thaw infectivity	Excipient: protect from sheer stress, chemical stress, aggregation and surface absorption. Dose prep. Improve viral transduction, reduce MOI (reduce dose range)
Viral Based Therapy	Optimize viral vector manufacture including transfection, prevent viral particle aggregation, protect from shear stress	Prevent against viral aggregation and absorption during processing	Support storage and post thaw infectivity	Excipient: protect from sheer stress, chemical stress, aggregation and surface absorption
Protein Based Therapeutics	Cell banking	Prevent against protein aggregation and absorption during processing		Excipient: protect from sheer stress, chemical stress, aggregation and surface absorption. Dose prep. Half-life extension of peptide

Performance

Over nearly four decades of albumin research by Sartorius-Albumedix, a vast amount of data has been generated, across various applications, highlighting the real-world benefits Recombumin® offers. Below is a small sample of Recombumin® performance data.

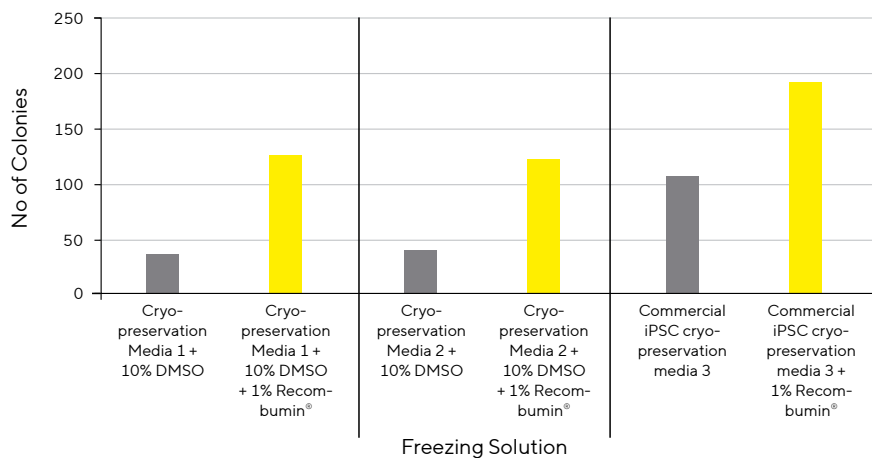
Recombumin® Consistently Promotes Cell Growth and Maintains Viability



Two human embryonic stem cell (hESC) lines (SA121 and SA181) were initially expanded in media containing Recombumin®, then transferred and seeded into each test media. The hESC cells were then grown for seven more passages before being analyzed by immunocytochemistry and QPCR. Cells were counted at each passage, and the doubling time was calculated.

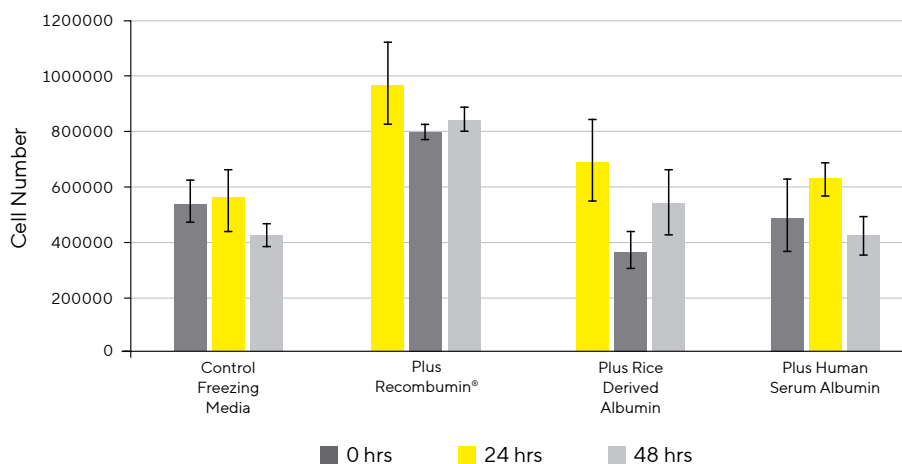
The data shows that Recombumin® was effective as a cell culture supplement in hESC culture applications.

Recombumin® Extends Post-Thaw iPSC Growth



Cells were cryopreserved in various media, including a medium specifically developed for the cryopreservation of iPSCs with and without albumin. Cell health was assessed by measuring the ability of the cells to regrow post-cryopreservation and counting the number of colonies that grew. Including Recombumin® in the cryopreservation media increased the number of iPSC colonies.

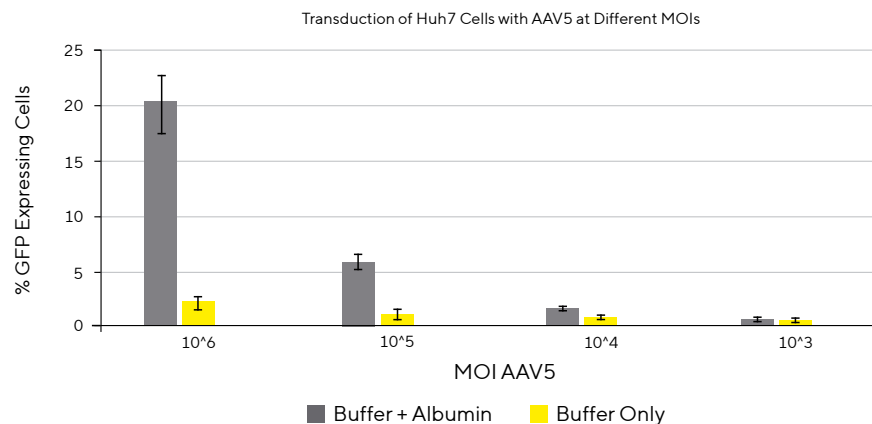
Recombumin® Extends the Post-Thaw Stability of T-Cells



T-cells were assessed up to 48 h post-thaw, and the number of live cells was counted. The addition of Recombumin® increased the stability of the cells such that live cell numbers were similar, or only reduced, slightly over a 48 h period. In contrast, media containing HSA and recombinant albumin derived from rice showed much lower live cell numbers.

This data shows that the use of albumin is beneficial, but the quality and source of albumin must be carefully selected to achieve optimal performance.

Recombumin® Improves AAV Transduction Efficiency



AAV5 was used to transduce Huh7 cells with the gene for the expression of GFP. The cells were transduced with different MOIs in either buffer alone or with the addition of albumin. Transduction performance was measured by the number of cells carrying the gene of interest and expressing protein and by the amount of AAV needed to transduce cells (which can be reduced up to 100-fold). The results show that significantly more cells were transduced in the presence of albumin than in its absence.

Product Specifications

	Recombunin® Prime	Recombunin® Elite
Manufactured in	Proprietary genetically modified yeast strain (<i>Saccharomyces cerevisiae</i>)	
Manufacture Quality	ICHQ7 cGMP Facility	
Location of Manufacture	United Kingdom	
Ships to	International	
Safety Data	Product used in the final formulation of marketed vaccines and therapeutic products and medical devices	Product used in final formulation in clinical phase therapeutics
Drug Master Files in Key Markets*	✓	✓

* Speak with your representative for additional details as required

Ordering Information

Item	Description	Medium Quantity Package	Order Number
Recombunin® Prime*	Recombinant human albumin	Liquid 50 mL Vial 20%w/v	200-010
	Trial volume of Recombunin® Prime to allow for customer evaluation	Liquid 5 mL Vial 20%w/v	200-001
Recombunin® Elite	Recombinant human albumin	Liquid 50 mL Vial 10%w/v	205-005
		Liquid 1 L BPC 10%w/v	205-100
	Trial volume of Recombunin® Elite to allow for customer evaluation	Liquid 5 mL Vial 10%w/v	205-0005

* Other volumes are available

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For more information, visit

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