

For Your Protein Stabilizer and Cell Culture Needs

Check Out All the Advantages of Human Serum Albumin

- ✓ Sets the standard for compatibility

 - Human serum albumin eliminates the problems caused by reactions to foreign proteins—animal or synthetic—and is a **proven growth medium**.
- ✓ Proven safe and effective

 - With its **excellent safety record**, protein manufacturers have relied on human albumin as an effective stabilizer for 40 years.
- ✓ Fewer regulatory hurdles than bovine albumin

 - With increasing concern about bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE), human serum albumin can mean **fewer regulatory hurdles**.
- ✓ Easier registration than synthetic albumin

 - Compared to synthetics, human serum albumin is a licensed therapeutic in more than 40 countries, **facilitating global registration** when used as an excipient.



- ✓ Lower cost and readily available

 - Human serum albumin **costs much less** than bovine and synthetic albumin and is in **plentiful supply**. It can help you deliver critical protein therapies to all your markets on schedule.

References: 1. Committee for Proprietary Medicinal Products (CPMP). *Note for Guidance on Virus Validation Studies: The Design, Contribution and Interpretation of Studies Validating the Inactivation and Removal of Viruses*. 1996. CPMP BWP/268/95. 2. Darling AJ. Considerations in performing virus spiking experiments and process validation studies. In: Brown F, ed. *Virological Safety Aspects of Plasma Derivatives*. Basel: Karger; 1993;81:221-229.



Talecris: The New Name for the Quality You Count on

Safety: Our first priority, our final concern

- Rigorous screening for **every** donor, **every** donated unit, and **every** plasma pool
- Robust, validated **virus clearance** for enveloped and non-enveloped viruses^{1,2}
 - 2 virus removal steps during fractionation followed by 2 virus kill processes, including the **unique Talecris acetone suspension technique** and pasteurization
 - **Patented Western blot assay** confirms removal of pathogenic prion proteins.
- Exceeds the highest regulatory requirements for effective clearance of enveloped and non-enveloped viruses
- Our dedication to safety has won the confidence of biotech companies worldwide and continues to play a significant part in the progress against disease.

Shaping the Future

The trust that Talecris products have earned in the past will help you shape the future of protein therapeutics around the world.

Our legacy is your future

- An **intimate knowledge** of the logistics and consequences of protein production
- **Complete regulatory documentation** and a global regulatory package that supports your submissions in more than 40 countries
- **Responsive** to your special needs
 - A wide selection of human serum albumin products with various protein strengths to meet your development needs
 - Site audits and quality assurance assistance
- **Available** in a variety of concentrations and vial sizes, including 20% (50 and 100 mL) and 25% (50 and 100 mL)

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Talecris also offers Human Plasma Protein Fraction 5% in 50 and 250 mL.

For more information, contact Talecris cell culture professionals at www.albuminexcipient.com or 1-919-316-6312.