

Talecris Human Serum Albumin

for your stabilizer
and cell culture needs...

COUNT ON US



EXPERIENCE

you can count on

- Decades of experience as a reliable supplier of human serum albumin for stabilizer and cell culture use in products worldwide
- More than 150 million grams of albumin sold worldwide from 1998 through 2002¹
- Talecris provides Human Serum Albumin, meeting United States Pharmacopeia (USP), European Pharmacopeia (EP), and/or Japanese specifications

Talecris Human Serum Albumin



you can count on

Assurance of world-class validation of pathogen safety

- ✿ Rigorous screening of every donor, every unit of donated plasma, and every plasma pool
- ✿ Validated and robust virus clearance steps for both enveloped and non-enveloped viruses
- ✿ Four different virus reduction steps: 2 removal steps during fractionation and 2 virus-kill steps, including Talecris' unique acetone suspension and pasteurization
- ✿ Exceeds the highest regulatory requirements for effective clearance of enveloped and non-enveloped viruses
- ✿ Patented Western blot assay confirmed removal of prion protein during spiked manufacturing simulations^{2,3}
- ✿ Talecris Human Serum Albumin is bovine free—one less regulatory issue to deal with

Validated virus clearance steps in the Talecris Human Serum Albumin Products (20% and 25%) production process¹

Process Steps	Reduction Factor (log ₁₀) for Enveloped Viruses			Reduction Factor (log ₁₀) for Non-enveloped Viruses		
	HIV	BVDV	PRV	Reo	HAV	PPV
Fractionation to Effluent II + III	3.4	3.6	3.9	2.1	1.4	1.0
Depth Filtration	3.4	<1.0	≥3.4	4.9	2.0	4.2
Precipitation/Acetone Suspension	≥5.1	7.5	≥4.2	2.3	NA	NA
Pasteurization	≥5.9	≥5.2	≥4.8	5.6	4.4	1.6
Total Reduction Factor (log₁₀)	≥17.8	≥16.3	≥16.3	14.9	7.8	6.8
Minimum Expected Reduction Factor^a (log₁₀)	10^b	10^b	10^b	6^c	6^c	6^c

^a Reductions typically expected by regulators.

^b Must include two robust steps that provide 4 log₁₀ clearance.

^c Must include one robust step that provides 4 log₁₀ clearance.

HIV: Human immunodeficiency virus

BVDV: Bovine viral diarrhea virus, a model for hepatitis C virus

PRV: Pseudorabies virus, a model for hepatitis B virus and human herpes viruses

HAV: Hepatitis A virus

Reo: Reovirus type 3, a model for viruses resistant to physicochemical agents

PPV: Porcine parvovirus, a model for human parvovirus B19

NA: Not applicable; most non-enveloped viruses are not susceptible to this method of inactivation

Talecris Human Serum Albumin

PROFESSIONALS

you can count on

- Experienced regulatory and quality assurance personnel
- Documents available to support and maintain **worldwide registrations**
- Working relationships with respective **regulatory agencies**
- **Responsive** to unique customer requirements, eg, customer site audit requests
- Talecris supplies the formulation, vial size, specification, and **documentation you need**

Contact Talecris Excipient and Cell Culture professionals at www.albuminexcipient.com or 1-919-316-6312

DOCUMENTATION

you can count on

CERTIFICATE OF ANALYSIS

Test Procedures	Manuf. Date	Expir. Date
2.02-02	06 Dec 03	3 Year Expiration
TESTS	REQUIREMENTS	
1. Appearance	Clear, Slightly Viscous Pale Yellow to Amber Colored	
2. Identity		
2.1. Precipitin Test		
Anti-Human	Positive	
Anti-Bovine	Negative	
Anti-Equine	Negative	
Date of Test	MM DD YY	
2.2. Identity (Grabar-Williams)	Main Component Is Albumin	
3. Volumetric Fill Check	Min. 50 mL	
4. pH of 1% Protein Solution	6.7-7.3	
5. Sodium	138-152 mmol/L	
6. Potassium	Max. 0.05 mmol/g Protein	
7. Protein	23.75-26.25%	
8. Protein Composition	Min. 96% Albumin	
9. Polymers and Aggregates	Max. 5%	
10. N-Acetyl-DL-Tryptophan	0.07-0.09 mmol/g Protein	
11. N-Acetyl-DL-Tryptophan	16.6-23.6 mmol/L	
12. Sodium Caprylate	0.07-0.09 mmol/g Protein	
13. Sodium Caprylate	16.6-23.6 mmol/L	
14. Prekallikrein Activator	Max. 35 IU/mL	
15. Aluminum	Max. 200 µg/L	
16. Heme	Max. 0.15 A @ 403 nm	
17. Acetone	Max. 0.05% W/V	
18. Sterility, EP	No Growth	
Date of Test	MM DD YY	
19. Pyrogen, EP	Must Comply	
Date of Test	MM DD YY	
Number of Rabbits	Report	
Rabbit Temperature Rise	Report Degrees C	
Rabbit Temperature Rise	Report Degrees C	
Rabbit Temperature Rise	Report Degrees C	
Rabbit Temperature Rise	Report Degrees C	
Rabbit Temperature Rise	Report Degrees C	
Rabbit Temperature Rise	Report Degrees C	
Sum of Temperature Rises	Report Degrees C	

Example of how Talecris Human Serum Albumin meets EP requirements

THE BATCH COMPLIES WITH SPECIFICATION

Talecris Human Serum Albumin

AVAILABILITY

you can count on

Talecris Human Serum Albumin, meeting USP, EP, and/or Japanese specifications, is available in a variety of formulations and vial sizes, including

- 20% (50 and 100 mL)
- 25% (50 and 100 mL)

Count on us to meet your biopharmaceutical stabilizer and cell culture needs. Contact us directly at

www.albuminexcipient.com
1-919-316-6312
1-919-316-6051 Fax

Talecris Biotherapeutics
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park, NC 27709

References: 1. Data on file, Talecris Biotherapeutics. 2. Lee DC, Stenland CJ, Hartwell RC, et al. Monitoring plasma processing steps with a sensitive Western blot assay for the detection of the prion protein. *J Virological Methods*. 2000;84:77-89. 3. Lee DC, Stenland CJ, Miller JL, et al. A direct relationship between the partitioning of the pathogenic prion proteins and transmissible spongiform encephalopathy infectivity during the purification of plasma proteins. *Transfusion*. 2001;41:449-455.

©2005 Talecris Biotherapeutics Printed in USA. 6/05 09015U

Talecris
BIOTHERAPEUTICS

 **Talecris Albumin Products**
Building on a legacy of excellence