

Bovine Serum Albumin

New Zealand Source

DESCRIPTION

Proliant Bovine Serum Albumin (BSA) New Zealand Source is a high purity "Fraction V" protein derived from the plasma of NZ-origin healthy animals. The material is initially fractionated by a modified Cohn procedure – a proprietary heat-shock method designed to minimize bacterial endotoxins. The product is further isolated from other plasma proteins and lipids by extensive dialysis and membrane filtration. Typical purity levels are in excess of 99%. New Zealand Source albumin product is ideal for the most sensitive cell culture and diagnostic systems.

APPLICATIONS

- Diagnostic reagent manufacturing
- Growth medium for cell and tissue culture
- Component of hybridoma culture
- Nutritional supplement and carrier for serum-free and serum-reduced media

FEATURES / BENEFITS

- High purity, non-cytotoxic and pyrogenic for safety and successful use in biological systems
- Low interference for diagnostic assays
- Complete Origin Traceability to New Zealand, a BSE and list A Disease-free country with isolated herds
- "Closed Loop" Manufacturing* – Minimizes Contamination and Maximizes Reproducibility.
- Superior Solubility/Filterability for Ease of Use
- Product Development and Technical Services designed for maximum responsiveness and flexibility
- Produced from MAFF-NZ certified Bovine Plasma
- Manufactured According to FDA Bulk Pharmaceutical Chemical GMP's.
- Validated for Prion (TSE) Clearance

SCIENTIFIC ANALYSIS

	Specification	Typical
Protein	≥ 96.0%	99%
Purity (albumin)	≥ 98%	100%
Moisture	≤ 5.0%	< 2%
pH	6.5-7.5	7.0
Ash	< 3%	1%
Endotoxin	≤ 3 EU/mg	0.1 EU/mg
Protease	≤ 0.005 Units/mg	≤ 0.005 Units/mg
IgG	not detected	not detected

PHYSICAL CHARACTERISTICS

Proliant Bovine Serum Albumin is a highly soluble white to yellow with tan to green cast lyophilized powder. A solution of up to 30% in de-ionized water is clear to slightly hazy and virtually particulate-free.

PACKAGING

Standard package size is 10 kg. Smaller samples sizes for evaluation are available.

STORAGE RECOMMENDATIONS

Store sealed in a cool, dry environment for 3 years, and up to 5 years with re-qualification.

ORDERING INFORMATION

Please order by product name "Bovine Serum Albumin, New Zealand Source" and refer to SKU # MD00310.

*Proliant's unique "Closed Loop" Manufacturing means that we collect only in exclusive abattoirs with an approved proprietary collection system. The material undergoes ante-and post-mortem inspection to ensure it is the highest possible grade before it released for manufacture. No other manufacturer can claim this important closed link, as they must buy their raw material from outside sources and the spot market.

Once the raw material reaches our GMP plant, the material is loaded directly into the process and manufactured through a series of closed tanks, lines, filters and separation equipment. In our plant there are no exposed filter presses or open tanks, nor is any non-food grade or noxious solvent material introduced into the process. There is also no possibility of contamination with other animal-derived products or bovine tissues in our completely dedicated facility. The result is a product that is reproducibly low in interfering analytes, protease and bacterial endotoxins.

Certificate of Analysis

Date Prepared: 28, November, 2018
 Date of Manufacture: 03, February, 2017
 Date of Expiry: 02, February, 2022
 Product Description: Bovine Serum Albumin Lyophilized Powder
 Standard Grade pH 7.0
 Lot #: **NZ70340101**
 SKU #: 69100

Analysis:

<u>Analyte</u>	<u>Specification</u>	<u>Result</u>	<u>Method</u>
Purity	≥ 98.0%	100.0%	Agarose Gel
Protein (Dry Basis)	≥ 98.0%	100.3%	By calculation
Moisture	≤ 5.0%	0.6%	AOAC 930.15
Ash	< 2%	1.0%	AOAC 923.03
BlgG	None Detected	Complies	Turbidimetric Analysis
Solubility	Clear to slightly hazy.	Pass	4% Solution in H ₂ O (visual clarity)
Protease	Yellow to yellow-green None Detected	None Detected	Enzymatic Assay (Detection limit 0.005 units/mg)
pH (10% Solution)/Temp	6.5-7.5/Ambient	6.7	10% Solution in H ₂ O
pH (1% Solution)/Temp	6.5-7.5/Ambient	6.8	1% Solution in NaCl
Heavy Metals (Pb)	≤ 10 ppm	< 0.2 ppm	AOAC 984.27 (Modified)
Endotoxin	≤ 3 EU/mg	< 0.01 EU/mg	LAL
APC	≤ 1,000 cfu/g	< 10 cfu/g	AOAC 990.12
Total Coliforms MPN	≤ 100 MPN/g	< 3 MPN/g	USFDA-BAM
Salmonella	Absent/25g	Absent	PCR-Salmonella by GeneScan
E. coli by MPN	≤ 10 MPN/g	< 3 MPN/g	USFDA-BAM
Asepsis	None Detected	None Detected	Culture
BVD Virus	None Detected	None Detected	Virus Isolation
Mycoplasma	None Detected	None Detected	Culture
Pathogen Inducing Cytopathy	None Detected	None Detected	Virus Isolation
Pathogen Inducing Haemadsorption	None Detected	None Detected	Virus Isolation


K Muggeridge
 Quality Department

28 Nov 2018
 Date