MP BIO HAS AN IDEAL OPTION FOR YOUR REQUIREMENTS

New Zealand Bovine Proteins

MP BIOMEDICALS NEW ZEALAND LIMITED

A specialized manufacturer of high-quality biological products, MP Biomedicals New Zealand Limited (MP Bio NZ) has gained an international reputation for providing the highest quality bovine plasma proteins to the biopharmaceutical, animal health, diagnostic industries and research institutes.

MP Bio NZ uses chromatographic techniques for separation and purification of its proteins, as opposed to the traditional methods of cold ethanol (Cohn) fractionation and BSA stabilized heat shock. This technologically advanced process leaves the protein molecules fully intact and, in turn, leads to a higher cell culture and cell expression in bioprocessing applications. Higher cell growth and production titers results in substantial savings in terms of time and process efficiencies, thereby leading to lower costs.

The manufacturing facility is located in Auckland, New Zealand. It is equipped with world-class equipment and has a team of industry experts who can respond quickly to customer expectations.

MP Bio NZ products minimize risk due to the following factors

- **Bovine Plasma sourced only from abattoirs in New Zealand, which has a negligible BSE risk status**
- **State of the art chromatographic extraction ensures high purity, intact proteins processed without the compromising effects of traditional methods**
- **Assured and secure supply chain**
- **ISO 9001 certification and a Quality System audited to cGMP principles, the highest level of process control, consistent product quality and complete traceability**
- **Highly flexible operations to enable better product mix and customized product offerings**

QUALITY ASSURANCE

Quality is an integral part of every operation at MP Bio NZ at every step – from sourcing of raw materials to the manufacture of finished product.

All products are manufactured using New Zealand sourced raw materials. The European Food Safety Authority (EFSA) publishes a Geographical BSA-Risk Assessment (GBR), in which New Zealand is classified as Negligible BSE Risk, the lowest category possible. No BSE or List A animal diseases are present in the raw materials that MP Bio NZ uses.

MP Bio NZ has an ISO 9001 certification, and its Quality Systems are audited to cGMP standards. MP Bio NZ is also an Approved Exporter and has a Risk Management Programme (RMP/HACCP) in place, approved by New Zealand's Ministry of Primary Industries (MPI). This provides customers the assurance of complete traceability of the products that MP Bio NZ supplies.

Documentation standards at MP Bio NZ are of the highest order and can support the exacting standards that are often sought by the pharmaceutical industry, which operates in a highly regulated environment.

CONTRACT MANUFACTURING

MP Bio New Zealand has the technical skills and facilities needed to offer contract manufacturing in the following areas:

- Freeze drying of Bovine products
- Chromatographic purification of Bovine Serum
- Extraction of proteins from Bovine Plasma

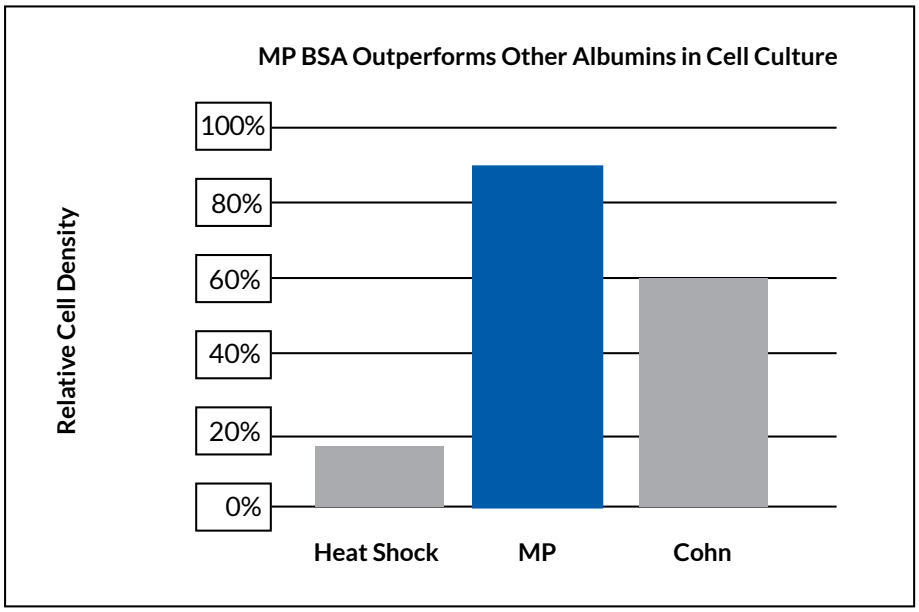
BOVINE SERUM ALBUMIN (BSA)

MP Bio AlbumiNZ™ BSA can be used in a wide range of applications, including biosimilars, media applications, stem cells, bacterial and viral vaccines, infectious disease research and embryo transfer.

The main biological function of albumin is to regulate the colloidal osmotic pressure of blood. It is also used as a transport protein since it binds water, Ca^{2+}, Na^{+}, and K^{+}, fatty acids, bilirubin, hormones and drugs.

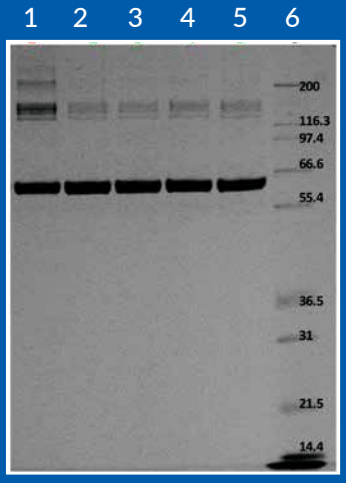
State of the art chromatographic purification process ensures

- Enhanced cell nutrition
- Greater cell number yield
- Higher value than competition
- Lipid-rich protein



MP Bio chromatographically purified bovine AlbumiNZ has demonstrated superior growth rates in cell culture (CHO and SP2/0 cells) compared with traditional Cohn and Heat Shock BSA.

NOTE *Cells were seeded in serum-free media and supplemented with various albumins in multi-well plates, with MTT analysis performed at day 3. Cell densities were calculated relative to FBS control (100%).*



10% Gel

Lane 1: Heat Shock BSA

Lane 2: AlbumiNZ™ Low Free Fatty Acid BSA

Lane 3: AlbumiNZ™ Low IgG BSA

Lane 4: AlbumiNZ™ Low Endotoxin BSA

Lane 5: AlbumiNZ™ Microbiological Grade BSA

Lane 6: MW Standards (kDa)

NOTE *SDS-PAGE reveals increased purity for the chromatographically purified AlbumiNZ, as evidenced by a higher monomer to dimer ratio and fewer bands.*

Features

- Large batch sizes of up to 240 kg
- Available as frozen liquid or lyophilized powder
- High cell processing performance resulting in high titers
- Full traceability
- Mild process avoids denaturing proteins
- Superior batch-to-batch consistency

A range of BSA for various applications

Microbiological Grade Bovine Albumin (Cat. No. 02180620)

Apart from being low in endotoxin and protease activity, this grade has a very low ammonium content. It has been found to work very well in bacterial and viral cell culture, animal vaccine production and as a media supplement in infectious disease research applications.

Low IgG Bovine Albumin (Cat. No. 02199897)

The material of choice for preparation of monoclonal antibodies, for southern and northern blots, in blocking agents for EIA and RIA assays, and in general immunoassay work. The IgG is removed using highly specific affinity chromatography, and each batch is guaranteed to have an IgG content of ≤ 0.05 mg/g of protein.

Low Free Fatty Acid Bovine Albumin (Cat. No. 02199899)

Low fatty acid bovine albumin is the material of choice for all in-vitro embryo production work, as well as a nutritional and surfactant additive for embryo transfer techniques. Used in general cell and tissue culture, in stem cell media as a supplement, and as a carrier in serum-free media. Every batch is guaranteed to have a free fatty acid content of ≤ 0.05 mg/g of protein.

Essentially Protease Free Bovine Albumin (Cat. No. 02199898)

Used in diagnostic applications or where very low or no proteolytic activity is desired. The protease content is neglible at ≤ 0.0002 units/g of protein.

Ultra-Low IgG Bovine Albumin (Cat. No. 02FC0076)

While the low IgG BSA (Cat.#02199897) has an IgG limit of up to 50 ppm, in certain applications this level becomes an antigen for cross-reacting secondary antibodies. Its presence can alter precious experimental data, resulting in reduced purification yields. These levels may also be problematic for certain recombinant protein or monoclonal antibody purification processes. For such applications, MP Bio NZ offers an ultra-low IgG grade of BSA where the IgG content is brought down to as low as 4 ppm.

Low Endotoxin Bovine Albumin (Cat. No. 02199896)

With an endotoxin limit of 1 EU/mg, this grade is used in general cell and tissue culture, as a media supplement in stem cell research and as a carrier in serum-free media.

BOVINE SERUM ALBUMIN (BSA)

Except for the low free fatty acid BSA, all other MP Bio NZ BSA grades returned a lipid content of 35 mg/g of BSA when tested by an independent laboratory. This is 2.5x higher than the lipid content in competitor BSA produced from a chromatographic and heat shock process.

This high lipid content can benefit cell culture researchers by way of reducing the need to add components such as cholesterol concentrate or other additives, and could lead to significantly higher titer values at scale.

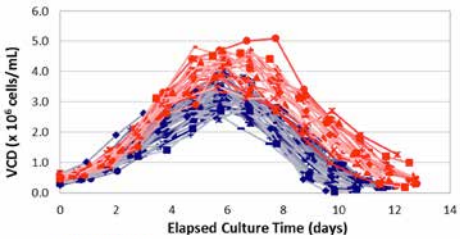
AlbumiNZ™		Microbiological Grade	Low Endotoxin	Low IgG	Ultra-low IgG	Essentially Protease Free	Low Free Fatty Acid
Cat. No.		02180620	02199896	02199897	02FC0076	02199898	02199899
Specifications							
Appearance	Off-white to light yellowish-brown powder	✓	✓	✓	✓	✓	Off-white powder
Bioburden (cfu/g)	≤ 100	✓	✓	✓	✓	✓	✓
Endotoxin (EU/mg)	≤ 1	≤ 3	✓	✓	✓	≤ 3	✓
Moisture by Karl Fischer (w/w)	≤ 5%	✓	✓	✓	✓	✓	✓
Mycoplasma	None detected	✓	✓	✓	✓	✓	✓
pH	6.5 – 7.5	✓	✓	✓	✓	✓	✓
Purity by SDS PAGE (w/w Total Protein)	≥ 97%	✓	✓	✓	✓	✓	✓
Solubility	Dissolves in ≤ 20 mins @ 15-25 °C	✓	✓	✓	✓	✓	✓
Total Protein (anhydrous w/w)	≥ 95%	✓	✓	✓	✓	✓	✓
Virus 9 CFR 113.53(c)	none detected		✓	✓		✓	✓
BVDV	none detected	✓	✓	✓	✓	✓	✓
IgG (mg/g)	≤ 0.05			✓	≤ 4 ppm		
Protease (units/mg Protein)	≤ 0.0002					✓	
Fatty Acid (mg/g)	≤ 0.05						✓

CUSTOMER TESTIMONIALS

Surpassing Industry Standards

The results shown below are a comparison between the bioprocess results using MP Bio BSA vs. an industry leading competitor. The scale of the bioreactor was 10,000 L and the processed cell line was a murine myeloma NS0. This evaluation was done by a prominent worldwide biopharma company.

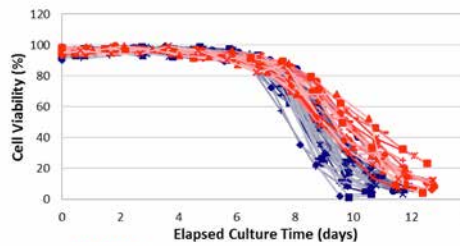
Improve your **Cell Growth**



A prominent NIAID researcher states:

"Chromatographically purified NZ BSA from MP Biomedicals has been tested successfully with parasite infected cell lines representing all major endemic continents. Additionally, DNA transfections using various selectable agents (WR99210, blasticidin S, trimethoprim) have shown to be successful and it is also compatible with the c-SNARF limiting dilution assay."

Improve your **Cell Viability**

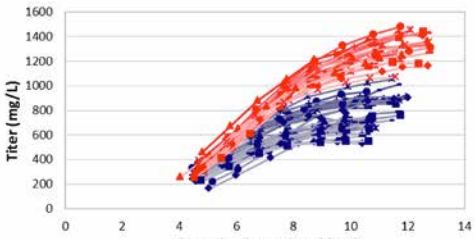


A customer on comparing the performance of AlbumiNZ with human albumin:

"Mouse embryos cultured in the New Zealand BSA had comparable cell numbers to the HSA control"

(customer evaluation, 2011)

Improve your **Productivity**



+ 52%
Improved Productivity

RED = MP Bio
BLUE = Leading Competitor

An embryo transfer customer on comparing AlbumiNZ with competitor BSA:

"The use of MP Bio-New Zealand BSA during IVF and IVC resulted in more and better quality embryos than a competitor BSA"

(Schumann, Theriogenology (2002) 57:1:527)

BOVINE THROMBIN

Thrombin (factor IIa) is a serine protease that converts fibrinogen into fibrin in blood coagulation. With its procoagulant and anticoagulant functions, it plays a significant role in thrombosis and hemostasis. It is an agonist for many cellular responses during inflammation and wound repair. Many diseases including stroke and myocardial infarction involves thrombosis, and thrombin is therefore a preferred target of antithrombotic drugs.

Drugs available to block thrombin action include heparins, hirudins (lepirudin and bivalirudin), Vitamin K antagonists and a new generation of direct thrombin inhibitors, such as Dabigatran and Argatroban.

Thrombin is used throughout the diagnostics industry in a variety of coagulation assays, clotting factor tests and defibrination of blood or plasma for serum controls. It also finds applications in clot-activated blood collection tubes, in the meat industry as a meat glue and in bio-inks to produce engineered/artificial tissue using 3D printing. Thrombin is also used for site specific cleavage of recombinant fusion proteins and in biochemical and medical research applications.

The High Specific Activity Thrombin is especially suited for use in medical devices for haemostasis. A validated 2-step virus inactivated product is available for use in such applications.

MP Bio NZ manufactures Thrombin from bovine plasma using prothrombin activated with thromboplastin extracted from bovine lung tissue.

Product Specifications

Test	High Specific Activity Thrombin (Cat. No. 02180539)	Low Specific Activity Thrombin (Cat. No. 02199907)
Packaging*	Glass Vial	Glass Vial
pH	5.7 - 6.7	7.0 - 8.0
Excipients	Sodium Citrate	For Information Only (contains Tris, HCl, NaCl)
% Protein	Report the result	≥ 50%
Thrombin Activity (Units / mg powder)	Report the result	Report the result
Thrombin Specific Activity (NIH Units / mg Protein)	> 2000	90 – 300

*Low Specific Activity Thrombin is also available as a bulk lyophilized powder in customized pack sizes of 75 MU or higher.

BOVINE FIBRINOGEN

Fibrinogen is a blood protein that is involved in the clotting cascade and converts to Fibrin in the presence of Thrombin.

Bovine Fibrinogen has been used in the study of haemostatic therapy in surgical and massive trauma patients. These studies have shown that Fibrinogen may prove to be more superior in stopping blood loss when compared to using fresh frozen plasma (FFP).

Fibrinogen can be used for preparation of Fibrin plates for analysis of fibrinolytic enzymes, as a substrate for clotting assays, and in the study of Fibrinogen degradation products.

MP Bio NZ manufactured Bovine Fibrinogen is 90% clottable and is supplied as a lyophilized powder.

Product Specifications

Test	Fibrinogen (Cat. No. 0882022)
Protein, Biuret	For Information - typically > 60%
% Clottable Protein, Biuret w/w	≥ 90%
Excipients	For Information - Trisodium Citrate, NaCl, Tween 80
Moisture by Karl Fischer	For Information - typically ≤ 10%
pH	For Information - typically between 5 - 7

BOVINE IMMUNOGLOBULIN G

Immunoglobulins, or Gamma Globulins, are plasma proteins with broad binding capacity. Produced by cells of the immune system, these proteins are designed to bind invading organisms such as bacteria and viruses, leading to their destruction. Immunoglobulin G (IgG) is the most prominent form.

MP Bio NZ Immunoglobulin G is a high purity, lyophilized powder, captured with a high specificity from pooled bovine plasma using a full chromatographic method. The technology gently extracts the IgG, maintaining the native configuration throughout the process.

Applications of IgG

- **Blocking reagent in immunoassays – ELISA, Western blotting, immune-diffusion**
- **Reference antigen or standard**
- **For conjugation of molecules requiring highly purified immunoglobulin**
- **Used in the manufacture of diagnostic kits**

Product Specifications

Test	IgG (Cat. No. 0864140)
Purity (SDS - PAGE), w/w Total Protein*	≥ 95%
Total Protein (anhydrous - Kjeldahl Nitrogen) , w/w	≥ 97%
pH (4% w/v Solution)	4.0 - 5.0
Moisture (Karl Fischer), w/w	≤ 10%
Sodium (ICP OES), w/w	≤ 1.5%
Chloride (Potentiometric Titration), w/w	≤ 2.4%

* Technical Grade IgG with a purity of ≥ 90% is also available

BOVINE TRANSFERRIN

Iron is an essential growth nutrient in almost all living organisms and is toxic in its free form. It must thus be carried by proteins such as Transferrin, which has the capacity to bind ferric ions. Transferrin is hence considered the most 'natural' means of managing iron transport.

Transferrin is the major serum protein produced in the liver and secreted into the blood. It is responsible for the transport of iron in almost all cell types. In cell culture applications, Transferrin is used to control iron metabolism. It is also used as a nutrient in cell and microbial culture and as a media supplement in the production of biopharmaceutical products.

MP Bio New Zealand offers two forms of Transferrin viz

- Holo-transferrin - Saturated with iron Fe^{3+} and used to supply iron in cell culture media
- Apo-transferrin - free of iron and used to remove iron in cell culture media
- Both forms of Transferrin are subjected to pasteurization (10 hr at 60 °C)
- Extracted using chromatographic methods

Primary applications of Transferrin

- Aids in prevention of iron toxicity in mammalian cell culture systems
- Assists in controlling iron metabolism in cell culture systems
- An integral part of serum-free or reduced-serum media
- Used in bio-manufacturing and tissue culture

Product Specifications

Test	HOLO Transferrin (Cat. No. 02152335)	APO Transferrin (Cat. No. 02152334)
Appearance	Red to Brown Powder	Off-white to Pink
Bioburden (CFU/g)	≤ 100	≤ 100
Endotoxin (EU/mg)	≤ 1	≤ 1
Iron (µg/g protein)	≥ 1200	≤ 40
Moisture by Karl Fischer, w/w	≤ 5%	≤ 5%
Mycoplasma	None Detected	None Detected
pH	6.0 – 8.0	7.0 – 8.0
Purity (SDS-PAGE), w/w Total Protein	≥ 95%	≥ 95%
Solubility (3% w/v in water)	Dissolves in ≤ 20 minutes at 20 - 25 °C	Dissolves in ≤ 20 minutes at 20 - 25 °C
Total Protein, anhydrous - Kjeldahl Nitrogen, w/w	≥ 95%	≥ 95%
Virus 9CFR 113.53(c)	Not Detected	Not Detected

MP™

MP Biomedicals

MP BIOMEDICALS

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