



MP Biomedicals - New Zealand Proteins



MP Bio New Zealand Proteins are
Chromatographically extracted from Bovine Plasma,
under Quality Systems that are ISO Certified
and Audited to cGMP Principles.

**MP Biomedicals has an ideal option
for your requirements.**

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Proteins

MP Biomedicals New Zealand Limited.

A specialized manufacturer of high quality biological products, MP Biomedicals New Zealand Limited has gained an international reputation in providing bovine plasma proteins to the bio-pharmaceutical, animal health and diagnostic industry. New Zealand sourced bovine plasma coupled with an ISO 9001 and cGMP audited quality system, that are further endorsed by EDQM TSE Certificates of Suitability (CEP) for key products, aim at the highest product quality standard in the bovine blood plasma industry.

As a manufacturer of the highest quality of bovine plasma proteins for the global market, MP Biomedicals New Zealand minimizes your risks due to the following factors:

- Bovine Plasma sourced only from within New Zealand, which has a negligible BSE risk status
- State of the art chromatographic extraction ensures high purity, intact proteins, processed without the compromising effect of traditional methods.
- Assured and secure supply chain
- An ISO 9001 certificate, and a Quality System audited to cGMP principles, ensure the highest level of process control and consistent product quality.
- Ministry of Primary Industries (MPI) approved manufacturing facility that ensures complete traceability.
- Highly flexible operations to enable better product mix and customized product offerings

MP Biomedicals New Zealand uses the chromatographic technique for separation and purification of its proteins, as opposed to the traditional methods of cold ethanol (Cohn) fractionation and BSA stabilised heat shock. This technologically advanced process leaves the protein molecules fully intact, and in turn leads to a higher cell culture and cell expression performance in the bio-processing applications for our customers. Higher performances in cell growth and production titres result in substantial savings in terms of time and process efficiencies, thereby leading to lower costs.

Quality Assurance

Quality is an integral part of every step of MP Biomedicals New Zealand's operations – right from sourcing of raw materials to the manufacture of finished product ready to leave the site.

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 we use.

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

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

Bovine Thrombin

Thrombin (factor IIa) is a serine protease that converts fibrinogen into fibrin in blood coagulation. The precursor of thrombin, prothrombin (inactive zymogen), is one of the several coagulation proteins containing γ -carboxyglutamic acid. Prothrombin is synthesized in the liver and secreted into blood circulation, and is activated by vascular injury by limited proteolysis following upstream activation of the coagulation cascade. Thrombin activity is regulated by serum inhibitors and by its own action.

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 involve thrombosis; therefore, thrombin is 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. Thrombin is also used for site specific cleavage of recombinant fusion proteins, and in biochemical and medical research applications.

MP Biomedicals manufactures Thrombin from bovine plasma using prothrombin activated with thromboplastin extracted from bovine lung tissue. All materials are New Zealand sourced.

Grades:

Type	Packing
Low Specific Activity	Glass Vial
	Bulk Container
High Specific Activity*	-

* We are currently working on High Specific Activity Thrombin (> 2000 Units/mg protein), and can supply samples for evaluation.

Product Specifications:

Test	Low Specific Activity Thrombin (Cat.# 02199907)
pH	7.0 - 8.0
Excipients	For Information Only (contains Tris, HCl, NaCl)
Protein	$\geq 50\%$
Thrombin Activity (Units/mg powder)	Report the result
Thrombin Specific Activity (Units/mg Protein)	90 - 300



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Singapore: 65.6775.0008
Korea, South: 82.2.425.5991

Australia: 61.2.8824.2100
China: 86.4000.150.0680
India: 91.22.27636921/22/24
New Zealand: 64.9.912.2460

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 bio-pharmaceutical products.

MP Biomedicals New Zealand offers 2 forms of Transferrin viz:

- Holo-transferrin - Saturated with iron (contains two molecules of Fe³⁺), and is used to supply iron in cell culture media
- Apo-transferrin - Iron-free (unsaturated), and is used to remove iron in cell culture media

Primary applications of Transferrin

- aids in prevention of iron toxicity in mammalian cell culture systems
- assist 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

Grades:

Type
Bovine Transferrin - HOLO
Bovine Transferrin - APO *

* Samples available. Process yet to be scaled-up.

Product Specifications:

Test	HOLO Transferrin (Cat.# 02152335)	APO Transferrin (Cat.# 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	Dissolves completely in 20 minutes at 20-25 °C	Dissolves completely 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

Bovine Fibrinogen

Fibrinogen is a blood protein that is involved in the clotting cascade and is converted to Fibrin in the presence of Thrombin. Thrombin rapidly proteolyzes Fibrinogen, releasing fibrinopeptide A. Thrombin then cleaves a second peptide, fibrinopeptide B, from Fibrin and the Fibrin monomers formed then polymerize spontaneously to form an insoluble gel. The insoluble Fibrin aggregates (clots), and the aggregated platelets then block the damaged blood vessel and prevent further bleeding. The amount of fibrinogen in the plasma can serve as a nonspecific indicator of whether an inflammatory process is present in the body. Fibrinogen from any mammalian source will be cleaved by thrombin from any mammalian source.

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

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

Product Specifications:

Test	Fibrinogen (Cat.#0882022)
% Protein, Biuret	For Information - typically > 70%
% 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

Uncompromised Reliability, Tangible Benefits, Minimum Risk



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Bovine Immunoglobulin G (IgG)

Immunoglobulins 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.

Applications of IgG:

- As a blocking reagent in immunoassays – ELISA, Western blotting, immune-diffusion
- Used as a reference antigen or standard
- For conjugation of molecules requiring highly purified immunoglobulin
- Used in the manufacture of diagnostic kits

MP Biomedicals 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. The product is readily soluble in saline and standard buffers, for ease of use.

Product Specifications:

Test	IgG (Cat.#0864140)
Appearance	Off-white powder
Purity (SDS - PAGE), w/w Total Protein	≥ 95%
Total Protein (anhydrous - Kjeldahl Nitrogen) , w/w	≥ 96%
pH (4% w/v Solution)	6.8 - 7.2
Moisture (Karl Fischer), w/w	≤ 5%
Sodium (ICP OES), w/w	≤ 1.5%
Chloride (Potentiometric Titration), w/w	≤ 2.4%



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Contract Manufacturing

MP Biomedicals New Zealand has the technical skills and the 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

New Products Coming Soon

MP Biomedicals New Zealand is currently working on the following newer products:

- Zero Fatty Acid BSA
- Nutritional Grade Bovine IGG
- BSA + Transferrin combination product
- High Specific Activity Thrombin (>2000 units/mg)
- Molecular Biology Grade Albumin
- Sterile Liquid BSA



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