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.

www.mpbio.com

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.

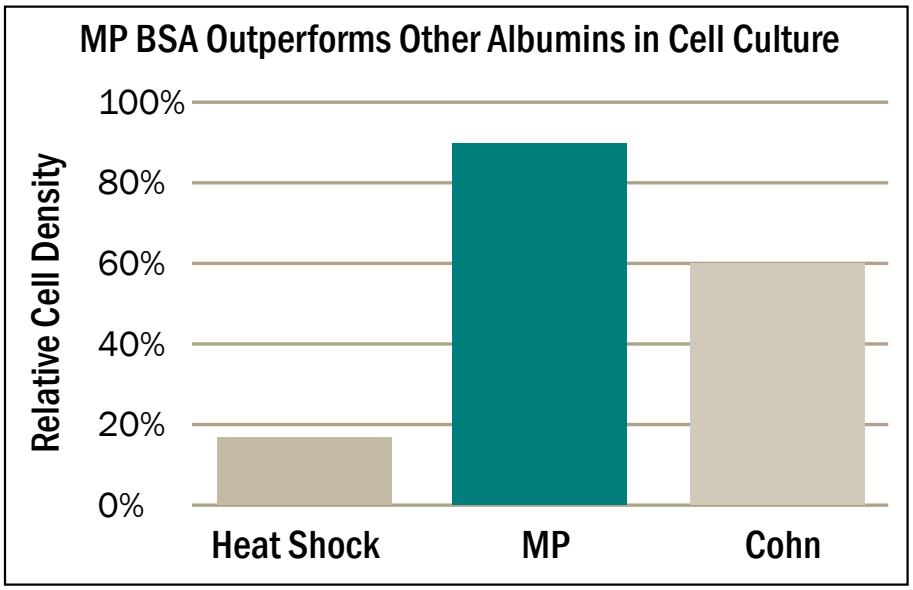
Documentation standards at MP Biomedicals are of the highest order and can cater to the exacting standards that are often sought by the pharmaceutical industry, which operates in a highly regulated environment.

New Zealand Bovine Serum Albumin (BSA) from MP Biomedicals

MP Biomedicals AlbumiNZ range of products is produced at its Auckland manufacturing site in New Zealand, with bovine plasma sourced from abattoirs in New Zealand. This allows MP Biomedicals total control over raw materials, and the end-to-end production processes. It also offers its customers the assurance that they have selected the finest BSA available globally.

- State of the art chromatographic purification process ensuring
    - Enhanced cell nutrition
    - Greater cell number yield.
    - Lipid-rich protein
    - Greater value than competition
    - Range of applications in biosimilars, and in various media applications in stem cells, vaccines, infectious disease, and embryo transfer

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



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

Uncompromised Reliability, Tangible Benefits, Minimum Risk

Features:

- Purified by chromatography
- From NZ BSE Free sourced bovine plasma
- Produced within cGMP certified and ISO 9001:2008 Quality system
- Large batch sizes ~160kgs, which can be increased to 240kg by special agreement
- Certified supply chain
- Available in liquid or powder

Benefits:

- High cell processing performance resulting in high titers
- Superior consistency from batch to batch
- Full traceability
- Full quality certification
- No denatured protein

Microbiological Grade Bovine Albumin (Cat. # 02180620)

Used for cell culture, animal vaccine productions and infectious disease media supplement.

Low Endotoxin Bovine Albumin (Cat. # 02199896)

Used for general cell and tissue culture, in stem cell media as a supplement, as a carrier in serum-free media and as a nutritional supplement.

Low IgG Bovine Albumins (Cat # 02199897)

The material of choice for preparation of monoclonal antibodies, for southern and northern blots, in blocking for EIA and RIA assays and general immunoassay work. We remove the IgG by highly specific affinity chromatography ensuring it will not co-purify during downstream processing of antibodies, not be erroneously recognized and measured in general immunoassay's. Every batch is guaranteed to have an IgG content of ≤ 0.05 mg/g of Protein.

Low Fatty Acid Bovine Albumin (Cat # 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 for general cell and tissue culture, in stem cell media as a supplement, as a carrier in serum-free media and as a nutritional supplement. At MP Biomedicals, we take selected lots of low endotoxin bovine albumins, which are then chromatographically depleted of fatty acids and other small molecules. Every batch is guaranteed to have a free fatty acid content of ≤ 0.05 mg/g of Protein.

Protease-reduced Bovine Albumin (Cat. # 02199898)

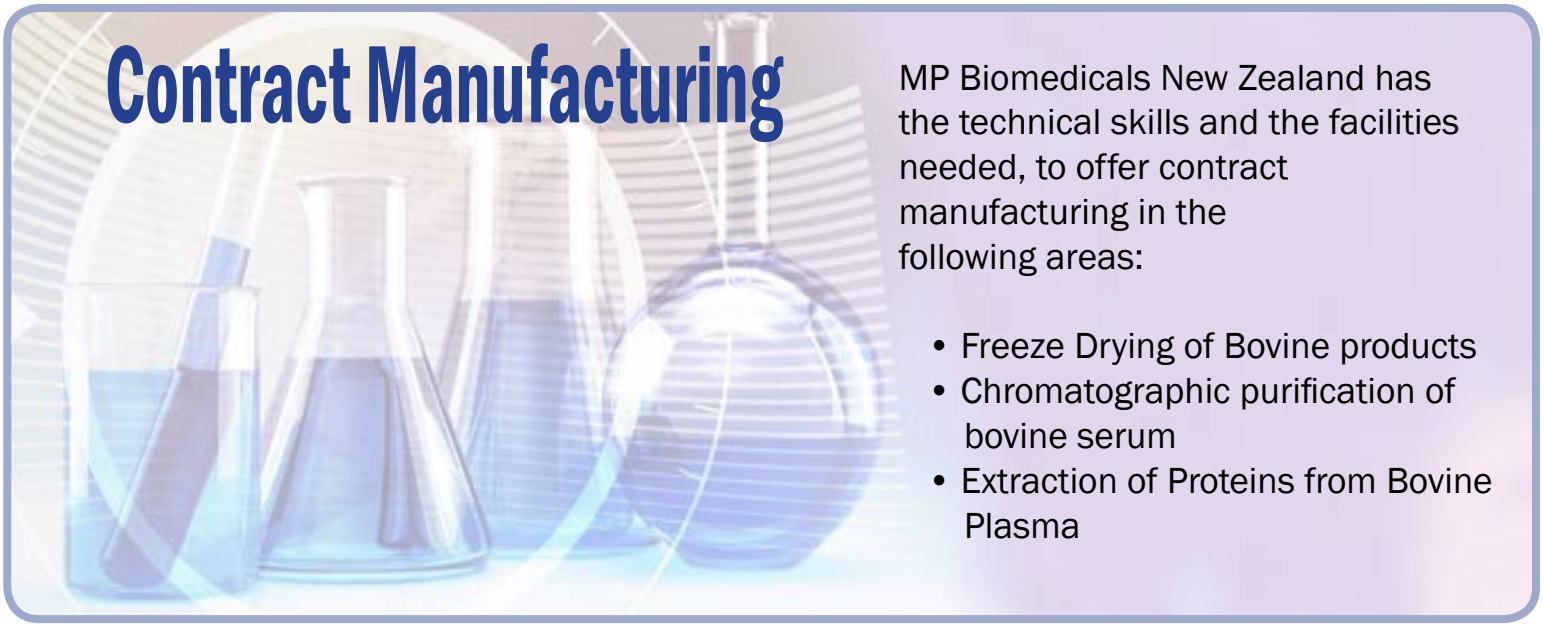
Used in diagnostic applications or where very low or no proteolytic activity is essential. The Protease content is almost nil at ≤ 0.0002 units/g of Protein.

Ultra-Low IgG Bovine Albumin (Cat.# 02FC0076)

Low IgG BSA's typically have an IgG content of up to 50 ppm. In certain applications, this level of IgG becomes an antigen for cross-reacting secondary antibodies, and 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. Hence the need for an Ultra-low IgG BSA with a very low content of IgG. MP Biomedicals offer an ultra-low IgG grade of BSA where the IgG content is brought down to as low as 5 ppm.

New Zealand Bovine Serum Albumin (BSA) Specifications

AlbumiNZ™		Microbiological Grade	Low Endotoxin	Low IgG	Ultra-low IgG	Protease Reduced	Low Fatty Acid
Product Number		02180620	02199896	02199897	02FC0076	02199898	02199899
Specifications							
Appearance	Off-white to light yellowish-brown Powder	•	•	•	•	•	•
Bioburden (cfu/g)	≤100	•	•	•	•		•
Endotoxin (EU/mg)	≤1	•	•	•	•		•
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 deg C	•	•	•	•	•	•
Total Protein (anhydrous w/w)	≥95%	•	•	•	•	•	•
Virus 9 CFR 113.53(c)	none detected		•	•			•
IgG (mg/g)	≤0.05			•	≤ 4 ppm		
Protease (units/mg Protein)	≤0.0002					•	
Fatty Acid (mg/g)	≤0.05						•



Contract Manufacturing

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

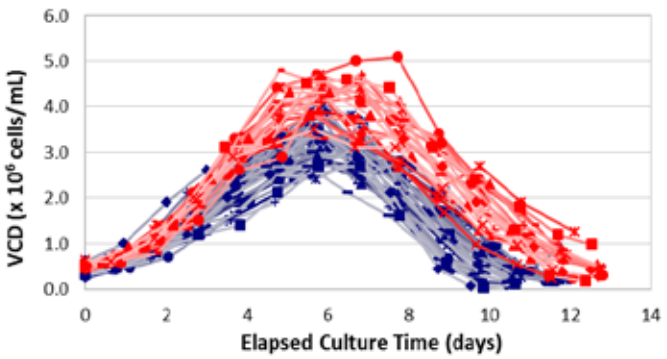
- Freeze Drying of Bovine products
- Chromatographic purification of bovine serum
- Extraction of Proteins from Bovine Plasma

MP Biomedicals Albumin Unsurpassed Performance in Cell Culture

Surpassing Industry Standards.

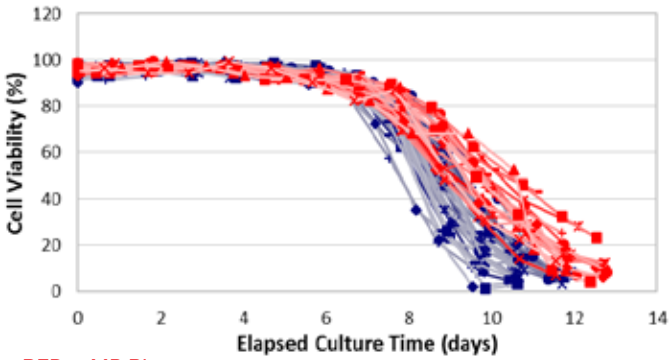
The results shown below are a comparison between the bioprocess results using MP Biomedicals New Zealand BSA vs. an Industry leading competitor. The scale of the bioreactor was 10,000 L and the processed cell line was a murine myeloma NSA. This evaluation was done by a prominent worldwide biopharma company.

Improve your **Cell Growth**



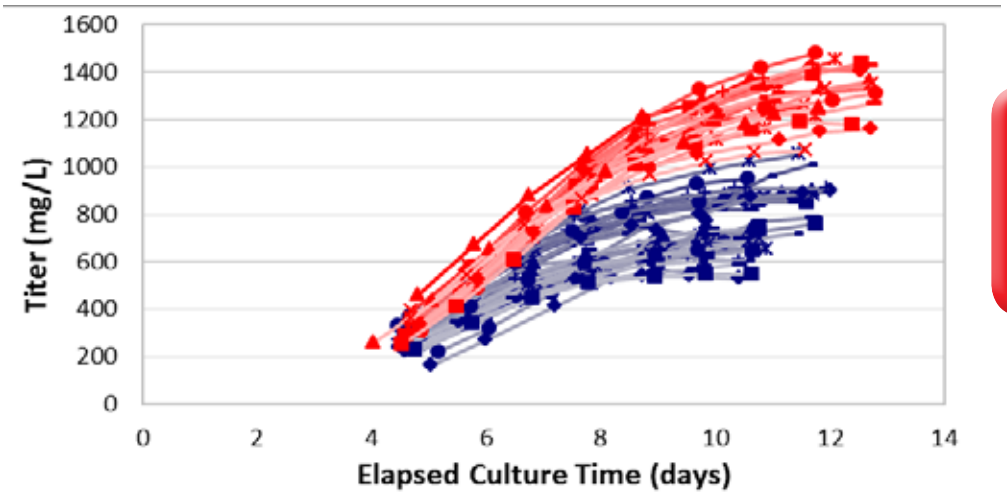
RED = MP Bio
BLUE = Leading Competitor

Improve your **Cell Viability**



RED = MP Bio
BLUE = Leading Competitor

Improve your **Productivity**



+52%

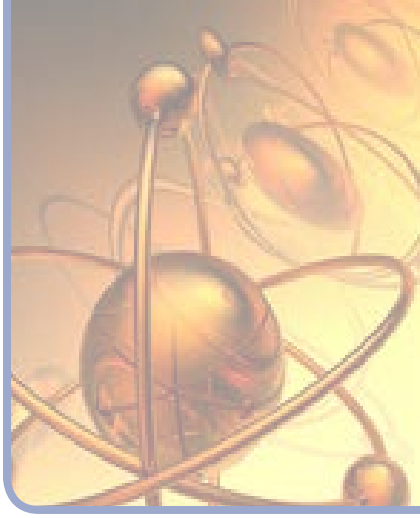
Improved Productivity

RED = MP Bio
BLUE = Leading Competitor

MP Biomedicals Albumin Quick Reference Guide

AlbumiNZ™	Microbiological Grade	Low Endotoxin	Low Fatty Acid	Protease Reduced	Low IgG
Product Number	02180620	02199896	02199899	02199898	02199897
Applications					
Culture Media, Animal Cells		•			•
Culture Media, Microbes	•				
Stem Cell Culture		•	•		
Embryo Cell Culture			•		
Serum-Free Media		•	•		•
Infectious Disease Media	•				
Monoclonal Antibody Production		•			•
Vaccines (Human & Animal)	•				
Blocking Reagent In:					
Particle Immunoassay's		•		•	
EIA/RIA		•		•	
ELISA		•		•	
Stabilizing/Enhancing Diluent in:					
Enzyme systems		•		•	•
RIA systems		•		•	
Binding & Transport Studies		•	•	•	
Protein Standard		•		•	
Elisa (block non-specific binding)		•		•	
As Carrier Protein for Haptens		•	•	•	
Animal Perfusion Studies		•	•		•

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

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	≥ 50%
Thrombin Activity (Units/mg powder)	Report the result
Thrombin Specific Activity (Units/mg Protein)	90 - 300

NA: 800.854.0530
EU: 00800.7777.9999
Japan: 03.6667.0730
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 Fe^{3+}), 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.

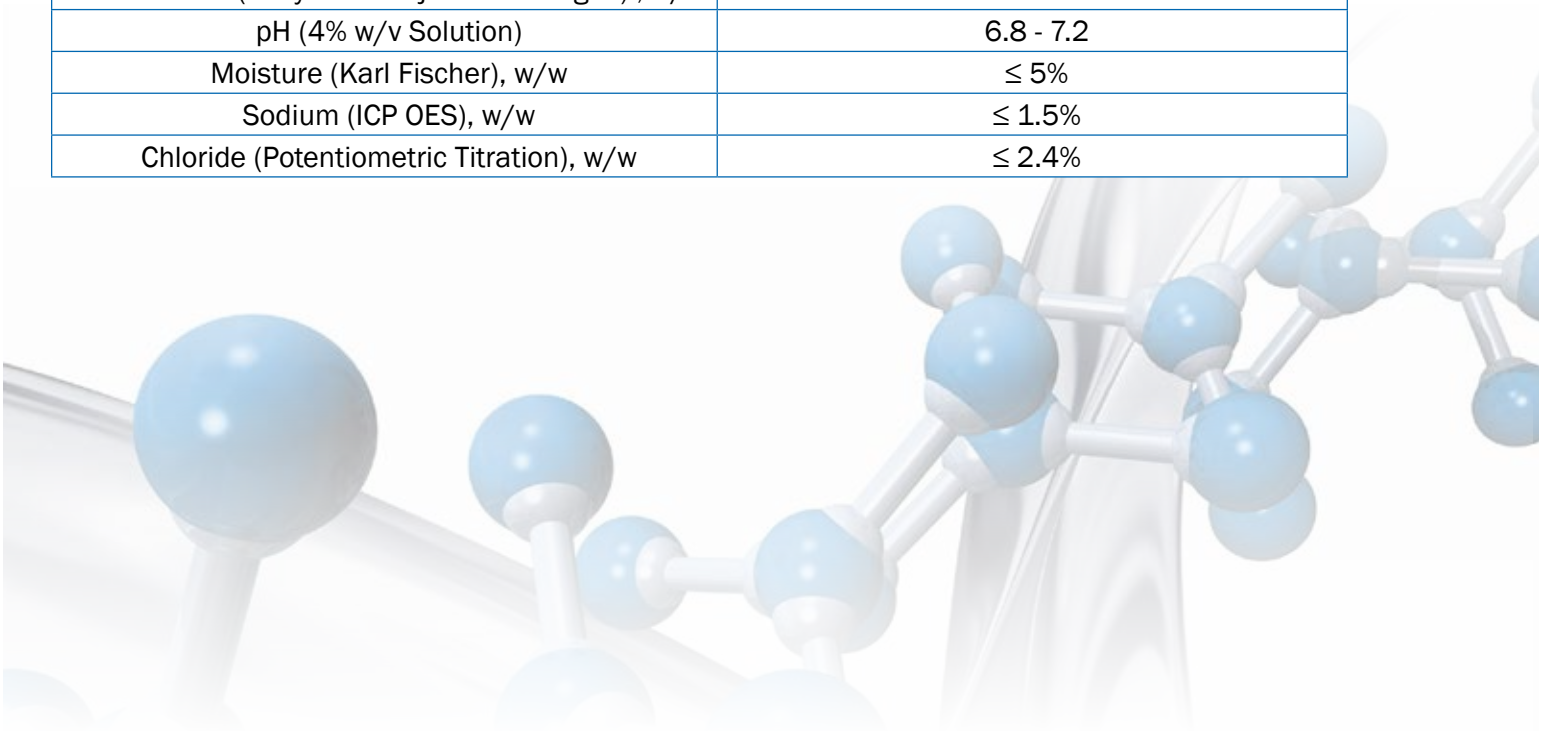
Applications of IgG:

- 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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