

Blog

Home / IVIG / How Is IVIG Made? The Intricate Steps of IVIG Manufacturing Revealed

🔍 Search

IVIG

How Is IVIG Made? The Intricate Steps of IVIG Manufacturing Revealed

By [Dr. Samantha Kaeberlein, PharmD](#) Updated on March 24, 2026



Intravenous immunoglobulin (IVIG) is a therapeutic product prepared from the pooled plasma of thousands of donors. Human plasma contains several essential components, including immunoglobulins (Ig), also known as antibodies. Immunoglobulins are important components of the immune system and help the body fight infections.

Ask About IVIG Home Infusion

(877) 778-0318

The process of purifying immunoglobulin from plasma to create patient therapies is complex and time-intensive. It takes approximately 9 months to produce a batch of IVIG products for therapeutic use.

The final IVIG product consists of a mixture of antibodies that are administered intravenously into the patient's bloodstream.

In this article, we will discuss the series of steps that every manufacturer follows to produce a final sterile solution of IVIG for therapeutic use.



1. IVIG Production Process

1.1. Collection of Plasma

1.2. Plasma Fractionation

1.3. Purification of IVIG

1.4. Removal of Harmful Pathogens

1.5. Formulation and Composition of IVIG

1.6. Final Testing and Packaging of IVIG

2. Conclusion

IVIG Production Process

The steps involved in the production of IVIG include plasma collection, fractionation, purification, formulation, testing, and packaging.

Collection of Plasma

The manufacturing process of IVIG begins with the collection of plasma from thousands of healthy donors. Donors are selected through rigorous screening to ensure the highest quality and safety of plasma.

Plasma used for IVIG production is obtained from two sources: About **20% comes from blood donors**, while the remaining **80% comes from plasma donors**.

Since immunoglobulins are a small part of plasma, many donations are required to produce enough IVIG to treat patients. For example, producing enough IG to treat one immune-deficient patient for a year takes about 130 donations from healthy individuals.

Plasma Fractionation

After blood plasma collection, a series of fractionation processes take place, during which plasma proteins such as immunoglobulins, clotting factors, and albumin are separated from other plasma components.

Cohn's fractionation technique, developed by Edwin J. Cohn in World War II, is typically followed, with some newer modifications, to extract a concentrated immunoglobulin solution from plasma. In this technique, small amounts of alcohol (ethanol) are used to reduce pH and ionic strength in order to separate albumin and other plasma proteins based on their solubility.

During the process, the temperature is kept low to decrease the possibility of contamination and allow large-scale fractionation.

Purification of IVIG

Once the immunoglobulins are separated via fractionation methods, rigorous purification ensues to produce a concentrated immunoglobulins solution. The purification process removes inactive proteins, impurities, and contaminants from the solution. For the purification of immunoglobulins, different chromatography methods, such as ion exchange chromatography using DEAE Sephadex®, hydrophobic charge induction chromatography, and size exclusion chromatography, are followed.



Each chromatography technique is unique and yields 95% – 97% of highly purified IgG from small volumes of human plasma in a one-step purification process. For instance, DEAE Sephadex® column chromatography produces a highly purified 95% IgG solution.

In contrast, size exclusion chromatography helps to separate the different forms of IgG immunoglobulin based on their respective size from the pooled plasma.

Furthermore, chromatographic procedures also help to remove an IgA immunoglobulin, which can cause severe anaphylactic shock in patients with IgA deficiency and have anti-IgA antibodies in their blood.

Removal of Harmful Pathogens

Since IVIG is composed of plasma pools from thousands of donors, there is a chance that a virus such as HIV or Hepatitis C may be contained in a sample. Although much care is taken when choosing IVIG donors by completing donor screening and checking donated samples for viruses or bacteria, the use of a fractionation process is vital in obtaining a high level of purity in a sample.

Furthermore, several methods are designed to remove or inactivate the viral pathogens, as follows:

- **Solvent/detergent (S/D) treatment** inactivates viruses by applying chemicals that destroy their outer coating (envelope).
- **Pasteurization** is a process in which IVIG solution is heated to 60 °C for 10 hours.
- **UVC radiation and low-dose radiation** methods are used to destroy the virus by attacking its genetic makeup.
- **Low pH treatment** disrupts the protective layer of the virus and changes protein conformation.
- **Nanofiltration** is a type of ultrafiltration method in which an IVIG solution passes through a membrane (filter) whose holes are too small for a virus to fit through.

Can IVIG help? | Free IVIG Treatment Info

[Schedule a Consultation](#)

Formulation and Composition of IVIG

Once IVIG is purified, it undergoes a formulation and stabilization process to ensure its efficacy and stability. Manufacturers formulate and stabilize the IVIG solution by adjusting the pH and adding stabilizing agents such as sugar or amino acids. This step makes each IVIG product differ in terms of formulation and composition.

Final Testing and Packaging of IVIG

IVIG products undergo stringent testing and quality control procedures throughout the production process. A variety of tests and assays are conducted to remove the pollutants, viral pathogens, or prions.

Once the quality control tests are completed, the final product is transferred to vials under an aseptic environment and incubated for several weeks to ensure high quality and safety.

After the final inspection, IVIG is labeled, packaged, and delivered to healthcare facilities for therapeutic use.

Conclusion

IVIG is made from the pooled plasma of thousands of donors, which is then purified through rigorous purification and quality control methods. From the collection of plasma to the formulation of sterile IVIG solution, good collection practices are followed at every step to ensure the product's safety, efficacy, and quality.

REFERENCES:



This information is not a substitute for medical advice or treatment. Talk to your doctor or healthcare provider about your medical condition prior to starting any new treatment. AmeriPharma® Specialty Care assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result, nor is it responsible for the reliability of the content. AmeriPharma® Specialty Care does not operate all the websites/organizations listed here, nor is it responsible for the availability or reliability of their content. These listings do not imply or constitute an endorsement, sponsorship, or recommendation by AmeriPharma® Specialty Care. This webpage may contain references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with AmeriPharma® Specialty Care.



MEDICALLY REVIEWED BY

Dr. Samantha Kaeberlein, PharmD

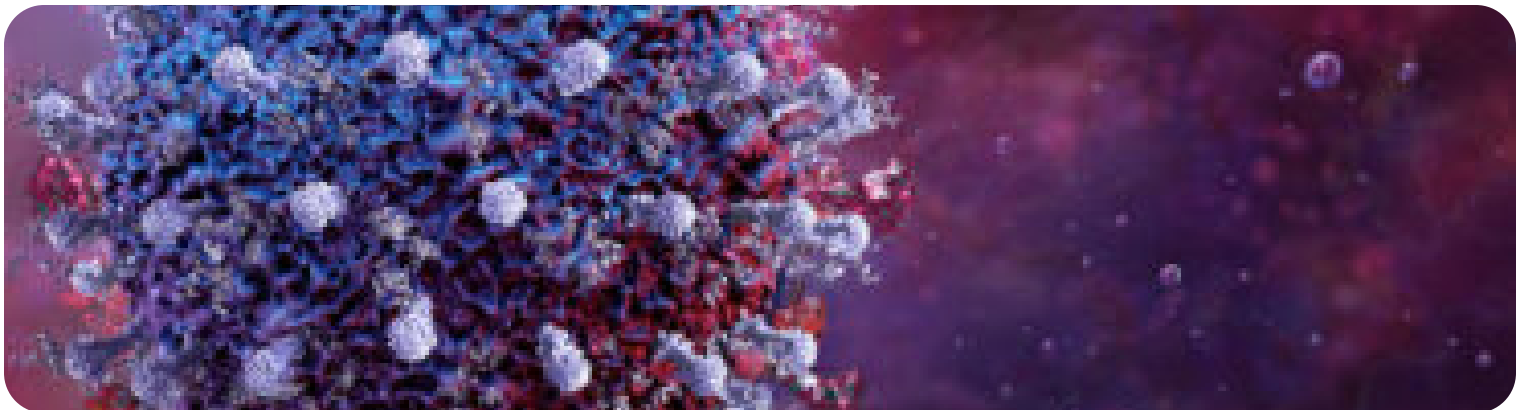
Dr. Samantha Kaeberlein, PharmD was born and raised in Canton, OH. She received her pharmacy degree from Northeast Ohio Medical University (NEOMED) in 2020. The most rewarding part of her job is providing medical guidance so patients can make informed, well-rounded decisions regarding their healthcare. Her areas of expertise are geriatrics and long-term care. In her free time, she enjoys spending time outdoors, reading, and hunting for the best cup of coffee in America.

RELATED POSTS



[IVIG](#)

IVIG Mechanism Of Action: A Detailed Look



[IVIG](#)

IVIG For Long COVID: Early Findings Suggest Potential Relief For Patients



IVIG

IVIG For Collagen-Vascular Disease-Associated Secondary Immunosuppression

RECENT POSTS

- [Alymsys for Cancer: Uses, How It Works, and Side Effects](#)
- [Myasthenia Gravis and Vaccines: What You Should Know](#)
- [Retacrit for Anemia: Benefits, Risks, Dosage, and Pricing](#)
- [Myasthenia Gravis and Exercise: Tips for Staying Active and Healthy](#)

[Lumakras for Cancer: Uses, How It Works, Benefits, and Risks](#)

CATEGORIES

Autoimmune Treatment	Cancer	CIDP	Discontinued	
Guillain-Barre Syndrome	Hemophilia	Hepatitis C	HIV	IVIG
Lambert-Eaton syndrome	Medicare	Multiple Sclerosis	Myasthenia Gravis	
Other Health Conditions	Rheumatoid Arthritis	TPN		

Related Posts

IVIG

IVIG for Major Burns Associated Secondary Immunosuppression

IVIG for Hematologic Malignancy-Associated Secondary Immunosuppression: Key Insights, Based on the Latest Evidence

IVIG For Major Surgery-Associated Secondary Immunosuppression

IVIG for Hyperimmunoglobulinemia E Syndrome (HIES)

When to Consider IVIG for Macrophage Activation Syndrome (MAS): Key Insights, Based on the Latest Evidence

IVIG for Hematophagocytic Lymphohistiocytosis (HLH)

IVIG

IVIG for Parvovirus B19-Induced Pure Red Cell Aplasia: Benefits, Success Rates, and Treatment Insights

IVIG

IVIG for Isoimmune Hemolytic Disease of the Newborn (HDN)

IVIG

IVIG for CAR-T Therapy-Related Hypogammaglobulinemia: Uses, Benefits, Dosage, and More

IVIG

IVIg for Bone Marrow Transplant: Is IVIg Therapy Actually Effective?

IVIg

IVIg for Opsoclonus-Myoclonus Syndrome (OMS)

IVIg

IVIg for Post-Transfusion Purpura: A Comprehensive Guide to Its Use and Doses

Contact Us

If you are interested in speaking to a specialist or wish to explore financial assistance opportunities, use the contact form below to get in touch with us.



By submitting, you agree to AmeriPharma's [Terms of Use](#), [Privacy Policy](#), and [Notice of Privacy Practices](#)

AmeriPharma® Specialty Care offers a broad range of specialty medications, including oral treatments, injectables, and home infusions. AmeriPharma handles prior authorizations, facilitates copay assistance, and coordinates care and nursing services in over 40+ US states and territories.

Phone: (877) 778-0318

Fax: (877) 778-0399

Email: info@ameripharma.us

Open on all federal holidays

24/7/365 Phone support

Patient Services

Home Infusion

Packaging & Delivery

Patient Advocacy

Financial Assistance

Conditions & Treatments

IVIG

Total Parenteral Nutrition (TPN)

Autoimmune Biologics

At-Home Autoimmune Neuromuscular Disease Treatment

Hemophilia

Cancer and Chemotherapy Treatment

Organ Transplant Rejection

Follow Us

AMERIPHARMA SERVICES

Infusion Center

MedBox

CorsanaCare

© 2026 AmeriPharma® Specialty Care. All Rights Reserved.

[Privacy Policy](#)

[Terms of Use](#)

[Notice of Privacy Practices](#)

[Notice of Nondiscrimination](#)

