Biotest

From Nature for Life

Solid Foundation Continuous Innovation

Solid Foundation
Continuous Innovation

"As specialists in collection of plasma, our extraordinarily stringent standards are designed to provide high-quality products in the most efficient—as well as effective—way possible."

Janice Smith, Vice President, Quality Operations,
Biotest Pharmaceuticals Corporation

For a listing of or more information about our plasma collection centers, please see the Biotest Pharmaceuticals Corporation Web site:

www.biotestplasma.com

The Foundation

Solid Foundation

Biotest AG ("Biotest") is a German-based global provider of plasma protein therapies, with a specialization in clinical immunology, hematology, and intensive care medicine. Biotest markets products in about 90 countries worldwide. These products meet or exceed standards for safety and efficacy in all countries where they are sold.

Biotest was founded in 1946 and focused on research in blood typing serology. Biotest's first commercial product, introduced in 1948, was the test serum anti-D, one of the first of its kind, which was used for the determination of the Rhesus factor. Since then, Biotest has been producing plasma proteins for over 60 years, and is one of the world's leading suppliers of plasma-derived therapeutics.

Biotest formed Biotest Pharmaceuticals Corporation ("Biotest Pharmaceuticals"), as a US subsidiary in 2007, with the purchase of Nabi Biopharmaceuticals' biologics strategic business unit, consisting of Nabi-HB® and other plasma business assets, including a plasma protein production plant and plasma collection centers across the United States. Biotest Pharmaceuticals is headquartered in Boca Raton, Florida. During the past 4 years, Biotest has invested over $50 million to expand and modernize the US manufacturing facility.

PLASMA COLLECTION FACILITIES

Biotest Pharmaceuticals is dedicated to the development, research, and manufacture of products of the highest quality. We apply the same high-quality standards from the time the plasma is collected, through manufacturing, to finished product delivery. Biotest Pharmaceuticals' plasma centers are state-of-the-art collection facilities staffed with qualified personnel, who are dedicated to the safety and reliability of our plasma supply.

Each plasma center undergoes inspection, approval, and licensing by multiple regulatory agencies, including the Food and Drug Administration (FDA), the German Health Authorities (GHA), as well as other international agencies. Additionally, each FDA licensed center is certified by the International Quality Plasma Program (IQPP), complying with the stringent Plasma Protein Therapeutics Association's (PPTA) voluntary standards when collecting, processing, and testing plasma donations. The IQPP standards go beyond established regulatory requirements in assuring the safety of the raw material. Our plasma centers operate in a manner to ensure quality control, avoid product shortages, and honor the strong commitment we have made to our customers.

To further ensure the safety and quality of the plasma we collect, all plasma donors undergo a medical examination and a confidential medical history interview. Prior to each donation, all donors must go through a rigorous screening and testing process to ensure they are healthy and meet all regulatory requirements before their plasma is accepted for use. Any plasma unit, which tests positive for a virus, is not used in the production process, and the donor of that unit is deferred from making future donations.

Manufacturing

The Boca Raton manufacturing facility has been licensed by the FDA since October 2001 to produce a commercial immune globulin product. Additionally, the facility has been certified by the PPTA Quality Standards of Excellence, Assurance and Leadership (QSEAL) program since 2008. The QSEAL program establishes standards in addition to those required by regulatory agencies that define the acceptability of plasma for use in the manufacturing of plasma protein products.

Manufacturing is conducted in our state-of-the-art, recently modernized, and expanded manufacturing plant in Boca Raton, Florida. This major modernization began in 2008 and was completed in July 2011. The facility changes were designed to expand the manufacturing capacity and improve the compliance of the facility with cGMPs. For plasma protein therapy products, the essential objective of cGMP compliance is to minimize risk, while maintaining adequate production to meet the therapeutic needs of patients. Through the use of scientifically sound design, our plant achieves a high level of quality. Biotest is committed to high-quality processes and continuous improvement.

Our manufacturing process employs a multistep viral removal/inactivation system, which further increases the safety of all our plasma protein based products. The following Biotest Pharmaceuticals' manufacturing processes have been validated for their capability to eliminate or inactivate viruses: precipitation during cold ethanol fractionation, solvent/detergent treatment, and nanofiltration. Incorporation of these processes in the manufacturing process ensures that our pharmaceutical/biological products fully comply with the requirements of the FDA and are safe and efficacious.

PLASMA COLLECTION

STORAGE (QUARANTINE)

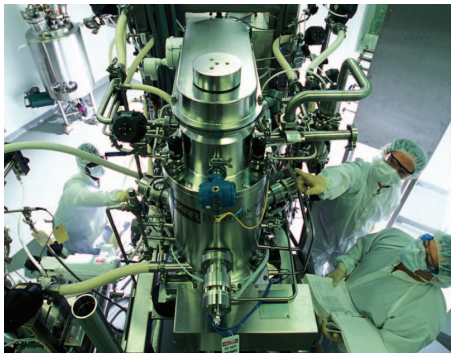
VIROLOGICAL TESTING OF EACH INDIVIDUAL PLASMA

VIRUS REMOVAL/INACTIVATION

PURIFICATION

NANOFILTRATION

FINAL FILLING/QUALITY CONTROL



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PRODUCTION

To ensure maximum performance of our plasma protein products, safety and quality control tests are integrated into the production process at several stages.

PLASMA COLLECTION

All plasma protein products produced in the Boca Raton, Florida facility are manufactured from US-sourced plasma collected in FDA licensed and IQPP certified collection centers.

PLASMA HOLD PROGRAM

All plasma is held for at least 60 days after collection prior to use in manufacture of product. This 60-day hold prevents the use of unsuitable plasma units and allows for the retrieval of such units, as a result of information received after donation (postdonation information) that would have disqualified the donor. This could include anything from subsequent reactive test results, high-risk behavior, or incorrect information received at the time of collection. Any questionable plasma units are excluded from the manufacture of pharmaceutical products, and the units are destroyed.

VIROLOGICAL TESTING OF EACH INDIVIDUAL PLASMA POOL

After the individual plasma units are pooled for production, a sample of the manufacturing plasma pool is tested for the presence of viral nucleic acid. Positive test results lead to rejection of the manufacturing lot.

VIRUS REMOVAL/INACTIVATION

The manufacturing process used in our facility employs 3 effective steps to remove/inactivate adventitious viruses to minimize the risk of virus transmission. The steps are "precipitation" during cold ethanol fractionation, classical "solvent/detergent treatment," and "35 nm virus filtration." In compliance with current guidelines, all 3 steps have been individually validated in a series of in vitro experiments for their capacity to inactivate or remove both enveloped and nonenveloped viruses.

Precipitation removes both enveloped and nonenveloped viruses, solvent/detergent treatment represents a virus inactivation step for enveloped viruses, and 35 nm virus filtration removes both enveloped and nonenveloped viruses by size exclusion. In addition to the steps above, maintaining a low pH level during several steps of the production process contributes to virus inactivation.

FINAL FILLING/QUALITY CONTROL

The products are filled into final containers using aseptic processes and undergo further rigorous quality control testing prior to release for shipment to customers.

"Biotest AG has invested over $50 million to modernize and expand the Biotest Pharmaceuticals' manufacturing facility in Boca Raton, Florida. This continuous innovation ensures that we meet the quality and safety standards set by regulatory agencies around the world."

- Jordan Siegel, CEO, Biotest Pharmaceuticals

Continuous Innovation

Continuous Innovation

With a strong scientific focus, Biotest remains true to our mission of introducing new disease-fighting biotherapeutics and continuing our history of technological discoveries. Biotest employs scientists internally, as well as collaborates with organizations outside the company to investigate and develop new products and technologies in core focus areas.

Currently, Biotest focuses its research and development efforts on the discovery of novel plasma protein therapies and monoclonal antibodies.

CLINICAL IMMUNOLOGY

Biotest's immunology research in plasma proteins is focused on antibody concentrates and polyvalent antibodies. One particular strength is the development and production of hyperimmunoglobulins, which are plasma proteins characterized with specific antibody content. Research efforts build on this foundation and are focused on effectors of humoral immunity in the adaptive immune system. These immunoglobulins perform a wide variety of functions, including defense against bacteria, viruses, and toxins, as well as regulation of the immune system.

Biotest's focus in the transplant market is to develop therapies that complement or enhance the body's immune system to allow for a successful organ transplant and continued health of both the patient and graft.

Biotest is building on its worldwide experience, as one of the leading providers of hyperimmune technology for hepatitis B virus (HBV), by developing an investigational human polyclonal antibody product containing antibodies that neutralize the hepatitis C virus (HCV). The hope is that by providing clinicians with an anti-hepatitis C product in the future, we will be able to improve outcomes for those liver transplant patients who have previously tested positive for HCV.†

MONOCLONAL ANTIBODIES

Biotest has identified 3 monoclonal antibodies that could help to establish a new therapeutic strategy in the treatment of several severe diseases. One is a novel monoclonal antibody that has the effect of activating regulatory T-cells, thus reactivating a natural control mechanism and allowing the body to counteract dangerous autoreactive T-cells. This antibody is currently in clinical trials for rheumatoid arthritis (RA) and psoriasis; additional preclinical studies are underway to evaluate its potential use in other immune-related diseases.† Other monoclonal antibodies being researched at Biotest include an immunoconjugate (combination of monoclonal antibody with a cytotoxic component) that, based on current knowledge, selectively binds to a tumor protein present in high quantities on multiple myeloma cells, and a monoclonal antibody to treat Systemic Lupus Erythematosus.†

†This product has not been approved for marketing by the Food and Drug Administration (FDA) or other foreign regulatory agencies. The drug candidate discussed is either presently being investigated in clinical trials subject to applicable FDA or foreign authority submissions or is in preclinical research and development.

From plasma collection, manufacturing, and distribution of plasma proteins—from nature to life—we are continually raising the bar and setting new standards of excellence.

Biotest: Partnering with the medical and patient communities

Biotest
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Key supporter of professional and patient groups

Since Biotest's therapies are used in serious and sometimes chronic diseases, we are committed to helping patients cope with the psychological and social ramifications of their diseases, by supporting many patient and professional groups around the world. A partial list of these groups follows:

PATIENT GROUPS

- World Federation of Hemophilia – Biotest AG has been providing financial support for the work of hemophilia organizations and their involvement in hemophilia diagnosis, treatment, and genetic counseling for over 30 years
- International Patient Organization for Primary Immunodeficiencies (IPOPI)
- Jeffrey Modell Foundation (JMF)
- Immune Deficiency Foundation (IDF)

PROFESSIONAL GROUPS

- Plasma Protein Therapeutics Association (PPTA) – As a member of the PPTA, Biotest Pharmaceuticals is dedicated to fulfilling the PPTA mission of increasing the availability of and access to safe and effective plasma protein therapeutics
- BioFlorida – Biotest Pharmaceuticals is a member and sponsor of this organization, whose local initiatives provide a climate for research and production of life improving technologies in Florida, which ultimately benefit people within the state and beyond

"Once you have heard a patient express the hope of arresting the course of a disease in order to live to see a grandchild go to school for the first time, you realize the importance of the swift development of new and effective therapies."

-Dr. Thomas Häder, Manager Corporate Clinical Research, Biotest AG

Biotest Pharmaceuticals: providing products for patients and the support that is essential to both patients and professionals

We welcome you to write, call, or email Biotest Pharmaceuticals with any questions or comments you may have about the company or its products.

Write
Biotest Pharmaceuticals Corporation
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5800 Park of Commerce Boulevard, NW
Boca Raton, FL 33487

For Corporate Directory call
Toll free: **800-327-7106**
Phone: **561-989-5800**
Fax: **561-989-5801**

For Customer Service and Medical Affairs call
Toll free: **800-458-4244**

For questions about our plasma centers and products,
email us at **plasma@biotestpharma.com**

Web site
www.biotestpharma.com

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