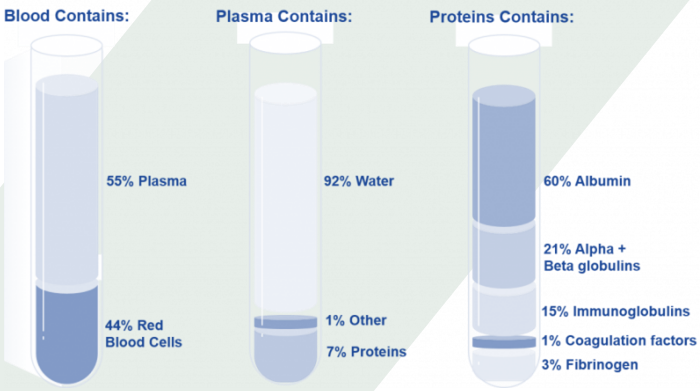
Abstract for Blood Plasma Fractionation Facility

The following abstract refers to Blood Plasma Fractionation Facility considering general and process information

Introduction

Blood fractionation facility (BPF) separates human blood plasma into its components, and to extract specific proteins or products that can be used for medical treatments. This process collects various therapeutic proteins that are important for treating a wide range of conditions such as immune disorders, bleeding or clotting disorders, burns, and chronic diseases or deficiencies, and lastly for surgical bleeding management and intensive care settings. These vital protein components include albumin, clotting factors, immunoglobulins, alpha-1 antitrypsin, and thrombin. After processing, these are called plasma-derived medicinal products (PDMPs) and are utilized as life-saving treatments, crucial for improving the quality of life for many patients.



BPF uses sophisticated technologies such as centrifugation, chromatography, and filtration, which ensure that the components are efficiently isolated and purified. These facilities provide a valuable resource, particularly for those who rely on blood-derived therapies for survival. For instance, immunoglobulins (IVIG) are used to boost the immune system in patients with immune disorders, while clotting factors are vital for patients with hemophilia.

Products and Application

The PDMPs will come in specialized containers, either vials or pre-filled syringes (PFS) depending on the form. BPF ensures a steady supply of essential plasma-derived products to hospitals and clinics worldwide, supporting both emergency and long-term patient care. These facilities operate under strict regulatory frameworks, such as Good Manufacturing Practices (GMP), to guarantee the safety and efficacy of their products.

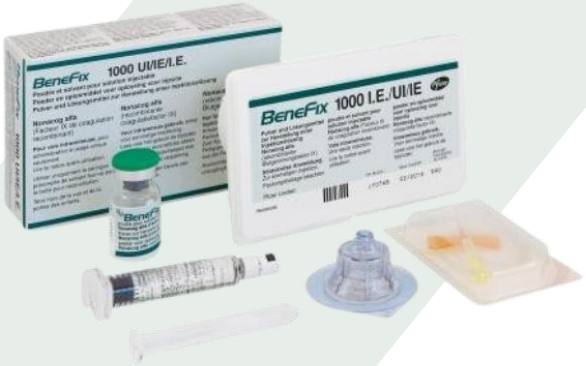
The BPF will mainly focus to fractionate four plasma-derived products:

1. Immunoglobulin: 5% and 10% intravenous immunoglobulin (IVIg). Composed of pooled immunoglobulin G (IgG) antibodies, used to help fight infections. Shelf-life is 24-36 months when stored correctly (refrigerated).
2. Albumin: Solution for infusion in 5%, 20% and 25% albumin concentrations. Lower concentration used to restore blood volume or fluid levels, and more concentrated form used in more severe cases of hypoalbuminemia (low albumin levels).
3. Factor Concentrates: Medications with concentrated forms of clotting factors. The facility will fractionate two factor concentrates, Factor VII and Factor IX. Used to treat bleeding disorders, especially hemophilia. To be sold in solid form, 1g of powder per vial.

The products consist of two types of containers, vials and PFS with accessories. The plasma products will be sold in the original solution form or in powder form (freeze dried).

The main components of PDMPs include:

- *Plasma proteins* or the core component e.g., human albumin, immunoglobulins, factor VII (Proconvertin) and coagulation factor IX
- *Trace proteins*, vitamins or nutrients or other substances that may be present in small quantities in the overall composition
- *Solvent*, the excipient that includes stabilizers, buffers, preservatives, and solubilizers to maintain the stability and efficacy of PDMPs through transport until usage by end users.



Product components and accessories include:

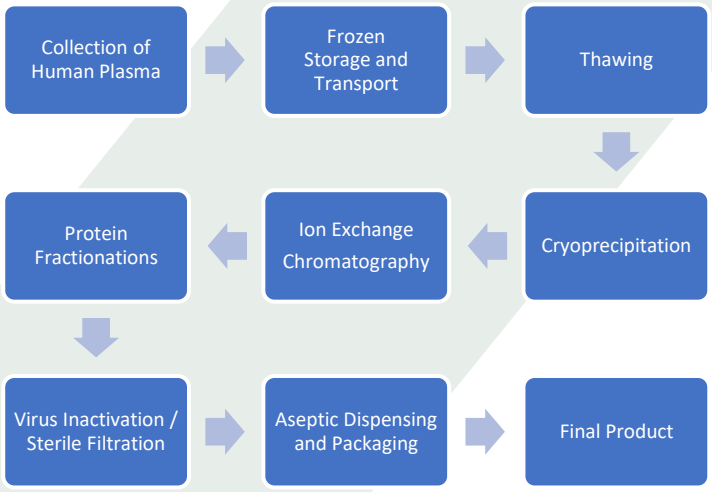
1. Vials: Transparent and robust container for the medicinal products, covered with a plastic stopper.
2. Vial adapter: To ensure sterile withdrawal of the product, reducing contamination risk.
3. Syringes and needles: Along with a solvent, pre-filled with proper dosage and ready to be injected straight out of the package.
4. Plunger rod: part of the PFS used to push out the medication in the process of administering injectable therapies.
5. Sterile Water for Injection: A separate vial containing the appropriate amount of sterile water for reconstituting the lyophilized powder, used to dissolve the product powder to create a ready-to-use solution.

Blood Fractionation Processing

Protein fractionations are done by various machines with integrated automation, digital control, and monitoring, ensuring the most effective method of separating, filling and packaging sterile pharmaceutical, biological and medical products that are in total compliance with FDA, GMP, and ISO9004 requirements. There are four products with different process line, however similar. The production process is structured into:

Raw Material Process

- Collection and Centrifugation
- Freezing to preserve functions and quality of plasma proteins
- Thawing with controlled temperature and agitation
- Cryoprecipitate - rich in clotting factors concentrates



Manufacturing Process

- Ion Exchange Chromatography
- Cold-Ethanol Fractionations

Fraction I (discarded)
Fraction II + III (discard Fraction III): to extract IVIG
Fraction IV + V (discard Fraction IV): to extract Albumin

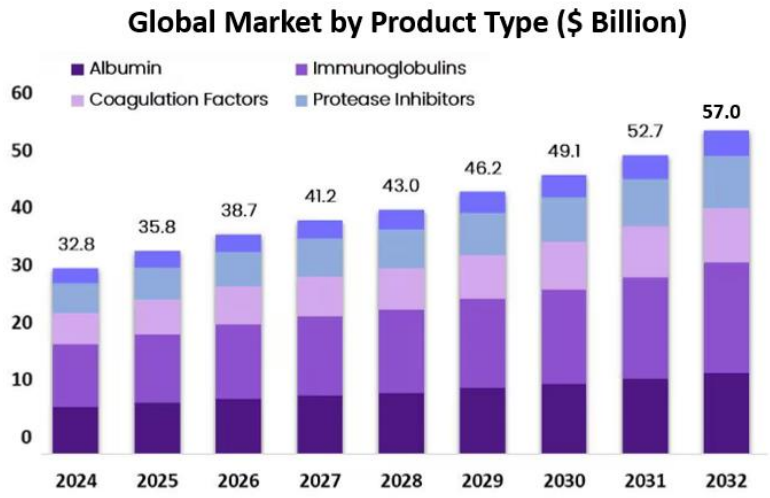
- Virus Inactivation and Elimination
- Distillation to recover Ethanol for further use in future cycles

Market Size

Plasma fractionation market was valued at approximately USD 32.8 billion in 2024, with projections indicating a compound annual growth rate (CAGR) of 7.3%, forecasting growth to USD 57 billion by 2032.

Main product types include albumins and immunoglobulins, followed by coagulation factors and protease inhibitors.

With hospitals and clinics as main users (more than half), and clinical research.



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