

SUPPORTING SECURE PLASMA FRACTIONATION

Essential raw materials and excipients for
plasma derived medicinal products (PDMPs)



HIGHLIGHTS

Trusted and long lasting partner of the plasma industry

EU-GMP certified production facility "Made in Germany"

IPEC-GMP for excipients certified by EXCiPACT standard

High-quality raw materials - designed for the special requirements of precipitation, elution, virus inactivation, formulation and stabilisation proteins and PDMPs

Warehouse and Logistics

- 3,200 pallet spaces for packaging materials, raw materials and finished products
- Temperature controlled
- Additional external storage capacities at warehousing service provider
- Customized logistics concepts

Your challenge - Our solution

CG PHARMA & BIOTECH

We support your plasma fractionation journey

As a leading developer, manufacturer and supplier of critical raw materials for plasma protein based manufacturers, CG Pharma & Biotech understands the complex challenges our partners face. We are your dedicated partner, providing reliable support from the start of development through to clinical phases and commercial production. Our commitment to the highest quality is reflected in our customised services and products, which are designed to seamlessly adapt to each client's individual requirements. The production of plasma-derived medicinal products (PDMPs) is a complex biopharmaceutical manufacturing process. Blood plasma, the fluid component of blood, contains different proteins with plenty of physiological functions, clotting factors and nutrients. Drugs derived from plasma are essential for the treatment of life-threatening and, for the most part, chronic diseases.

PLASMA MANUFACTURING – A HIGHLY COMPLEX AND DEMANDING PROCESS

The production of human plasma is a complex and regulated biopharmaceutical process that involves strict adherence to safety and quality standards. The end result is a range of life-saving medical products that contribute to improving the health and well-being of countless individuals worldwide.

STREAMLINE YOUR SUPPLY CHAIN BY OUTSOURCING ACTIVITIES

In the plasma manufacturing chain, various cleaning and process solutions, buffers, chromatography chemicals, virus inactivation and polishing solutions are necessary for the up- and downstream process. Manufacturers and suppliers of these materials have to secure strict and reproduceable quality standards.

If your organization chooses to focus exclusively on the core plasma production process, we would be pleased to offer you our GMP-compliant manufacturing services for process chemicals, buffers and excipients. Outsourcing these process steps optimises your supply chain, increases your internal productivity, and contributes to long-term cost reduction. Furthermore, it reduces the risk of supply chain disruptions by establishing a logistics concept with defined safety stocks, 365/24/7 availability, and close collaboration with our supply chain.

A "make or buy" decision involves determining whether to create a product or service in-house or purchase it from an external source. In the context of customised GMP (Good Manufacturing Practice) biopharmaceutical process solutions, this decision carries several advantages.



PLASMA MANUFACTURING

Highly complex and demanding process

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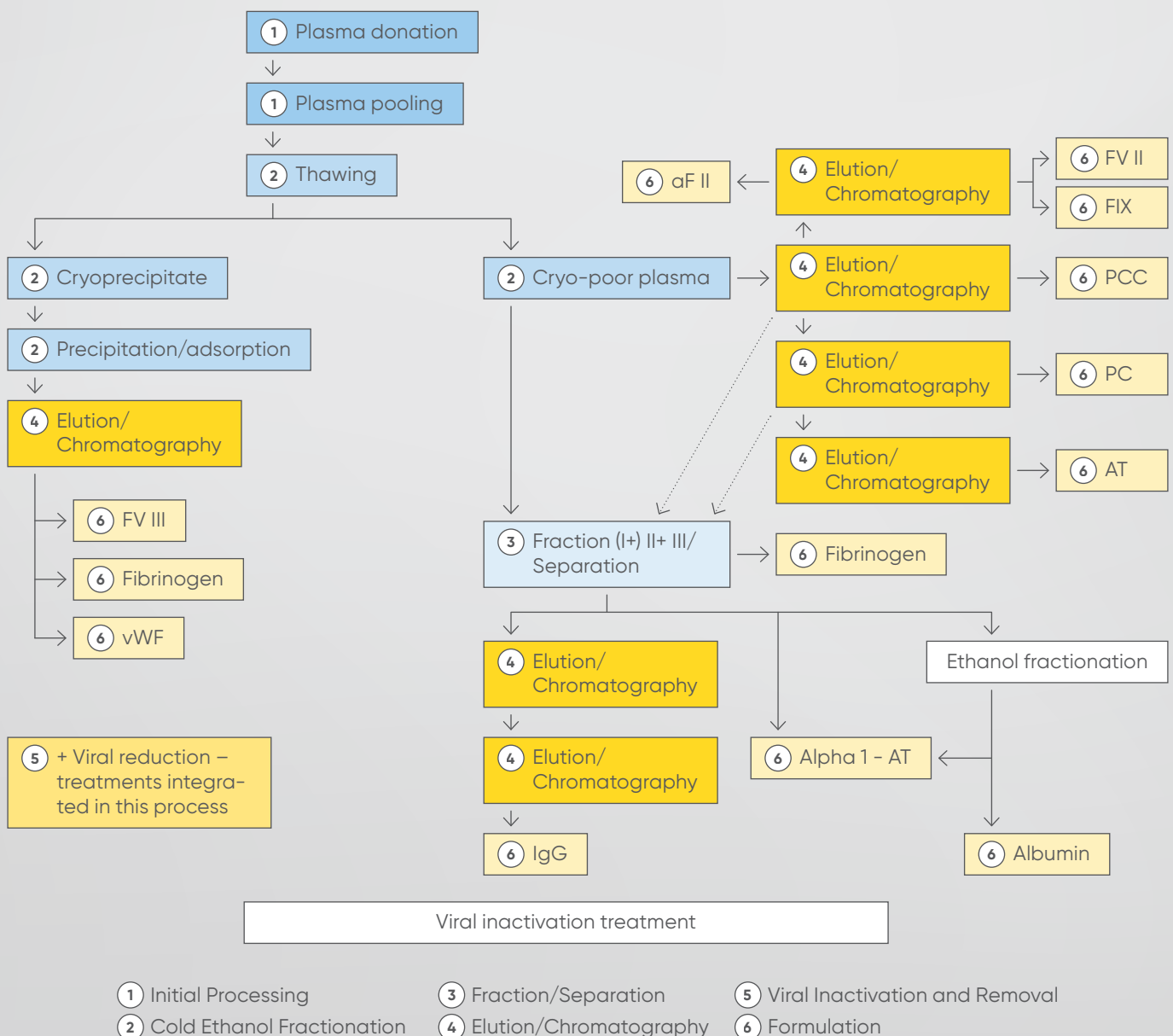
Plasma and its components - key characteristics

- Sensitive to handling and production processes
- Expensive to source
- Limited in supply compared to high market demand
- Require the highest standards of quality and safety

Ensuring an outstanding production process is essential to guarantee plasma protein-based medicinal products of the highest value. Process chemicals and excipients play a critical role throughout the entire plasma value chain.

Three Reasons to choose CG Pharma & Biotech as your preferred partner for plasma fractionation and PDMP production:

- Extensive experience in supporting the plasma industry
- EU-GMP certified manufacturing facility with Class C/D cleanrooms
- Tailored solutions for plasma fractionators – customized formulations and a comprehensive standard product catalogue



OUR PRODUCTS AND SERVICES

Supporting your plasma fractionation

At CG Pharma & Biotech, we understand the critical importance of ensuring the safety, efficacy and purity of biological medicinal products derived from blood plasma. As a trusted partner in the plasma industry, we offer a comprehensive portfolio of raw materials tailored specifically to the intricate processes of plasma processing.

Our extensive range of high-quality raw materials, starting materials and excipients is designed to meet the unique needs of virus inactivation, precipitation elution and buffer solution preparation, all essential stages in the production of life-saving plasma-derived therapies. Thanks to our modular approach, you have the flexibility to select and combine the solutions that perfectly fit your needs.



EXAMPLES OF CUSTOMISED BUFFER-SOLUTIONS AND ITS FUNCTIONS DURING PLASMA PROCESSING	
PRODUCTS	APPLICATIONS
Acetate buffer	Used in precipitation steps, especially for albumin fractionation, to maintain a stable pH
Phosphate buffer	Used in washing and resuspension steps to stabilize proteins and maintain physiological pH.3
Glycine buffer	Used in albumin purification and stabilization, especially during pasteurization steps
Tris buffer (tris(hydroxymethyl) aminomethane)	Used in chromatography steps for immunoglobulin purification due to its effective pH buffering capacity
Sodium chloride solution (saline)	Used for dilution, washing, and resuspension of plasma fractions.6
Histidine buffer	Used in final formulation of immunoglobulin products to stabilize the protein
Citrate-phosphate-dextrose (CPD) solution	Used as an anticoagulant and preservative during plasma collection
Ethanol buffers	For rinsing of hydroxyapatite-exchange column
Various buffers	For equilibration, wash, regeneration and purification of proteins

PRODUCTS (extract)					
	PROCESS STEPS				
	PRECIPITATION	ELUTION/ CHROMATOGRAPHY	BUFFER	VIRUS INACTIVATION	FORMULATION/ STABILISATION
6-Aminohexanoic acid	X	-	-	X	-
Acetic acid glacial (and dilutions)	X	-	X	X	-
Ammonium acetate	-	X	X	-	-
Ammonium sulphate	-	X	-	-	-
Citric acid 1-hydrate	-	-	X	-	-
Citric acid anhydrous	-	-	X	-	-
Di-potassium hydrogen phosphate anhydrous	-	-	X	-	-
Di-sodium hydrogen phosphate anhydrous	-	-	X	-	-
EDTA disodium salt 2-hydrate	-	-	X	-	-
Glycine	-	X	-	-	-
Guanidine hydrochloride	-	X	-	-	-
Hydrochloric acid (various concentrations)	-	-	X	-	-
Imidazole	-	X	-	-	-
L-Arginine	-	-	-	-	X
L-Histidine	-	X	-	-	-
L-Lysine	-	-	-	-	X
Macrogol 4,000 (PEG)	X	X	-	-	-
Maltose monohydrate	-	-	-	-	X
Mannitol	-	-	-	-	X
Magnesium sulphate 7-hydrate	-	X	-	-	-
Octanoic acid	X	-	-	X	-
Octoxynol	-	-	-	X	-
Polysorbate 80	-	X	-	X	-
Potassium di-hydrogen phosphate	-	-	X	-	-
Sodium acetate 3-hydrate	X	-	X	X	-
Sodium caprylate	X	-	-	-	X
Sodium chloride	-	X	X	-	-
Sodium di-hydrogen phosphate 1-hydrate	-	-	X	-	-
Sodium hydroxide pellets	X	-	X	-	-
Sodium hydroxide solution	-	-	X	-	-
Sorbitol	-	X	-	-	X
Sucrose	-	X	-	-	X
Tris(hydroxymethyl) aminomethan (tris buffer)	-	-	X	-	X
Tri-sodium citrate 2-hydrate	-	-	X	-	-
Trehalose	-	-	-	-	X
Tri-n-butylphosphat	-	-	-	X	-
Urea	-	X	-	-	-

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