SECURITY FOR YOUR PLASMA DERIVATIVES

Raw Materials for Plasma Fractionation

PanReac AppliChem
ITW Reagents

Blood Plasma Fractionation

Human plasma contains proteins of high therapeutic value, which are prepared from the pooled plasma of many donors. They are also called plasma derivatives, i.e. concentrates of specific plasma proteins, which are obtained through a process known as fractionation. The main fractionation steps include precipitation, purification and virus inactivation. Therefore, plasma derivatives are heat-treated and/or solvent detergent-treated to kill certain viruses like those that cause HIV or hepatitis.

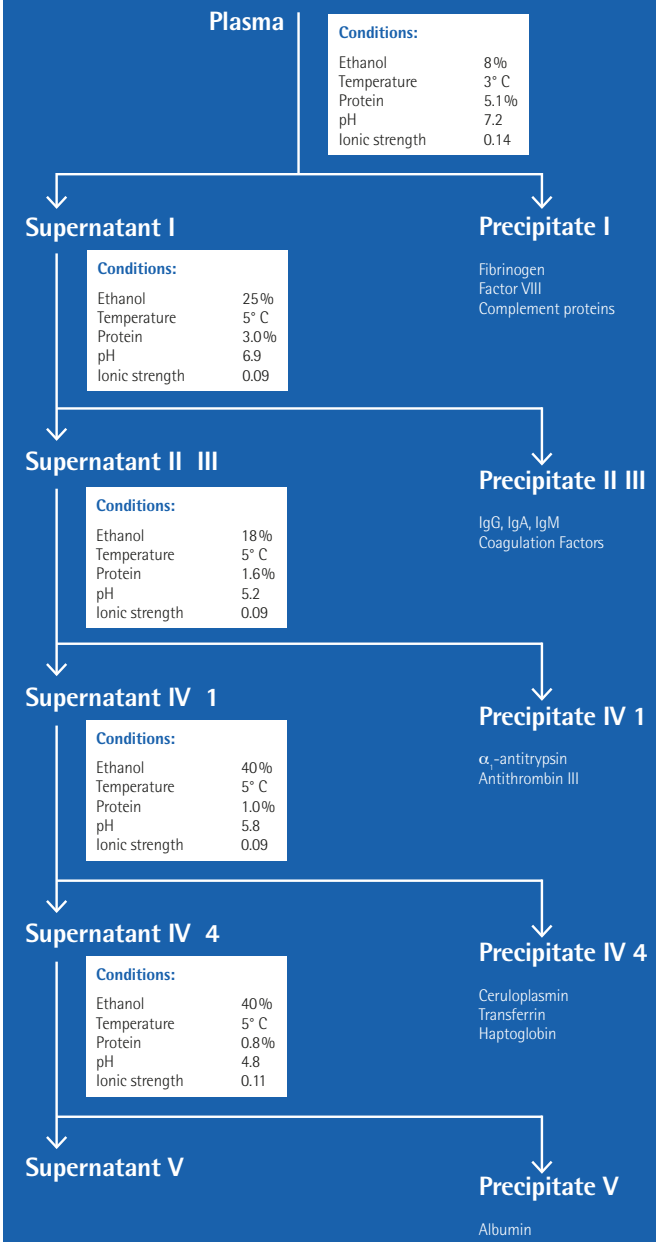
Plasma derivatives include:
- Factor VIII
- Factor IX
- Anti-Inhibitor Coagulation Complex (AICC)
- Albumin
- Immunoglobulins, including Rh Immunoglobulin
- Anti-Thrombin III
- alpha 1-Proteinase Inhibitor

These proteins are used for e.g. haemophilia or autoimmune disorders treatment.

We are fully aware of the safety and quality requirements to prepare such therapeutic proteins. Therefore, PanReac AppliChem shall be your first choice as supplier of reagents for plasma fractionation.

- High Quality **Raw materials** that fulfill Pharmacopoeia specifications.
- **Documentation** for register and approval available (MSDS, regulatory certification, manufacturing process)
- **Effectiveness** of the purification process guaranteed – reliably

Blood Plasma Fractionation Scheme
This reaction scheme is an example of how a plasma fractionation may be performed. The scheme was adapted from Curling, J. (2002) *BioPharm Int.* **15**(10), 16-26



Raw materials for the precipitation of proteins

Whatever parameter has to be modified: pH, ionic strength or ethanol concentration, with PanReac AppliChem's reagents, you may adjust to the required conditions to precipitate the plasma proteins.

Raw materials for protein purification

Fractions obtained from plasma after precipitation are still complex mixtures and do require further purification steps.
Purification techniques include:
- Filtration
- Affinity Chromatography (AC)
- Immobilized metal ion affinity chromatography (IMAC)
- Size exclusion chromatography (SEC)
- Ion exchange chromatography (IEX)

A good elution is achieved by increasing the salt concentration, modifying pH and polarity, adding chaotropes and/or detergents. Additionally, it is critical to select the appropriate buffer. Please note that the table on the next page only represents a selection of the products available.

Raw materials for virus inactivation

The virus inactivation is an essential step to prevent contamination by viruses such as Hepatitis or HIV. Apart from a very strict control and selection of donors, some virus inactivation steps are carried out before final product release.

The chemical treatment used for virus inactivation are:

- Low pH treatment
- Pasteurization (requires a stabilizer like sucrose, glycine or sodium caprylate)
- Solvent/detergent treatment

In other words:

"Your commitment is our commitment!"

Raw materials supplied by PanReac AppliChem

Description	Code	Precipitation	Elution	Buffer Selection	Virus Inactivation
Acetic Acid glacial (USP, BP, Ph. Eur., JP) pharma grade	191008	●		●	●
Octanoic Acid (USP-NF, BP, Ph. Eur.) pharma grade	BH2786	●			●
Sodium Acetate 3-hydrate (Ph. Eur., BP, USP) GMP – IPEC grade	631632	●		●	●
Sodium Hydroxide (Ph. Eur., BP, USP, JP) GMP-IPEC grade	631687	●		●	
Sodium Caprylate (Ph. Eur., BP) pharma grade	Z96454	●			●
6-Aminohexanoic Acid (Ph. Eur., BP, USP) GMP – IPEC grade	63B764	●			
Ammonium Acetate (Reag. Ph. Eur.) ACS	Z31114		●	●	
Ammonium Sulfate BioChemica	A1032		●		
Copper(II) Sulfate 5-hydrate (BP, Ph. Eur.) pure, pharma grade	141270		●		
Glycine (Ph. Eur., BP, USP) GMP – IPEC grade	631340		●		
Guanidine Hydrochloride ultrapure	A3240		●		
Imidazole pharma grade	192536		●		
Magnesium Sulfate 7-hydrate (Ph. Eur., BP) GMP – IPEC grade	631404		●		
Sodium Chloride (Ph. Eur., BP, USP) low in endotoxins, GMP – IPEC	631659		●	●	
D(+)-Sucrose (USP-NF, BP, Ph. Eur.) low in endotoxins, GMP – IPEC grade	631621		●		
Triton® X-100 BioChemica	A1388		●		●
Tween® 80 (USP-NF, BP, Ph. Eur.) pure, pharma grade	142050		●		●
Urea crystal (USP, BP, Ph. Eur.) pharma grade	191754		●		
Citric Acid anhydrous (Ph. Eur., BP, USP) GMP – IPEC grade	631808			●	
Citric Acid 1-hydrate (Ph. Eur., BP, USP) GMP – IPEC grade	631018			●	
EDTA Disodium Salt 2-hydrate (Ph. Eur., BP, USP) GMP – IPEC grade	631669			●	
Hydrochloric Acid 2 mol/l (2N) pharma grade	192108			●	
MES 1-hydrate for buffer solutions	A1074			●	
Potassium di-Hydrogen Phosphate (USP-NF, BP, Ph. Eur.) pure, pharma grade	141509			●	
di-Potassium Hydrogen Phosphate anhydrous (Ph. Eur., BP, USP) GMP – IPEC grade	631512			●	
tri-Sodium Citrate 2-hydrate (Ph. Eur., BP, USP) GMP – IPEC grade	631655			●	
Sodium di-Hydrogen Phosphate 1-hydrate (BP, USP) GMP – IPEC grade	631965			●	
di-Sodium Hydrogen Phosphate anhydrous (USP, BP, Ph. Eur.) pure, pharma grade	141679			●	
TRIS (USP, BP, Ph. Eur.) low in endotoxins, pure, pharma grade	Z41940			●	

This is a selection of PanReac AppliChem products. Please inquire for further products.

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