ClearLine	Technical data sheet Plasma	Ref : 509572

Human Plasma Pooled

Collected from the source:
When searchers choose their plasma an important factor that should be taken into consideration is the source, which also emphasises the traceability of the plasma.
Our system of vertical integration allows us to be certain of the origins and traceability of our human plasma. The donors are volunteers.
Each manufactured batch is rigorously controlled, from the collection of plasma in authorised organisms, and throughout all stages of its treatment and production through to final packaging on the authorised organisms and on our premises.
The plasma is processed from donation of human blood that was collected on Anticoagulant Citrate Phosphate Dextrose (CPD) then centrifuged or processed from apheresis on Anticoagulant Acide Citrate Dextrose (ACD-A). Apheresis is a technique for collecting certain blood components by extracorporeal circulation of blood. The components that are to be collected (plasma in our case) are separated by centrifugation and extracted, while the components not collected are reinjected into the donor.
The plasma is collected or imported and treated in agreement with the European regulations.

Country of Origin:
The country in which the blood was taken from the donor.
BioWest plasma are sourced from Germany, Poland, United Kingdom, Lithuania, USA or France.

Storage conditions:
- 18°C to - 40°C, protected from light.
Bottles can be stored between -40°C and -80°C for a short period (few days).

Shelf life:
4 years.

Filtration:
Final Filter Size: 0.2µm

pH:
pH specification: Not applicable

Osmolality:
Determined by a lowered freezing temperature. The osmometer is calibrated against standard solution.
Osmolality specification: Not applicable

Endotoxin:
All plasma are tested to determine the levels of endotoxins. BioWest carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia.
The endotoxin reagent is standardized against the US reference endotoxin.
Endotoxin specification: Not applicable

Haemoglobin:
The haemoglobin level is measured by spectrophotometer.
Haemoglobin specification: As low as possible

Cell Culture:
Not applicable

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Total Protein:
Determined by Biuret Colorimetry.
Total Protein specification: Not applicable

Sterility tests:
All plasma are tested for the absence of aerobic and anaerobic bacteria, fungi and yeast.

Virus test:
All of our human plasma is tested negative or non-reactive for:
- Hepatitis B antigen (HBs Ag)
- Hepatitis C virus and antibodies (HCV)
- HIV Type 1 virus and antibodies HIV ½
- Syphilis

Other tests:
Dry extract:
Dry extract specification: Not applicable

Treatments:
Not applicable

Recommended use:
- Respect storage conditions of the product
- Do not use the product after its expiry date
- Store product in an area protected from light
- Manipulate the product in aseptic conditions (e.g.: under laminar air flow)
- Wear clothes adapted to the manipulation of the product to avoid contamination (e.g.: gloves, mask, hygiene cap, overall…)
- In order to preserve all product qualities, it is recommended to thaw out the flask, to aliquote, then to re-freeze the produced flasks rather than to thaw out and re-freeze the flask at each use.
- It is recommended to use the product immediately after its thaw out.

The product is intended to be used in vitro for scientific purposes only and not for drug, human or veterinary use.

Remarks:
Not applicable

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