

# Technical data sheet

Ref: FT BP-116 Page: 1/2

Version date: 08/04/2024

# Bovine Plasma w/ Sodium Citrate

CAT N°: BP-116

# **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 plasma.

Each manufactured batch is rigorously controlled, from the collection of plasma and throughout all stages of its treatment and production through to final packaging on our premises.

BioSera Bovine Plasma is derived from centrifuged Bovine whole blood collected from bovine with cleaned and disinfected equipment, with the addition of Sodium Citrate. The blood with sodium citrate is centrifuged and the supernatant called "Plasma" is put in jugs before freezing. The plasma is collected and treated in agreement with the European regulations.

# **Country of Origin:**

The country in which the plasma was taken from the animal.

The product is originated from 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 solutions.

Osmolality specification: Not applicable

#### **Endotoxin:**

All plasma are tested to determine the levels of endotoxins. BioSera 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: Not applicable

#### **Cell Culture:**

Not applicable

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L'unité de production pour BIOSERA à Nuaillé est certifiée ISO 9001



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#### **Total Protein:**

Not applicable

### **Sterility Test:**

All plasma are tested for the absence of aerobic and anaerobic bacteria, fungi and yeast. The sterility test is based on the European Pharmacopoeia requirements.

#### **Virus Test:**

Not applicable

#### Other tests:

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 research or further manufacturing only and not for use as an Active Pharmaceutical Ingredient or food or animal feed.

#### **Remarks:**

Not applicable