



TECHNICAL DATASHEET

- General informations

Product	: Rabbit Plasma in EDTA, sterile filtered 0,2 µm
Code n°	: 0.5.RPE (500 mL bottle) ; 1.RPE (1 litre bottles)
Batch sizes	: from 10 to 200 liters
Filling sizes	: 500 ml bottle, 1 litre bottle
Origin	: Italy
Shelf life	: 5 years from date of production if the product is stored at proper temperature and without any cycle of freeze and thaw
Storage Temperature	: - 10 °C to -20 °C

Use: Further manufacturing in bio-pharmaceutical field. Not for human or animal consumption.

Stability and storage: The product must be stored in a temperature range within -10 °C and -20 °C. If stored at this temperature range the serum is stable for five years from the date of production. It is recommended to not make more than one cycle of freeze and thaw, but to make various aliquots.

Turbid material or flocculation can be observed if the product is thawed or stored for a long time at cold temperatures, this is common concerning serum, and it is not detriment of its functionality.



- Biological specifications

Biological Test		
Test	Specifications	Results
Sterility, absence of Bacteria Fungi and Yeast <i>2.6.1 Eur. Phar.</i>	Sterile	Sterile
Biochemical Tests		
Test	Specifications	Results
Total protein <i>BCA method</i>	4,0 – 6,5 g/dL	
Hemoglobin <i>Triton/NaOH method</i>	< 50 mg/dL	
Endotoxin <i>LAL Kinetic Method</i>	< 50 EU/mL	
pH <i>pHmeter</i>	7,0 – 8,5	
Osmolality <i>Osmometer Freezing reduction point</i>	260 – 350 mOsm/KgH ₂ O	