

TECHNICAL DATASHEET

- General informations

Product : Donor Horse Serum, sterile filtered 0,2 μm

Code n° : 0.5.SHS (500 mL bottle); 1.SHS (1 litre bottles) 5.SHS (5

litres jug)

Batch sizes : from 50 to 2000 liters

Filling sizes : 500 ml bottle, 1 litre bottle, 5 litres jug,

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 -5 $^{\circ}$ C and -20 $^{\circ}$ 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.

P. IVA 02046270670



- Biological and virological specifications

Biological Test				
Test	Specifications	Results		
Sterility, absence of Bacteria Fungi and Yeast 2.6.1 Eur. Phar.	Sterile	Sterile		
Biochemical Tests				
Test	Specifications	Results		
Total protein BCA method	6,0 - 8,5 g/dL			
Hemoglobin Triton/NaOH method	< 40 mg/dL			
Endotoxin LAL Kinetic Method	< 40 EU/mL			
pH pHmeter	7,0-8,0			
Osmolality Osmometer Freezing reduction point	260 – 350 mOsm/KgH ₂ O			

Virological Tests		
Test	Specifications	Results
EIA (Equine Infectious Anemia)	Negative – Coggins test or ELISA test	Negative