



TECHNICAL DATASHEET

- General informations

Product	: Donor Horse Serum, heat inactivated, sterile filtered 0,2 μ m, gamma-irradiated at 25 or 35 kGy
Code n°	: 0.5.SIGHS (500 mL bottle) ; 1.SIGHS (1 litre bottles) 5.SIGHS (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.

Heat inactivation: It is done at + 56 °C for 30 minutes in a designated vessel.

Gamma-irradiation: It is outsourced and the dose-mapping study of the gamma-irradiation process is available on request. The company gives an attestation of gamma-irradiation for each gamma-irradiated batch. The company can perform gamma-irradiation from 5 kGy to 35 kGy, with a window of + 7 kGy from the nominal dose

Stability and storage: The product must be stored in a temperature range within -5 °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 and virological 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>	6,0 – 8,5 g/dL	
Hemoglobin <i>Triton/NaOH method</i>	< 40 mg/dL	
Endotoxin <i>LAL Kinetic Method</i>	< 40 EU/mL	
pH <i>pHmeter</i>	7,0– 8,0	
Osmolality <i>Osmometer Freezing reduction point</i>	260 – 350 mOsm/KgH ₂ O	

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