



TECHNICAL DATASHEET

- General informations

Product	: Guinea Pig Serum suitable for complement fixation assay, sterile filtered 0,2 μm
Code n°	: 0.05 GPC (50 ml bottle); 0.1 GPC (100 mL bottle) 0.5.GPC (500 mL bottle)
Batch sizes	: from 0,5 to 100 liters
Filling sizes	: 50 mL vial, 100 ml bottle, 500 ml bottle
Origin	: Italy
Shelf life	: 3 years from date of production if the product is stored at proper temperature and without any cycle of freeze and thaw
Storage Temperature	: below – 70 °C

Manufacturing:

Guinea pig serum suitable for complement fixation assay is tested for complement activity and certified to possess functional classical and alternative pathways of activation. GPS was prepared from mixed breed guinea pigs. Each sample of blood was collected without anticoagulants and after coagulation the liquid portion was separated by centrifugation. Serum was filtered through a 0.20 μm filter, aliquoted and frozen at -70 °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 with - 70 °C. If stored at this temperature range the serum is stable for three 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. When it is thawed the complement activity decreases sensibly over few hours, even if it is kept on ice. We suggest to aliquot and freeze again at -70° even if this can lower the complement activity of the GPS. 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>	3,0 – 6,0 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 – 8,5	
CH50* <i>R.I.D.hemolytic assay</i>	≥ 200	

*= One CH50 unit is defined as the input of Guinea Pig Serum yielding 50% lysis of 1×10^8 EA when incubated for 60 minutes at 37 °C in a total reaction volume of 1.5 mL GVB++. Usually our GPS suitable for complement assay has a CH50 of at least 700