



TECHNICAL DATASHEET

- General informations

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| Product | : Adult Bovine Serum, heat inactivated sterile filtered 0,2 μ m, Gamma-irradiated at 25 or 35 kGy |
| Code n° | : 0.5.SIGBS (500 mL bottle) ; 1.SIGBS (1 litre bottles) 5.SIGBS (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.

The blood is taken from animals older than 12 months of age.

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 gammairradiation 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 -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 and virological specifications

| Biological Test | | |
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| 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 – 9,5 g/dL | |
| Hemoglobin <i>Triton/NaOH method</i> | < 50 mg/dL | |
| Endotoxin <i>LAL Kinetic Method</i> | < 50 EU/mL | |
| pH <i>pHmeter</i> | 6,9 – 8,5 | |
| Osmolality <i>Osmometer Freezing reduction point</i> | 240 – 340 mOsm/KgH ₂ O | |

| Virological Tests | | |
|---|--------------------------|----------------|
| Test | Specifications | Results |
| BVDV-1,2 (Bovine Viral Diarreha virus) – ELISA TEST | Report the concentration | |