



Li StarFish S.r.l.  
Via Cavour, 35 - 20063 Cernusco S/N (MI), Italy  
Tel. +39-02-92150794 - Fax. +39-02-92157285  
info@listarfish.it - www.listarfish.it

|                         | <b>Cat. No.</b> | <b>Volume</b> |
|-------------------------|-----------------|---------------|
| <b>FBS Pharma Grade</b> | GMP-100350      | 100 ml        |
| AUS origin              | GMP-100790      | 500 ml        |
| <br>                    |                 |               |
| <b>FBS Pharma Grade</b> | GMP-100360      | 100 ml        |
| Gamma Irradiated        | GMP-100800      | 500 ml        |
| AUS origin              |                 |               |
| <br>                    |                 |               |
| <b>FBS Pharma Grade</b> | GMP-100220      | 100 ml        |
| USA origin              | GMP-100660      | 500 ml        |
| <br>                    |                 |               |
| <b>FBS Pharma Grade</b> | GMP-100230      | 100 ml        |
| Gamma Irradiated        | GMP-100670      | 500 ml        |
| USA origin              |                 |               |

## General

FBS Pharma Grade is a high quality Fetal Bovine Serum which complies with all current directives, regulations and guidelines regulating the manufacture of biopharmaceutical products. These regulations comprise the EMEA guideline 1793/02 of the committee for proprietary medical products (CPMP), EMEA guideline 743/00 of the committee for veterinary medical products (CVMP), the Ph. Eur. (European Pharmacopoeia) 5.4 monograph of Bovine Serum (04/2006:2262) and US Code of Federal Regulation (9CFR). An extensive test panel of mycoplasma, ten different viruses, BVD antibodies and BVD antibody interferences as well as biochemical and cell culture parameters minimize the risks in biopharmaceutical processes.

FBS Pharma Grade is suitable for cell based products which need to be produced and registered in compliance with the EU regulation 2005/567 for Advanced Therapies (AT).

## Applications

- Biopharmaceutical industry
- Vaccine production
- Production of recombinant antibodies
- Production of recombinant growth factors

## Features

- Tested according to Ph. Eur. 5.4 monograph 04/2006:2262
- Tested according to CPMP/BWP 1793/02
- Tested according to CVMP/ 743/00
- Tested according to 9CFR
- No BVD antibody interferences
- 35kGy effective single box gamma irradiation
- Batch size up to 2.600 litres
- Australian and U.S. origin\*

## Gamma Irradiation

- Reduction of gamma sensitive viruses and mycoplasma
- Single box irradiation ensures low maximum energy dosage
- Irradiation dosage of 35 kGy
- Ensured constant low temperature
- Less damage of sensitive serum components
- Batch homogeneity not influenced

## Product Specifications

|                  |  |
|------------------|--|
| pH               | 6.8 – 8.2  |
| Osmolality       | 280 – 365 mOsmol/kg  |
| Total Protein    | 3.0 – 4.5 g/dl   |
| Albumin          | value  |
| Endotoxin        | < 25 EU/ml   |
| IgG              | < 250 µg/ml  |
| Haemoglobin      | < 4 mg/ml  |
| Sterility        | tested   |
| Mycoplasma       | not detected   |
| Virus tested for | Parainfluenza Type 3 (PI-3), Bovine Virus Diarrhoea Virus (BVD-V), Bovine Herpes Virus Type 1 (BHV-1), Blue Tongue Virus (BTV), Bovine Adenovirus (BAV), Bovine Reovirus (BRV), Bovine Parvovirus (BPV), Bovine Respiratory Syncytial Virus (BRSV), Rabies Virus, BVD-1 AB, BVD-2 AB, Rabies AB, BVDV AB Inhibitory, BVDV AB Interferences |
| Shelf Life       | 5 years  |
| Storage          | ≤ -15 °C   |

For each batch complete documentation can be requested.

\* Other origins available on request

Li StarFish distribuisce: