

# FBS Pharma Grade

MAXIMUM SAFETY FOR BIOPHARMACEUTICAL INDUSTRY



# FBS | Pharma Grade

## THE FIRST FBS TESTED ACCORDING TO ALL CURRENT DIRECTIVES AND GUIDELINES

Foetal Bovine Serum is necessary in many biopharmaceutical applications. In order to minimize the contamination risk from animal derived products the FDA, as well as the European counterpart, the EMEA, has released important directives, regulations and guidelines for the use of Bovine Sera in biopharmaceutical or diagnostic processes.

PAA Laboratories, the largest manufacturer of FBS in Europe, has now released a new standard for FBS:

### **FBS Pharma Grade.**



The safety guidelines and monographs for bovine sera provide a general quality specification for these products. All stages of serum production are subject to a suitable quality assurance system. The following guidelines regulate the manufacturing process as well as the quality control and minimize any risk for biopharmaceutical and diagnostic industries.

#### **The FDA's Code of Federal Regulation (9CFR), §113.28,47,53**

#### **The EMEA Guideline 1793/02 and 743/00**

#### **The European Pharmacopoeia Monograph of Bovine Serum 5.4 (04/2006:2262)**

The guidelines describe clearly and categorically:

- The traceability of serum must be fully described from the abattoir to the final sterile container of serum
- Appropriate steps are taken to ensure the homogeneity of the intermediate pools of serum and the final batch
- Final measures and sterility testing post filtration
- General and specific tests for viral contamination must be carried out as described below
- Validated inactivation steps for viral removal have to be carried out for use in veterinary medicinal products

We have the capability to supply FBS Pharma Grade in batch sizes up to 2600 litres.

## THE TEST PORTFOLIO OF FBS PHARMA GRADE

The following tests have to be carried out on the batch prior to inactivation

### **Viral contaminants**

- Bluetongue Virus (BTV)
- Bovine Adeno Virus (BAV)
- Bovine Parvovirus (BPV)
- Bovine Respiratory Syncytial Virus (BRS-V)
- Reovirus (Reo-3)
- Bovine Virus Diarrhoea Virus (BVD-V)
- Rabies Virus
- Parainfluenza Virus (PI-3)
- Bovine Herpes Virus (BHV-I / IBR)

### **Viral antibodies**

- BVD-1-AB
- BVD-2-AB
- Rabies-AB

### **Special BVD tests**

- Comparative BVD virus growth inhibition
- BVD-AB Interferences

These tests must be carried out on the batch after inactivation

- Tests on presence of viruses which were found prior to inactivation
- It must be demonstrated by a validation that the virus is completely inactivated after inactivation

## FBS PHARMA GRADE FOR ADVANCED THERAPY APPLICATIONS

FBS Pharma Grade fulfils the requirements of the biopharmaceutical industry as well as all manufacturers of advanced therapy products. Therefore PAA's FBS Pharma Grade tested at the highest safety level is ideal for stem cell cultivation, gene therapy, somatic cell therapy, tissue engineering and re-implantation experiments.

### SINGLE BOX GAMMA IRRADIATION

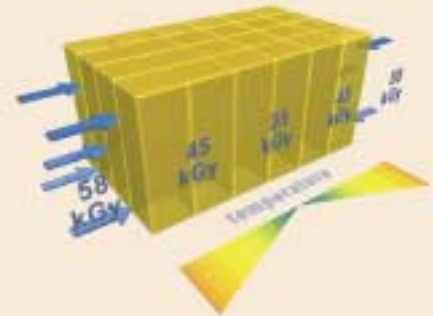
PAA has established fully validated process parameters and controls for maximum inactivation of contaminants by a unique gamma irradiation process in small sized boxes at 35 kGy. When FBS bottles are arranged in a pallet during gamma irradiation, high irradiation doses (58 kGy) are necessary to irradiate the centrally located core bottles with the required dose (> 30kGy). This and the associated higher temperature may affect the serum quality. If the irradiation is performed in single boxes, the maximum dose of irradiation does not exceed 38.7 kGy. Gentle irradiation as used by PAA is less likely to affect final serum quality.

#### FEATURES

- Tested according to all current biopharmaceutical guidelines for bovine derived products
- Australian and U.S. origin
- No BVD antibody interferences
- Gentle irradiation at 35 kGy
- Manufactured according to cGMP
- Comprehensive documentary traceability

#### APPLICATIONS

- Vaccine production
- Production of recombinant monoclonal antibodies
- Production of recombinant growth factors
- Advanced cell therapy



Pallet irradiation



Single box irradiation

Other tests to be carried out (a selection is suitable to identify the serum)

#### Identity

- Identity of bovine origin
- Electrophoretic pattern

#### Proteins, enzymes and biochemicals

- Albumin
- $\alpha$ -,  $\beta$ -,  $\gamma$ -Globulins
- Haemoglobin
- Total Protein
- Aspartate transaminase
- Alanine transaminase
- Cholesterol
- Bilirubin
- Creatinine
- Glucose

#### Ions

- Phosphorous
- Potassium
- Calcium
- Sodium

#### Physical and chemical analysis

- pH
- Osmolality
- Endotoxin

#### Micro-organisms

- Mycoplasma
- Bacterial and fungal sterility





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**ORDER INFORMATION**

	<b>Cat. No</b>	<b>Volume</b>
FBS Pharma Grade AUS origin	A15-511	500 ml
FBS Pharma Grade Gamma Irradiated AUS origin	A15-512	500 ml
FBS Pharma Grade USA origin	A15-211	500 ml
FBS Pharma Grade Gamma Irradiated USA origin	A15-212	500 ml

