



# TICO EUROPE

YOUR PARTNER IN LIFE SCIENCE PRODUCTS



# Fetal Bovine Serum

## INTRODUCTION

Fetal Bovine Serum (FBS) is used as a supplement to basal growth medium in cell culture. Fetal bovine Serum is also known as Fetal Calf Serum (FCS). FBS is obtained from fetuses harvested in slaughterhouses from healthy cows fit for human consumption. Fetal Bovine Serum is the serum produced from the blood from unborn Bovine fetus and contains many substances which are needed to stimulate the cultured cells to grow in laboratories and live properly. FBS is the serum of first choice for culturing cells, tissues and organs in research applications due to its broad applicability: almost every cell type thrives with it. It is therefore extensively being used both in research, medicine and the life science industry.

## COLLECTION & PROCESSING

FBS is the liquid fraction of clotted whole blood. FBS is centrifuged to separate the clot from the liquid phase. This results in a product that is depleted of cells, fibrin and clotting factors. Controlling the initial collection of fetal blood is a crucial factor in the quality of the final serum product. Only raw material that meets Tico Europe's specifications is approved for production. The batches of raw FBS material are thawed and tested for endotoxins and hemoglobin content and only the accepted material is pooled.

The pooled material is blended and membrane filtered for sterility according to our validated filtration protocol. Our FBS is triple filtered through 0.1 µm filters. After filtration the FBS is dispensed into bottles by an aseptic filling process. Our FBS is produced in a controlled environment (clean rooms) specially designed with controlled air pressure and particulate matter. After filling of the bottles the sterile final product is frozen to -20°C and held in quarantine until quality control tests have been completed.

Our facility can manufacture batches up to 1000 litres. This way every batch is controlled throughout the process, from collection to final packing. This ensures complete traceability right back to the source.

## TRACEABILITY

For every batch of serum that is released, seamless traceability is assured, giving information on:

- ▶ The geographic origin of the animal
- ▶ The animal's race
- ▶ Type of feeding the animal received during breeding
- ▶ The composition of the fodder

In addition, a veterinary certificate documenting that the animals used are healthy and a certificate of analysis attesting the product's conformity to the specifications is provided by the competent authority.

Tico Europe FBS is available in PET bottles of 50, 100 and 500ml.

## QUALITY CONTROL

Before labelling, our FBS batches are validated in external quality control laboratories.

### **Sterility >**

Quality control is established by applying standards equivalent to those required for the aseptic production of pharmaceuticals.

### **Mycoplasma control >**

The presence/absence is determined according to the GMP standards.

### **Viral testing >**

All pharmaceutical sera are of bovine origin. The raw materials and final products are tested for the presence of:

- ▶ BVD virus antibodies
- ▶ BVD virus antigens
- ▶ Bovine Leucosis virus antibodies
- ▶ IBR virus antibodies

### **Physico-chemical parameters >**

The osmolarity and pH are tested for each batch against product specifications. The instruments used for these tests are calibrated regularly according to GLP (Good Laboratory Practice).

### **Endotoxin determinations >**

The potential endotoxin content of the sera is determined by chromogenic substrate and kinetic turbidimetric tests, using LAL reagents.

### **Biochemical parameters >**

These tests provide, among other parameters, the quantitation of total protein and albumin content.

### **Validation of performances in cell culture >**

Performance validation of the sera in cell culture is done on immortalized cell lines. Product conformity is given with respect to the predefined specifications:

- ▶ successful passaging of x number of generation times
- ▶ cell proliferation
- ▶ morphological state of the cells observed by microscopy





## LABELLING & STORAGE

After QC approval, the products are labelled with the following information, according to standard procedures:

- ▶ Product name
- ▶ Product catalogue number
- ▶ Pack Size
- ▶ Batch number
- ▶ Storage conditions
- ▶ Expiry date
- ▶ The declaration: "In vitro use only"

Standard FBS is stored at  $-20^{\circ}\text{C}$ .

## PRODUCTION PROCEDURE

Origin of pharmaceutical grade material



Traceability of the animals' fodder, formulations available on request



Blood drawn by employees



Centrifugation under controlled temp.



Serum frozen at  $-20^{\circ}\text{C}$  (quarantine)



Control of raw material



Pooling of batches



Filtration at  $3 \times 0,1\mu\text{m}$



Filling and packing in PET flasks, sterile batches of 1000 litres



Final quality control

## SHIPPING & DELIVERY

Shipping and delivery is contracted to companies specialised in transportation of refrigerated materials. Delivery time is 24-48h. For products not immediately available, our Customer Service team will provide information about the planned delivery date.

## BATCH RESERVATION

All Tico Europe sera have a shelf life of 5 years. In order to offer customers the opportunity to select serum from the batch which works best with the particular cells being used and continue to use bottles from the same batch of serum over a period of time, Tico Europe offers a product reservation system.

Samples of different serum batches are provided to customers for evaluation under working conditions. After evaluation, the most satisfactory serum batch may be chosen and reserved. The reserved batch will be stored in the Tico Europe warehouse and shipped upon request.

## HANDLING SERUM PRODUCTS

Although the product has been sterile filtered aseptic procedures must be followed at all time. Granules, flocculence material may appear in FBS for various reasons. This particulate matter does not affect the FBS performance. Repeated freezing/thawing of serum may increase the amount of precipitate and is therefore not recommended. If you do not intend to use the complete bottle FBS aliquot it into usable quantities in sterile containers before freezing a second time.

To remove flocculence, transfer the FBS to sterile tubes and centrifuge the material briefly and filter the resulting supernatant along with your media.

## ADDITIONAL TREATMENT

FBS is also available heat inactivated and gamma irradiated.

### Heat inactivation >

Sterile filtered FBS is heated to 56°C for 30 minutes with continuous agitation. This process will inactivate various components of the serum including complement factors which can interfere with certain immunoassays. However, the routine treatment is not desirable for all applications, it is recommended to test the benefit of heat inactivation prior to having a batch treated this way. Heat inactivation can increase the presence of precipitates and may also impede the growth enhancing properties of FBS.

### Gamma irradiation >

Gamma irradiation is known as an effective method for inactivating viruses in animal origin material. After the FBS has been sterile filtered and bottled in the final packing it is then exposed to 25 – 35 kGy to guarantee freedom of micro-organisms. As the gamma irradiation is carried out in the final packing, it will cause PET bottles to darken color. It can also negative influence the performance of the FBS and reduce shelf life.

## FETAL BOVINE SERUM FREQUENTLY ASKED QUESTIONS

### [What is the difference between fetal bovine serum and fetal calf serum? >](#)

There is no difference. Both terms describe exactly the same product.

### [How do I heat-inactivate my FBS? >](#)

Heat inactivation is done in a waterbath at 56°C for 30 minutes. The water level should be higher than the level of serum. Swirl the bottle every 10 minutes. To be sure, use a second bottle of similar size as a control and add an equivalent volume of water to the control bottle. Place a thermometer in the control bottle to when 56°C is reached. The timer must be set for 30 minutes from this point. Only use a calibrated thermometer.

### [How should I thaw FBS? >](#)

We recommend to thaw the FBS at 2 – 8°C. However you may thaw the FBS at room temperature. Swirl the bottles gently to mix serum during the thawing process.

### [Why is the color of the FBS not exactly the same as my previous lot? >](#)

The color of FBS is brown-red to brown. It is dependent on mainly the hemoglobin concentration of the specific batch. The color does not affect the FBS performance.

### [My FBS contains precipitates. What are they and how to handle? >](#)

The precipitates contain fibrin and lipoproteins. This is a normal characteristic and will not affect the product performance. To remove the precipitates, centrifuge the FBS or let it simply settle to the bottom of the bottle and transfer the FBS carefully to another sterile bottle.

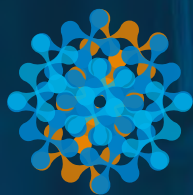
### [My FBS arrived partly thawed, what should I do? >](#)

We recommend to defrost the FBS completely, swirl the FBS bottle and re-freeze the FBS. The quality of the FBS will not have been affected.

## PRODUCT INFORMATION

Cat. No.	Product name	Unit
FBSEU500	Fetal Bovine Serum EU-approved	500 ml
FBSEU100	Fetal Bovine Serum EU-approved	100 ml
FBSEU050	Fetal Bovine Serum EU-approved	50 ml
FBSEU500HI	Fetal Bovine Serum EU-approved Heat inactivated	500 ml
FBSEU500GI	Fetal Bovine Serum EU-approved Gamma irradiated	500 ml
FBSEU500IG	Fetal Bovine Serum EU-approved IgG content very low	500 ml
FBSEU500ES	Fetal Bovine Serum EU-approved for embryonic stem cell culture	500 ml
FBSEU500HC	Fetal Bovine Serum EU-approved for hybridomas culture	500 ml

Sera from other origins available upon request.



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