How to Select Fetal Bovine Serum (FBS)?

Fetal Bovine Serum (FBS) is a mixture formed by removing fibrinogen and other components from fetal bovine plasma. It plays an essential role in cell culture research in vitro and is one of the most commonly used sera. As a common supplement for cell culture in most laboratories worldwide, selecting high-quality, batch-stable FBS can help improve researchers' experimental progress and efficiency. Therefore, the following guidelines can be referred to when selecting FBS:

1. Appearance

(1) Color

FBS contains trace amounts of hemoglobin. Depending on the concentration, it can appear yellow or red. According to the Chinese Pharmacopeia, the hemoglobin content should be ≤ 20 mg/dL. As long as the hemoglobin content is within this range, the color depth does not affect the quality and does not influence cell culture.

(2) Precipitation

During normal use, slight flocculent precipitates may appear. These precipitates are mainly caused by the aggregation of fibrinogen. The reasons for precipitation vary and are closely related to the manufacturer ’ s processing methods, including blood collection, freezing, transportation, and production, which may involve multiple freeze-thaw cycles. Each freeze-thaw cycle can result in the precipitation of some fibrinogen, which does not affect the serum ’ s quality.

(3) Clarity

Imported FBS tends to be thinner and lighter in color due to lower protein and lipid content, whereas domestic serum is usually thicker and darker in color.

2. Main Testing Indicators

Based on the 2020 Chinese Pharmacopeia (3604 Newborn Bovine Serum) and the 2020 United States Pharmacopeia (USP < 90 > Fetal Bovine Serum - Quality Attributes and Functionality Tests), the primary testing indicators are as follows:

(1) Pathogen-Related Testing

① Bacteria, fungi, mycoplasma, and other microorganisms

With improvements in serum production conditions, bacteria, fungi, bacteriophages, and other microorganisms are now almost completely controlled. Mycoplasma is also removed by filtration through a 0.1 μ m filter. According to pharmacopeia standards, serum should be free from bacteria and mycoplasma. Heat inactivation or gamma irradiation can further reduce microbial contamination risks, minimizing animal-derived component risks.

Bovine-origin viruses

② The Chinese Pharmacopeia requires testing for BVDV, PI-3, BAdV-3, BPV, REO3, and RV viruses, while the USP also tests for BVDV, BPV, BAdV-3, BTV, BRSV, REO3, RV, and BHV-1/IBR, PI-3 viruses. Testing methods include observing cell culture growth and immunofluorescence antibody assays (IFA) for bovine-origin viruses.

Bacterial endotoxins

③ The Chinese and U.S. pharmacopeias require endotoxin levels to be less than 10 EU/mL. Endotoxins, derived from the cell walls of broken bacteria, indicate the level of Gram-negative bacterial contamination. Endotoxins cannot be removed by filtration and can affect cell growth characteristics. High endotoxin levels indicate possible contamination of the serum.

(2) Physiochemical Indicators

① pH

The pH range of serum indicates the physiologic environment it supports for cell vitality and confirms that the serum is not adulterated. The Chinese Pharmacopeia specifies a pH of 7.00-8.50, while the USP specifies 7.00-8.00. Domestic FBS is typically above 7.5, and imported FBS is usually below 7.5, which may be related to the age of the cattle.

② Osmolarity

Osmolarity reflects the electrolyte and solute concentration in serum, ensuring it has not been diluted. The Chinese Pharmacopeia specifies 250-330 mOsmol/kg, while the USP specifies 280-360 mOsmol/kg.

③ Total Protein

This reflects the age of the bovine. Fetal bovine serum has the lowest protein concentration. The Chinese Pharmacopeia specifies 35-50 g/L (3.5-5.0 g/dL), and the USP specifies 3.0-4.5 g/dL. Higher values may indicate older cattle, while lower values may suggest water dilution.

④ Hemoglobin

The Chinese Pharmacopeia specifies <200 mg/L (20 mg/dL), and the USP specifies <30 mg/dL. The redder the serum, the higher the hemoglobin content. This indicator reflects the rigor and standardization of the blood collection process. Proper handling reduces hemolysis.

⑤ Other Indicators

FBS typically has a very low γ-globulin ratio compared to other serum types. Higher levels of γ-glutamyltransferase (GGT) are characteristic of non-FBS sera. Immunoglobulin (IgG) levels above 300 μg/mL may indicate non-FBS serum.

(3) Serum Functionality Tests

Both the Chinese and U.S. pharmacopeias include tests for serum's ability to support cell proliferation, including growth curves, doubling time, cell counts, viability, and cloning efficiency.

3. **Source of Blood**

The origin of the serum directly impacts its quality, with different regions producing serum of varying quality. Due to environmental factors and technical differences in China, domestic FBS is generally of lower quality than imported FBS, which mainly comes from Australia, New Zealand, and South America (Uruguay).

(1) Australian Serum

Originating mainly from Australia and New Zealand, it is widely considered the highest quality and most reliable, though it is also the most expensive due to factors like production volume and transport costs.

(2) South American Serum

Sourced mainly from Uruguay, it offers a better balance of quality and price, but quality can vary between brands depending on production methods.

(3) Domestic Serum

Due to environmental factors and widespread antibiotic use, the quality of most domestic FBS is generally lower, though it is also cheaper.

LUXCELL Brand Fetal Bovine Serum (FBS):

Traceable Source

(1) Our blood is sourced from beef cattle farms in southwestern China, not from dairy farms in northern regions like Inner Mongolia, avoiding issues with antibiotic overuse and residue.
(2) We manage the entire process from the farm to blood collection and processing, ensuring traceability of the source cattle’s farm and quarantine status.
(3) Our serum’s traceability meets cGMP requirements.

Sterile Production Process and GMP Compliance

(1) Our FBS is produced in GMP-compliant facilities using a sterile, single-use process.
(2) We perform sterile filtration through 4-level, up to 0.1 μm pore size filters.
(3) The maximum batch size is 1000L, reducing batch frequency and minimizing batch-to-batch variations.
(4) We avoid the need for cleaning validations and the associated risks of contamination.

Multiple Quality Inspections and Batch Stability

(1) We conduct quality control on every single source blood batch before production.
(2) Our FBS undergoes quality testing for various cell types, including hematopoietic stem cells, T-cells, mesenchymal cells, fibroblasts, primary cells, and cancer cell lines.
(3) Dual quality testing of both source blood and final product ensures the serum’s quality and batch consistency.

Gamma-Irradiated FBS Available

(1) Gamma irradiation is a common and effective method for pathogen inactivation, minimizing animal-derived risks.
(2) Our premium irradiated FBS has been verified to retain cell growth capabilities, providing higher assurance to customers with stricter requirements.