Fetal Bovine Serum Biopharm
Gamma Irradiated ≥ 30 kGy & EDQM certified

CAT N°: SxxxA

Collected from the source:
When researchers choose their serum an important factor that should be taken into consideration is the source, which also emphasises the traceability of the serum.
Our system of vertical integration allows us to be certain of the origins and traceability of our FBS.
Meeting the highest quality demands, all selected batches of FBS Biopharm respect the requirements of the monograph 2262 of the European Pharmacopoeia. Each batch comes from EDQM certified countries.
Each manufactured batch is rigorously controlled, from the collection of serum and throughout all stages of its treatment and production through to final packaging on our premises.
BioWest Fetal Bovine Serum Biopharm is derived from clotted whole blood aseptically collected from fetus via cardiac puncture.
The serum is imported and treated in agreement with the European regulations.

Country of Origin:
The country in which the serum was taken from the donor/animal is EDQM certified.
BioWest Fetal Bovine Sera Biopharm could be sourced from the following countries:

S181A: Brazil, Colombia, Paraguay
S152A: USA
S156A: Chile
S158A: Uruguay
S160A: Costa Rica, Panama
S165A: Mexico
S140A: France, Spain, Denmark, The Netherlands, Ireland

To order a treated serum (other than Fetal Bovine Serum), please replace the last number of the Cat N° of standard serum by the letter A.

Storage conditions:
- 18°C to - 40°C, protected from light.
Bottles can be stored between -40°C and -80°C for a short period (few days).

Shelf life:
5 years

Filtration:
Final Filter Size: 0.1µm x 3

pH:
Determined using pHmeter.
Specification: 6.8 - 8.0

Osmolality:
Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions.
Specification: 280 – 365 mOsm/kg (method EP §2.2.35)

Endotoxin:
The sera are tested to determine the levels of endotoxins. BioWest carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia (method EP §2.6.14).
The endotoxin reagent is standardized against the US reference endotoxin.
Specification: < 25 EU/ml

Haemoglobin:
The haemoglobin level is measured by spectrophotometer.
Specification: < 30 mg/100ml

Cell Culture:
Biological performance is assessed using cell culture medium supplemented with the serum being tested. During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum.

Cell Culture Tests:

Cell Growth, Plating Efficiency, Cloning Efficiency.

Cell Lines Tested:

The following cell lines are tested with the serum:
HELA -Cancer Cell/Human.
L929 -Fibroblast-Mouse/ As Macrophage
SP2/0-AG14 -Mouse/Lymphoma
MRC- 5 -Human/Lung.

Total Protein:
Determined by Biuret Colorimetry.
Specification: 30 – 45 g/l (method EP §2.5.33)

Sterility tests:
All sera are tested for the absence of aerobic and anaerobic bacteria, fungi, yeast and Mycoplasma.
The sterility test is made according to the European Pharmacopoeia requirements (method EP §2.6.1).
The sera are tested for the absence of Mycoplasma by PCR (method EP §2.6.7).

Virus test (before gamma irradiation):
General tests:
- Haemadsorbing Agents eg PI3 virus by cell culture
- Cytopathogenic Agents eg. IBR / BHV-1 by cell culture

Specific tests:
List of tested viruses according EMEA (European Medicines Agency):

- Bluetongue (BTV) by culture & PCR detection
- Bovine adenovirus (BAV) by culture & PCR detection
- Bovine parvovirus (BPV) by culture & PCR detection
- Bovine respiratory syncytial virus (BRS-V) by culture & PCR detection
- Pestivirus (e.g. BVDV-1, BVDV-2, BDV, CSFV, Giraffe-1 and Hobi-like viruses) by cell culture
- Rabies virus (RABV) by Immunofluorescence
- Reovirus 3 (REO-3) by culture & PCR detection

The specification for all virus tests is “Not detected”.

Other tests:
- Antibodies against Bovine viral diarrhoea virus type 1 & 2 (BVD) by cell culture. The specification is “Not detected” (detection limit 0,15 log ND50).
- Biochemistry tests: cholesterol, α-globulin, β-globulin, γ-globulin, albumin, creatinine, bilirubin, glucose, ASAT (SGOT), ALAT (SGPT), phosphorus, potassium, calcium, sodium. Results are within the expected range for FBS.
- Electrophoretic pattern consistent with FBS
- Bovine Origin confirmed by immunochemical method (method EP §2.7.1)

Treatments:
To ensure the highest safety for all applications each batch is gamma irradiated at a guaranteed dose of 30 kGy minimum (exceeding the EMEA/CVMP/743/00-Rev.2 requirements).

A validation of the homogeneity of gamma irradiation dose has been conducted to prove that each bottle receives a minimum dose of 30 kGy.

Biowest has also conducted a virus inactivation study to prove that a 30 kGy irradiation dose is sufficient to inactivated a wide range of virus of concern. This study is available on request.

Recommended use:
- Respect storage conditions of the serum
- Do not use the serum after its expiry date
- Store serum in an area protected from light
- Manipulate serum in aseptic conditions (e.g.: under laminar air flow)
- Wear clothes adapted to the manipulation of serum to avoid contamination (e.g.: gloves, mask, hygiene cap, overall…)
- In order to preserve all serum qualities, it is recommended to thaw out the flask, to aliquote, then to re-freeze the produced flasks rather than to thaw out and re-freeze the flask at each use.
- It is recommended to use the serum immediately after its thaw out. However, if it is not useful, it is possible to store thaw out serum, at +2°C / +8°C, until 26 weeks without significant decrease of its performances in cell culture.

FBS Biopharm is the high quality FBS grade of choice for Biopharmaceutical production, Vaccine production and all applications where the highest standard of product quality and documentation is required.

Remarks:
It is the responsibility of the end-user to verify that the FBS Biopharm is suitable for use in its applications. Especially, it is the responsibility of the end-user to verify that the use of FBS Biopharm made by end-user is allowed by local low applicable in the country of the end-user. Biowest cannot be considered responsible of any damage caused on material, final product or people resulting in incorrect or unauthorized use of the FBS Biopharm.

All tests are done before gamma irradiation.