Fetal Bovine Serum Biopharm (EDQM certified),

CAT N° : S181A

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 come 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.

Filtration :
Final Filter Size : 0.1µm, x 3

Sterility :
All sera are tested for the absence of aerobic and anaerobic bacteria, fungi, yeast and Mycoplasma.
The sterility test is based on the European Pharmacopoeia requirements.
The sera are tested for the absence of Mycoplasma by culture.

Virus Tested :
List of tested viruses according EMEA (European Medicines Agency):

- Bluetongue (BTV)
- Bovine adenovirus (BAV)
- Bovine parvovirus (BPV)
- Bovine rhinotracheitis (IBR)
- Parainfluenza (PI3)
- Bovine respiratory syncytial virus (BRS-V)
- Bovine viral diarrhoea virus (BVD)
- Rabies virus (RABV)
- Reovirus 3 (REO-3)
- Bovine Leukaemia virus (BLV)
- Vesicular Stomatitis Virus strains Indiana and New Jersey (VS)

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.
The endotoxin reagent is standardized against the US reference endotoxin.
The specification is < 10 EU/ml.

Haemoglobin :
The haemoglobin level is measured by spectrophotometer.

Osmolality :
Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions. The specification is 275 to 345 mOsm/kg

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.

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

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: Uruguay, Paraguay, Brazil, Chile, Costa Rica, Mexico and Panama.

Storage conditions :
Store at -20°C

Shelf life :
5 years

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.

Applications:
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.
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.