MOREGATE BIOTECH
AUSTRALIA AND NEW ZEALAND

AUSTRALIAN OR NEW ZEALAND ORIGIN

Adult Bovine Serum - Raw (ABSR)

Adult Bovine Serum – Raw (ABSR), is obtained from blood taken from cattle deemed fit for human consumption following ante and post mortem veterinary inspection. The blood is collected in slaughter-houses supervised by government veterinarians.

The blood is collected in lined sanitary buckets and allowed to clot naturally without the addition of any clotting factors. The blood is then transferred to a temperature controlled clean environment where the liquid component of the blood is drained and separated using a continuous flow separator before being dispensed into 5L Bottles and immediately frozen.

Specifications

SPECIFICATION - ADULT BOVINE SERUM - RAW (ABSR)	
Product	Adult Bovine Serum - Raw
Catalogue No.	ABSR
Certificate of Suitability	New Zealand R1-CEP2001-093
Source	Bovine blood from healthy animals which have been inspected ante and post mortem by Australian or New Zealand Government veterinarians and passed as fit for human consumption.
Collection Method	Blood is collected into sanitary containers. Serum is produced in temperature controlled conditions. The blood is drained and separated using a continuous flow separator. It is then immediately frozen.
Irradiation	Irradiation can be performed on request
Pack Size	5 Litre container or to Customer Specifications
Storage	-20 degrees Centigrade
Expiry Date	Six years from the date of manufacture

TEST	METHOD	SPECIFICATION
Aerobic Microbial Count	CFU/ml	< 1000 CFU/mL

Regulatory

EP/USP

The European Pharmacopeia consists of a number of general and specific monographs covering various classes of products.

The monographs set out requirements to be met and followed for all products in the class.

Recently the EP has introduced a Monograph for Bovine Serum – Monograph No 04/2006:2262 to be found in E.P. 5.4

This monograph provides a definition of Bovine Serum and sets out details of production, and requirements for viral inactivation parameters, quality control testing, storage conditions and labelling.

Moregate Bovine Serum products meet these requirements and Certificates of Analysis are modeled on the QC test requirements.

The United States Pharmacopeia-National Formulary (USP-NF) contains standards for medicines, dosage forms, drug substances, excipients, medical devices, and dietary supplements.

Within the Pharmacopeia are Monographs and general chapters.

The monographs consist of information such as the ingredient name, definition, packaging and labelling requirements, storage and a specification.

The specifications list tests to be performed along with the procedure to be followed and the acceptable limit.

EMEA/CPMP/CVMP

The European Medicines Agency (EMEA) is a decentralised body of the European Union with headquarters in London. It sits alongside the European Directorate for the Quality of Medicines (EDQM).

The main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The EMEA publishes guidelines on quality, safety and efficacy testing requirements.

These guidelines are prepared by committees, and those guidelines which relate to the use of Bovine Serum, including Fetal Bovine Serum, in the manufacture of medicines include:

CPMP: Committee for Proprietary Medicinal Products

Note for Guidance on the Use of Bovine Serum in the Manufacture of Human Biological Medicinal Products

Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products. (Also adopted by the CVMP)

CVMP: Committee for Veterinary Medicinal Products

Requirements and Controls applied to Bovine Serum used in the production of Immunological Veterinary Medicinal products.

These Guidelines include requirements for Virus Testing of Fetal Bovine Serum and other Bovine Serum. Further reference to these requirements can be found in “Virus Testing”.

All Moregate Biotech Fetal Bovine Serum and other Bovine Serum meet the requirements of the Guidelines in relation to Fetal Bovine Serum and Bovine Serum.

USDA 9CFR PART 113.53C

Ingredients of animal origin used in the United States of America, in the manufacture of veterinary and human biologics are required to be in compliance with the Code of Federal Regulations, Title 9 – Animals and Animal Products, Chapter 1 - Animal and Plant Health Inspection Service, Department of Agriculture Part 113-53c, commonly referred to as 9CFR Part 113-53c.

This legislation sets out the requirements for detection of extraneous viruses, detailing the methods to be used and the list of viruses that shall be tested for.

Over time 9CFR Part 113-53c became the accepted standard for the testing of animal sera, particularly Fetal Bovine Serum for adventitious viral agents.

Bovine Respiratory Syncytical Virus, Bovine Viral Diarrhea Virus, Bovine Parvovirus, Bluetongue Virus, Bovine Adenovirus, Rabies Virus and Reovirus are tested for by fluorescent antibody

Infections Bovine Rhinotracheitis tested for by Cytopathic Agents.

Infectious Influenza 3 tested for by Haemadsorbing Agents

EDQM

The European Directorate for the Quality of Medicines (EDQM) has originated from the European Pharmacopoeia Secretariat which, with the addition of new responsibilities changed its name to the European Department for the Quality of Medicines (EDQM). The EDQM sits alongside the European Medicines Agency (EMEA).

Amongst other activities, the EDQM is responsible for the European Pharmacopeia and the issuing of Certificates of Suitability (CEP).

Certificates of Suitability (CEP) are recognised by all signatory states of the European Pharmacopoeia Convention and by the European Union. Other countries have also chosen to recognise them. In the case of Fetal Bovine Serum and other Bovine Serum a CEP can be used by the manufacturers of Fetal Bovine Serum and other Bovine Serum which is intended for use in the manufacture of pharmaceutical products to demonstrate compliance with the Bovine Serum monographs of the European Pharmacopoeia and the EDQM requirements for substances concerned by TSE risk.

The discovery of Bovine Spongiform Encephalopathy (BSE), which is one of a group of similar infections now referred to as Transmissible Spongiform Encephalopathies (TSEs), and it’s spread over many countries of the European Union as well as its discovery in Canada, the USA and Japan is well known. The European events provided the impetus for the Council of Europe Public Health Committee (CEPHC) to pass Resolution AP-CSP (99) 5 addressing the TSE concerns and creating a Certificate of Suitability (COS) pursuant to Directive 75/318/EEC.

The granting of a CoS to a manufacturer, for a particular product, certifies that the product in question has been assessed for the level

of risk of transmission of TSEs, and that the risk level is considered low enough that the product is certified as suitable for use in the manufacture of medicinal products in the European Union.

The process of approval requires the manufacturer to submit a dossier that covers all relevant aspects of the collection of raw material and further processing that is performed to reach the product that is offered to end users. This dossier is detailed and covers the specific material that is collected, the collection method, process validation, testing, traceability, quality systems and an expert review.

Only after this dossier has been examined and approved by two rapporteurs and, if necessary, by a panel of experts appointed by the European Directorate for the Quality of Medicines (EDQM) is the manufacturer granted a COS.

Moregate Biotech has been granted a COS for:

- Fetal Bovine Serum – Australian Origin – CEP2000-187
- Fetal Bovine Serum – New Zealand Origin – CEP2000-188
- Adult Bovine Serum - New Zealand Origin – CEP2001-093
- Adult Bovine Serum (Defibrinated) - New Zealand Origin – CEP2000-174
- Bovine Plasma – New Zealand Origin – CEP2003-199
- Bovine Serum Albumin – manufactured in Australia from New Zealand origin Bovine Plasma – CEP2003-205
- Bovine Plasma – Australian Origin - CEP 2005-192
- Bovine Serum Albumin – manufactured in Australia from Australian origin Bovine Plasma - CEP 2005-191

Copies of the Certificates of Suitability are available upon request

MSDS

HAZARDS IDENTIFICATION

- Not hazardous
- Get Medical attention immediately

First Aid Measures
Get Medical attention immediately.

Ingestion
If swallowed, give several glasses of water to drink to dilute.

Skin Contact
Wash skin with soap and copious amounts of water.

Eye Contact
Flush with water for at least 15 minutes, lifting upper and lower eyelids occasionally.

ACCIDENTAL RELEASE

Procedures for Personal Precaution
Exercise appropriate precautions to minimize direct contact with skin or eyes.

Methods for Cleaning Up
Mop up
Ventilate area and wash spill site after material pickup is complete

HANDLING AND STORAGE

Handling
Normal measures for preventive fire protection

Storage
Keep tightly closed under correct storage conditions

EXPOSURE CONTROLS / PERSONAL PROTECTION

- Wash thoroughly after handling.
- Protective gloves

Disposal Considerations
Contact a licensed professional waste disposal service to dispose of this material.

Transport Information

- Non-hazardous for road transport
- Non-hazardous for sea transport
- Non-hazardous for air transport

Note: The above information is believed to be correct, but shall be used as a guide only.

Disclaimer: For pharmaceutical use only.