

Certificate of Analysis

Foetal Bovine Serum

Pharmaceutical Grade

Triple 0.1µm Sterile Filtered

Certified Australian Origin

Certified Suitable by EDQM Certificate Number:
R0-CEP 2014-336-Rev 01

Batch No.:	
Origin:	Australia
Species:	<i>Bos taurus</i>
Catalogue Number:	10114111
Date of Manufacture:	
Expiry Date:	

1. General:

	Test	Method	Specification	Result
1.1	Appearance	Visual inspection	Clear, straw-coloured fluid, free of any particulate matter	Clear, straw-coloured fluid, free of any particulate matter
1.2	pH	pH meter	6.9 – 7.8 pH	7.6 pH
1.3	Osmolality	Freezing point depression	280 – 365 mOsm/kg	310 mOsm/kg
1.4	Haemoglobin	Spectrophotometry	≤ 25 mg/dL	17.5 mg/dL
1.5	Total Protein	Biuret method	30 – 45 g/L	36 g/L
1.6	Total IgG	ELISA	≤ 300 µg/mL	120 µg/mL
1.7	Endotoxin	LAL	≤ 10 EU/mL	<1 EU/mL
1.8	Sterility	Cell culture	No microbial presence	No microbial presence
1.9	Bacteria	Cell culture	Not detected	Not detected
1.10	Fungi	Cell culture	Not detected	Not detected
1.11	Mycoplasma	Cell culture	Not detected	Not detected

2. EMEA: CPMP/CVMP

	Test	Method	Specification	Result
2.1	EMA 7.3.1 General Tests - <i>Cytopathic agents,</i> <i>Haemadsorbing agents</i>	See 4.10 & 4.11	See 4.10 & 4.11	See 4.10 & 4.11
2.2	EMA 7.3.2 Test for specified viruses	See 4.1 - 4.11	See 4.1 - 4.11	See 4.1 - 4.11
2.3	EMA 7.3.3 Recommendation for bovine viral diarrhoea virus (BVDV)	See 4.5	See 4.5	See 4.5
2.4	EMA 7.3.4 Detection of anti - BVDV antibodies	See 7.4	See 7.4	See 7.4
2.5	EMA 7.3.5 Other Bovine viruses - <i>BPyV</i>	See 4.8	See 4.8	See 4.8

3. Growth promotion:

	Test	Method	Specification	Result
3.1	CHO-K1 ATCC	Cell count, microscopy	≥85% FBS	114.7%
3.2	Hybridoma	Cell count, microscopy	≥85% FBS	93%
3.3	MDBK	Cell count, microscopy	≥85% FBS	91.9%
3.4	MRC5	Cell count, microscopy	≥85% FBS	142%
3.5	Vero	Cell count, microscopy	≥85% FBS	88.2%

4. Virus Testing:

	Test	Method	Specification	Result
4.1	Bluetongue	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.2	Bovine Adenovirus	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.3	Bovine Parvovirus	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.4	Bovine Respiratory Syncytial Virus	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.5	Bovine Viral Diarrhoea Virus	Fluorescent antibody (9 CFR 113.47)	As detected (Virus burden before any inactivation treatment)	Not detected
4.6	Rabies Virus	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.7	Reovirus 3	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.8	Bovine Polyomavirus	Fluorescent antibody (9 CFR 113.47)	Not detected	Not detected
4.9	Bluetongue	Virus isolation	Not detected	Not detected
4.10	Bovine Herpesvirus 1	Virus isolation	Not detected	Not detected
4.11	Parainfluenza 3	Virus isolation	Not detected	Not detected

5. Biochemistry:

	Test	Method	Specification	Result
5.1	Alanine Transaminase (ALT)	Spectrophotometry	As reported	3 U/L
5.2	Alkaline Phosphatase (ALP)	Spectrophotometry	As reported	227 U/L
5.3	Anion gap	Calculated	As reported	27.7 mmol/L
5.4	Aspartate Aminotransferase (AST)	Spectrophotometry	As reported	34 U/L
5.5	Albumin	Electrophoresis	As reported	25.6 g/L
5.6	Beta Hydroxybutyrate (BHB)	Spectrophotometry	As reported	0.05 mmol/L
5.7	Bicarbonate	Monometric	As reported	22.3 mmol/L
5.8	Bilirubin (total)	Spectrophotometry	As reported	4.5 µmol/L
5.9	Calcium	Spectrophotometry	As reported	3.49 mmol/L
5.10	Chloride	Spectrophotometry	As reported	105 mmol/L
5.11	Cholesterol	Spectrophotometry	As reported	1 mmol/L
5.12	Creatinine	Spectrophotometry	As reported	253 µmol/L
5.13	Creatinine Phosphokinase (CK)	Spectrophotometry	As reported	98 U/L
5.14	Gamma Glutamyltransferase (GGT)	Spectrophotometry	As reported	9 U/L
5.15	Globulin	Electrophoresis	As reported	10.6 g/L
5.16	Glucose	Spectrophotometry	As reported	5.7 mmol/L
5.17	Glutamate Dehydrogenase (GLDH)	Spectrophotometry	As reported	3 U/L
5.18	Lactate Dehydrogenase (LDH)	Spectrophotometry	As reported	525 U/L
5.19	Magnesium	Spectrophotometry	As reported	1.43 mmol/L
5.20	Phosphate	Spectrophotometry	As reported	3.3 mmol/L
5.21	Phosphorus	Spectrophotometry	As reported	3.31 mmol/L
5.22	Potassium	Flame Emission	As reported	12.6 mmol/L
5.23	Sodium	Flame Emission	As reported	142 mmol/L
5.24	Triglyceride	Spectrophotometry	As reported	0.83 mmol/L
5.25	Urate	Spectrophotometry	As reported	0.128 mmol/L
5.26	Urea	Spectrophotometry	As reported	6.7 mmol/L

6. Serum Electrophoresis

	Test	Method	Specification	Result
6.1	Albumin	Agarose Gel Plate	As reported	18 g/L
6.2	Alpha 1 Globulins	Agarose Gel Plate	As reported	5 g/L
6.3	Alpha 2 Globulins	Agarose Gel Plate	As reported	8 g/L
6.4	Beta Globulins	Agarose Gel Plate	As reported	4 g/L
6.5	Gamma Globulins	Agarose Gel Plate	As reported	1 g/L
6.6	Electrophoresis Pattern	Agarose Gel Plate	Typical	Typical

7. Antibody testing

	Test	Method	Specification	Result
7.1	Akabane Virus	ELISA	Not detected	Not detected
7.2	Bluetongue Virus	ELISA	Not detected	Not detected
7.3	Bovine Herpesvirus 1	VNT	Not detected	Not detected
7.4	Bovine Viral Diarrhoea	VNT	As detected	Titre 32
7.5	Enzootic Bovine Leukosis	ELISA	Not detected	Not detected
7.6	Parainfluenza 3	ELISA	Not detected	Not detected

Measles, mumps, and rubella do not infect *bos taurus*, and rabies virus is not present in Australia.

The products described above were derived from animals of Australian origin and the products were treated solely within Australia. Foot-and-mouth disease and rinderpest do not exist in Australia.

The serum is intended for research or pharmaceutical/technical purposes only. The country of import/origin is free from TSE group of diseases and the product is free from pathogens especially Bovine Viral Diarrhoea (BVD).

Signed _____

QC