BIOCHROM AG

CERTIFICATE OF ANALYSIS

Manufactured by BIOCHROM AUSTRALIA PTY LTD,
2/14 Pearl Street, Brooklyn Vic. 3012, Melbourne, Australia
Phone: +49 30 7799060 – Fax: +49 30 7710012

Product: **GAMMA IRRADIATED FETAL BOVINE SERUM (FBS), origin Australia, manufactured in Australia**
complies with EP monography No. 2262, EP 5.2.8, EMA/410/01 rev. 3
0.1 µm sterile filtered
Dose of gamma irradiation > 30 kGray
(measured dose min 33.1 kGray - max 45.0 kGray)

Catalog no.: S 4115
Lot no.: 0285 B
Final batch volume: 935 L
No. of gamma irradiated units: 1870
Processed from raw material (name or number): 1050113

Date of production: 09.05.2013
Date of approval: 05.12.2013
Expiry date: 05 / 2019

Test	Units	Specification range	Results
Appearance, colour		clear, amber	complies
Sterility (Ph.Eur. 2.6.1) before γ-irr.		No evidence of microbial growth	complies
pH (Ph.Eur. 2.2.3)		6.8 - 8.2	7.77
Osmolality (Ph.Eur. 2.2.35)	mOsmol/kgH_2O	280 - 365	360
Hemoglobin (IPL)	mg/100mL	≤ 25	19.37
Culture testing (BHK 21)			
Growth promotion performance		compliance with control	complies
Cloning efficiency		compliance with control	complies
Endotoxin (Ph.Eur. 2.6.14)	EU/mL	< 10	< 1.0
Identification DRID (Ph.Eur. 2.7.1)		exclusively of bovine origin	complies
Extraneous agents (EMEA/CVMP/743/00, EMEA/BWP 1793/02 and EP 5.2.5) before γ-irr.			
Cytopathic effect (CPE) *)		no CPE	complies
Haemadsorption (HAD) *)		negative	complies
BVDV/MDV non CPE *)		not detected	**positive**
BVDV/MDV CPE *)		not detected	complies
IBRV/BHV-1 *)		not detected	complies
PIV 3 *)		not detected	complies
BTV **)		not detected	complies
RABV **)		not detected	complies
BAV 3 *)		not detected	complies
BPV *)		not detected	complies
ReoV 3 *)		not detected	complies
BRSV *)		not detected	complies
Extraneous agents (EMEA/CVMP/743/00, EMEA/BWP 1793/02 and EP 5.2.5) after γ-irr.			
BVDV/MDV non CPE *)		not detected	complies
BVDV/MDV CPE *)		not detected	complies

BIOCHROM AG

CERTIFICATE OF ANALYSIS

Manufactured by BIOCHROM AUSTRALIA PTY LTD,
2/14 Pearl Street, Brooklyn Vic. 3012, Melbourne, Australia
Phone: +49 30 7799060 – Fax: +49 30 7710012

Product: **GAMMA IRRADIATED FETAL BOVINE SERUM (FBS), origin Australia, manufactured in Australia**
complies with EP monography No. 2262, EP 5.2.8, EMA/410/01 rev. 3
0.1 µm sterile filtered
Dose of gamma irradiation > 30 kGray
(measured dose min 33.1 kGray - max 45.0 kGray)

Catalog no.: S 4115
Lot no.: 0285 B
Final batch volume: 935 L
No. of gamma irradiated units: 1870
Processed from raw material (name or number): 1050113

Date of production: 09.05.2013
Date of approval: 05.12.2013
Expiry date: 05 / 2019

Serum inhibitory test *)	Units	Specification range	Results
Titration of BVDV CPE by $TCID_{50}$ using BT cells cultured in the absence or present of the test article			
Titre determined using cells cultured in the presence of test article	log/mL	registration	6.5
Titre determined using cells cultured in presence of horse control serum	log/mL	registration	6.625
Difference	log	< 2	0.125

Test to detect BVDV antibodies *)	Units	Specification range	Results
Titration of BVDV Type 1 CPE by $TCID_{50}$ in absence or presence of the test article serum			
Titre determined in the presence of test article	log/mL	registration	5.25
Titre determined in presence of horse control serum	log/mL	registration	6.875
Reduction	log	registration	1.625[a]
Titration of BVDV Type 2 non CPE by $TCID_{50}$ in absence or presence of the test article serum			
Titre determined in the presence of test article	log/mL	registration	6.25
Titre determined in presence of horse control serum	log/mL	registration	6.875
Reduction	log	registration	0.625[a]

[a] Log difference > 0.5 log $TCID_{50}$/mL. This log difference is considered a reduction.

Conclusions:

1. The assay meets the criteria for a valid test.
2. Inhibitory properties were within acceptance criteria.
3. Antibodies against BVDV Type 1 CPE and BVDV Type 2 non CPE were detected, reducing the titre 1.625 log and 0.625 log, respectively.
4. There are no indications for the presence of BVDV in the gamma irradiated test sample.
5. Other bovine viruses were not detected in the sample.

Test	Units	Specification range	Results
Bovine virus antibodies against BTV **)		negative	complies
RABV (RFFIT) **)	IU/mL	< 0.5	< 0.5

BIOCHROM AG

CERTIFICATE OF ANALYSIS

Manufactured by BIOCHROM AUSTRALIA PTY LTD,
2/14 Pearl Street, Brooklyn Vic. 3012, Melbourne, Australia
Phone: +49 30 7799060 – Fax: +49 30 7710012

Product: **GAMMA IRRADIATED FETAL BOVINE SERUM (FBS), origin Australia, manufactured in Australia**
complies with EP monography No. 2262, EP 5.2.8, EMA/410/01 rev. 3
0.1 µm sterile filtered
Dose of gamma irradiation > 30 kGray
(measured dose min 33.1 kGray - max 45.0 kGray)

Catalog no.: S 4115
Lot no.: 0285 B
Final batch volume: 935 L
No. of gamma irradiated units: 1870
Processed from raw material (name or number): 1050113

Date of production: 09.05.2013
Date of approval: 05.12.2013
Expiry date: 05 / 2019

Mycoplasma testing (Ph. Eur. 2.6.7), before γ-irr.			
Mycoplasma *)		not detected	complies
Test	**Units**	**Specification range**	**Results**
Parameter / Biochemical assay *)**			
Alk. Phosphatase	U/L	100 - 900	195
AST (GOT)	U/L	10 - 90	43
ALT (GPT)	U/L	1.5 - 20.0	7
γ-GT	U/L	1 - 40	8
Bilirubin total	µMol/L	≤ 6.00	5.13
LDH	U/L	75 - 1500	103
CK total	U/L	10 - 400	111
Cholesterol	mMol/L	0.25 - 1.45	1.09
Triglycerides	mMol/L	report result	0.76
Creatinine	µMol/L	20 - 400	190.9
Urea	mMol/L	0.5 - 9.0	5.16
Glucose	mMol/L	1.5 - 10.0	5.99
Protein	g/L	30 - 45	35
Electrolytes: *)**			
Sodium	mMol/L	100 - 190	130
Potassium	mMol/L	4 - 20	11.3
Calcium	mMol/L	2.0 - 5.0	2.72
Magnesium	mMol/L	0.5 - 2.5	1.06
Phosphate	mMol/L	2.2 - 4.0	3.76
Iron	µMol/L	3 - 40	30.3
Capillary Elelectrophoresis: *)**			
Albumine absolute	g/L	11 - 37	16.7
α-Globulin absolute	g/L	2 - 27	16.1
β-Globulin absolute	g/L	0.8 - 7.5	1.8
γ-Globulin absolute	g/L	≤ 5	0.4
Immunoglobulin G **)**			
Immunoglobulin G (ELISA)	µg/mL	registration	211.0

CERTIFICATE OF ANALYSIS

Manufactured by BIOCHROM AUSTRALIA PTY LTD,
2/14 Pearl Street, Brooklyn Vic. 3012, Melbourne, Australia
Phone: +49 30 7799060 – Fax: +49 30 7710012

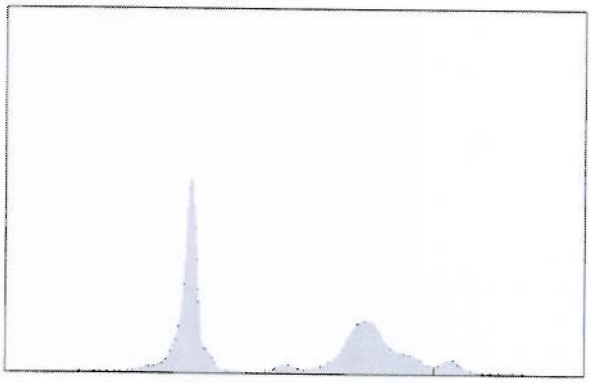
Product: **GAMMA IRRADIATED FETAL BOVINE SERUM (FBS), origin Australia, manufactured in Australia**
complies with EP monography No. 2262, EP 5.2.8, EMA/410/01 rev. 3
0.1 µm sterile filtered
Dose of gamma irradiation > 30 kGray
(measured dose min 33.1 kGray - max 45.0 kGray)

Catalog no.: S 4115
Lot no.: 0285 B
Final batch volume: 935 L
No. of gamma irradiated units: 1870
Processed from raw material (name or number): 1050113

Date of production: 09.05.2013
Date of approval: 05.12.2013
Expiry date: 05 / 2019

Hormones: ***)	Units	Specification	Results
Estradiol	pg/mL	report result	23.7
Progesterone	ng/mL	report result	< 0.20
Testosterone	ng/mL	report result	< 0.03

Electrophoretogram: *)**



Country of serum processing: Australia
This product has come from cattle born, raised and slaughtered in Australia, where BSE is not known to exist. Obtained from cattle fit for slaughter and for human consumption.

Storage: ≤ -20°C

Berlin, 05.12.2013

.....
Dr. H. Delventhal
Quality control manager

Tests performed at: *) Microsafe, Leiden NL, **) FLI Federal Research Institue for Animal Health, Insel Riems, ***) veterinary medical laboratory, Augsburg, ****) CellTrend GmbH, Luckenwalde