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	Date of Issue:	10-JAN-2022	Approved by:	Dr. Iman Kamranfar
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	Title:	TECHNICAL DATA SHEET		

Product Name	Fetal ExCell		
Filtration/Treatment	Gamma irradiated – 25kGy to 50kGy		
Origin	EU Eligible		
Product Codes	S-SFBS-EU-035		
Shelf Life	5 Years from DOM		
Storage Temperature	<-15°C		
Shipping Temperature	dry ice		
Physical and Chemical Analysis	Method	Specifications	Units
Identity	Internally Validated	Bovine	n/a
Appearance	Visual	Clear yellow-amber to dark amber liquid	n/a
Specific Gravity	Mass Balance	> 1.01	g/ml
pH	Electronic pH Meter	6.8 - 8.2	n/a
Osmolality	Osmometer	260 - 340	mOsm/kg
Endotoxin	LAL Kinetic	< 10	EU/ml
Free Hemoglobin	Colorimetric	< 50	mg/dl
Protein Profile			
Total Protein	IDEXX Catalyst One	3.0 – 5.0	g/dl
Albumin	IDEXX Catalyst One	1.4 - 3.6	g/dl
Globulin	IDEXX Catalyst One	0.4 - 2.6	g/dl
IgG	ELISA	< 500	µg/ml
Electrophoretic Pattern	Capillary Electrophoresis	Normal	n/a
Sterility			
Sterility	Internally validated	Pass	
Mycoplasma	qPCR	Not detected	n/a
Antibiotic Testing			
Tetracycline	IDEXX Snap Test	Test and report	n/a
Oxytetracycline	IDEXX Snap Test	Test and report	n/a
Chlortetracycline	IDEXX Snap Test	Test and report	n/a
Virus Testing			
BVDV/BHV-1/PI-3 (CPE)	Cell Culture	Not detected	n/a
Rabies Virus	qPCR	Not detected	n/a
Bluetongue Virus (BTV)	qPCR	Not detected	n/a
BRSV	qPCR	Not detected	n/a
Reo Virus	qPCR	Not detected	n/a
BAV	qPCR	Not detected	n/a
BoPV-1, -2	qPCR	Not detected	n/a
Antibody Testing			
BVDV - Antibody Type 1	Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA)	Test and report	n/a
BVDV - Antibody Type 2	Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA)	Test and report	n/a
BHV-1	Detection of Antibodies (ELISA)	Test and report	n/a
PI-3	Detection of Antibodies (ELISA)	Test and report	n/a

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Biochemistry			
Aspartate Aminotransferase (AST)	IDEXX Catalyst One	Record	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Record	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Record	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Record	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Record	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Record	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Record	mmol/L
Urea (BUN)	IDEXX Catalyst One	Record	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Record	μmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Record	μmol/L
Calcium (Ca)	IDEXX Catalyst One	Record	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Record	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Record	μmol/L
Magnesium (Mg)	IDEXX Catalyst One	Record	mmol/L
Sodium (Na)	IDEXX Catalyst One	Record	mmol/L
Potassium (K)	IDEXX Catalyst One	Record	mmol/L
Chloride (CL)	IDEXX Catalyst One	Record	mmol/L
Cell Culture Testing - Option 1			
Cell Line	Method	Specifications	Results
L-929, HELA, MRC-5	Morphology	Tested vs. Control Serum	Scoring System 1
L-929, HELA, MRC-5	Density	Tested vs. Control Serum	Scoring System 2
L-929, HELA, MRC-5	Cell Count	Cell count [log10/ml]/dead cells vs. Control	Record
Scoring system			
Scoring system	Meaning		Results
1 - Morphology	Dead Cells		0
	Many Cells degenerate and many dead cells		1
	Cells partially degenerate and many dead cells		2
	Few cells degenerate and few dead cells		3
	Without pathological findings		4
2 - Density	Single cells/cell aggregates		0
	< 50% confluency		1
	50 - 90% confluency		2
	confluency		3
	overly confluent		4
Cell Culture Testing - Option 2			
Cell Line	Method	Specifications	Units
BHK-21, MRC-5	Multiple Passage - Records results vs. control at day: 0, 3, 6, 12	>75% of control growth	%
BHK-21, MRC-5	Plating Efficiency - Records results vs. control at day: 0, 3, 6, 12	>75% PE vs. control PE	%
BHK-21, MRC-5	Cloning Efficiency - Records results vs. control at day: 0, 3, 6, 12	>75% CE vs. control CE	%

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EFFECTS OF GAMMA IRRADIATION:

Decline in Viral Titre

A gamma irradiation dose-dependent reduction in survival for enveloped and non-enveloped viruses will be detected. Viruses will show a significant reduction in titre at 25kGy and will be below the level of detection (0.5 TCID50 / ml) at 35kGy.

Other Effects

- Reduction of haemoglobin levels with a decrease in serum metabolites.
- Minor discoloration of the product and bottle.
- Possible decrease in growth promotion, plating/cloning efficiency with certain cell lines.

RECOMMENDED USE:

Storage

To effectively preserve the integrity of animal serum, it should be stored frozen and protected from light. The recommended storage temperature is <-15°C.

Multiple thaw/freeze cycles should be avoided, as they will accelerate the degradation of serum nutrients and can encourage the formation of insoluble precipitates. For this reason, serum should never be stored in “frost-free” freezers. These types of freezers periodically warm themselves to avoid internal ice deposits and are detrimental to the stability of frozen serum products.

Suggested Thawing Procedure

1. Remove the serum bottles from the freezer and allow them to adjust to room temperature for approximately 10 minutes.
2. Place each container in a 30 to 37 °C water bath or incubator. Excessive temperatures will degrade heat labile nutrients. If using a water bath, prevent the bottle caps from being submerged.
3. Gently agitate the bottles every 10 – 15 minutes until the serum is completely thawed.

Efficient and Effective Usage

After thawing, use the serum promptly. Liquid serum may be stored refrigerated (2 to 8 °C) up to four weeks. To avoid thaw/freeze cycles or long periods of refrigeration, it is recommended that any unused serum be immediately dispensed into small, useful aliquots and refrozen for future use.

THIS PRODUCT IS NOT INTENDED FOR HUMAN OR ANIMAL CONSUMPTION OR THERAPEUTIC USE.