



Foetal Bovine Serum, Sterile-filtered, non-USA Origin

Product no:	S-001#-BR
LSP Batch no:	A30420

Quality Profile			
Test	Result	Specification	Method
Adventitious Agents			
Mycoplasma	Not Detected	Not Detected	Filter Capture Test
Bacteria & Fungi	Not Detected	Not Detected	Current USP <61>, <62>/EP 2.6.13
PI3	Not Detected	Not Detected	9CFR, Part 113.53 (c)
IBR	Not Detected	Not Detected	9CFR, Part 113.53 (c)
BVD-Ab	Not Detected	Not Detected	9CFR, Part 113.53 (c)
Sterility	Pass	Pass	Current USP <71>/EP 2.6.1

Physical & Chemical Analysis			
Appearance	Clear straw to amber	Clear straw to amber	Visual
pH at RT	7.38	6.5 - 8.5	pH Meter
Osmolality (mOsm/kgH2O)	317	260 –340	Freezing point depression
Haemoglobin (mg/ml)	16.11	≤ 25	Spectrophotometric (Mayo)
Endotoxin (EU/mL)	0.651	≤10	Current USP <85>/EP 2.6.14
Total protein (g/dL)	3.99	3.0 – 4.5	Current USP <1057>/EP 2.5.33
GGT (IU/l)	4.5	< 10	Photometric
IgG (µg/mL)	203.0	≤ 350	ELISA

Mass Balance for Batch	Compliant	Compliant	
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Electrophoretic profile			
Alpha-globulin (g/L)	15.1	Normal profile	Capillary electrophoresis
Beta-globulin (g/L)	5.4	Normal profile	Capillary electrophoresis
Gamma-globulin (g/L)	1.1	Normal profile	Capillary electrophoresis

Heat Inactivated	No
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Biological Performance



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<i>Growth Promotion / Cytotoxicity</i>	<i>Results (% of control)</i>	<i>Specification (% of control)</i>
Cell line:		
MRC 5	95	≥75%
L 929	97	≥75%
C2C12	103	≥75%
LLC-PK1	89	≥75%
VERO	109	≥75%
Sp20 Ag14	121	≥75%
MDCK	105	≥75%
Cloning Efficiency		
Cell line:		
Sp20 Ag14	100	≥75%

Date processed:	09 Apr 2020
Raw material origin:	Brazil
CVED no:	GB.2020.0009853-V1 GB.2020.0013486-V3 GB.2020.0009852-V1
Processing:	3 x 0.1µm filtered
Expiry date:	Mar 2025
Store:	From -10°C to -30°C

Additional Chemical Profile			
<i>Test</i>	<i>Result</i>	<i>Specification</i>	<i>Method</i>
Albumin (g/l)	18.3	Result	Calculation
Globulin (g/l)	9	Result	Photometry
Urea (mmol/l)	5.9	Result	Photometry
Creatinine (µmol/l)	265	Result	Photometry
Sodium (mmol/l)	137	Result	Potentiometry
Potassium (mmol/l)	11.5	Result	Potentiometry
Calcium (mmol/l)	3.5	Result	Photometry
Magnesium (mmol/l)	1.3	Result	Photometry
Phosphorus (mmol/l)	2.9	Result	Photometry
ALP (iu/l)	291	Result	Photometry
AST (iu/l)	26.7	Result	Photometry
GLDH (iu/l)	4.1	Result	Photometry
Cholesterol (mmol/l)	0.9	Result	Photometry
Triglycerides (mmol/l)	0.62	Result	Photometry
Total Bilirubin (umol/l)	3.3	Result	Photometry
LDH (iu/l)	857.5	Result	Photometry
Creatinine Kinase (iu/l)	60	Result	Photometry

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Glucose (mmol/L)	3.1	Result	Photometry
Copper ($\mu\text{mol/l}$)	2.4	Result	Photometry
Zinc ($\mu\text{mol/l}$)	32.8	Result	Photometry
Selenium ($\mu\text{g/l}$)	12.8	Result	Atomic Absorption Spectroscopy
Iron ($\mu\text{mol/l}$)	34.7	Result	Photometry

Signed:



Patricia Dias
Laboratory Technician
18 May 2020

Approval:



Saba Frezghi
Laboratory Manager
20 May 2020