



Rocky Mountain Biologicals, Inc

Certificate of Analysis

Lipogro® -Cholesterol – Lipoprotein Complex, 0.1 micron filtered, New Zealand Origin

Product number: LPG-APG-XXX Lot Number: 20150303LP

Date of Manufacture: 03/2015 Expiration date: 03/2017

Storage temperature: 2 – 8°C

Not for human or animal consumption

Basis for Release

Chemical Analysis			Viral Analysis (9CFR 113.53)		
Test	Specification	Result	Test	Specification	Result
Cholesterol Concentration	9.00 – 11.00 g/L	9.56 g/L	BVD Cytopathic	Not Detected	Not Detected
Total Protein	13.0-18.0 g/L	13 g/L	BVD Non- Cytopathic	Tested	Not Detected
pH	7.0 – 8.4	7.8	PI3 Hemadsorbing	Not Detected	Not Detected
Sodium	≤ 50 mEq/L	21 mEq/L	IBR Cytopathic	Not Detected	Not Detected
Potassium	0 – 10 mEq/L	< 1.0 mEq/L	Bovine Adeno 3	Not Detected	Not Detected
Calcium	≤ 5.0 mg/dL	< 5.0 mg/dL	Bovine Adeno 5	Not Detected	Not Detected
Microbiological Analysis			BPV	Not Detected	Not Detected
Test	Specification	Result	BRSV	Not Detected	Not Detected
Endotoxin	< 50 EU/mL	22 EU/mL	REO Virus	Not Detected	Not Detected
Sterility 21 CFR 610.12/ USP34	No growth	No Growth	Rabies	Not Detected	Not Detected
Mycoplasma	None detected	Not Detected	Blue Tongue	Not Detected	Not Detected
Identity Analysis					
Test	Specification				Result
Appearance	Clear Amber Solution, free of visible particulates				Pass

PRODUCT MEETS EUROPEAN UNION REQUIREMENTS FOR PRODUCTION OF TECHNICAL BLOOD PRODUCTS

Approval

Quality Assurance – Print Name: <i>Stacey Black</i>	Quality Assurance – Sign Name: <i>Stacey Black</i>	Date: <i>02/16/16</i>
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Lipogro is derived from bovine serum, processed from blood collected from healthy animals, of New Zealand origin.