Certificate of Analysis

stemulate.com

Product: Stemulate™ PL-XX-VVV
Lot Number: GBYYXXXX
Expiration Date: YYYY-MM
GMP GRADE

Country of Origin: United States
Storage Conditions: -15 to -30 degrees centigrade
For In-Vitro Use
Not for Human or Animal Consumption

Manufactured by COOK General BioTechnology
1102 Indiana Ave. Indianapolis, IN 46202
Phone: 317-917-3450 Fax: 317-917-3444

Product Integrity Analysis

Test	Specification	Result
Endotoxin	< 10EU/mL	< X EU/mL
Mycoplasma	Not Detected	
Sterility: Bacterial/Fungal	No Growth	
pH	6.8-7.8	X.X
Osmolality	260-340 mOsm/kg	XXX mOsm/kg
Total Protein[1]	4.0-6.0 g/dL	X.X g/dL
Cell Growth Verification	Pass	
Adventitious Agents[2,3]		
Anti-HIV I/II	Negative	Negative
Anti-HCV	Negative	Negative
Anti-HBc	Negative	Negative
Anti-HTLV – I/II	Negative	Negative
HBbsAg	Nonreactive	Nonreactive
STS	Nonreactive	Nonreactive
WNV RNA	Nonreactive	Nonreactive
HCV RNA	Nonreactive	Nonreactive
HIV-1 RNA	Nonreactive	Nonreactive
HBV DNA	Nonreactive	Nonreactive

Biochemical Analysis

Component	Amount
Sodium	mmol/L
Potassium	mmol/L
Chloride	mmol/L
Bicarbonate	mEq/L
Triglyceride	mg/dL
Cholesterol	mg/dL
AST	U/L
GGT	U/L
CK	U/L
Iron	µg/dL
Magnesium	mg/dL
Glucose	mg/dL
Phosphorus	mg/dL
Creatinine	mg/dL
Bilirubin	mg/dL
Calcium	mg/dL
Albumin	g/dL
Globulin	g/dL

Quality Systems Approval:

_____ _____

Print/Signature Date

References
1. Doumas, et al Standards for Total Serum Protein Assays. Biuret Method. Clin. Chem. 21/8, 1159-1166 (1975).
2. FDA: Vaccines, Blood, and Biologics Infectious Disease Tests
3. All adventitious agent testing is performed on raw material donors per FDA 21 CFR Part 610 for transfusable materials.