AXENIA BIOLOGIX

Custom Serum Manufacturing Report

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The Axenia BioLogix custom manufacturing report provides a comprehensive summary of our customer-directed manufacturing process, from raw materials receipt to finished product delivery. This report provides our customers with complete documentation to ensure traceability and conformance of their finished product.

Customer:
Manufacturing Date:

Finished Product Name:
Finished Product Number(s):
Finished Product Lot Number:
Finished Product Country of Origin:
Finished Product Expiration Date:

Axenia Process Guide SOP:
Axenia Process Overview:

- Receive, traceably document and store at below 20˚C all raw serum to be used.
- Obtain lot identification and labelling requirements from Customer.
- Thaw all raw serum to be used to between 0 and 5˚C. Document thaw conditions and profile. Transfer thawed serum to coldroom. Verify coldroom temperature is between 0 and 5˚C.
- Perform environmental monitoring for Class 100 (ISO 5) cleanroom.
- Verify sterility of all filtration train components (disposable liners, cartridge filters, bladders, etc.) and PPE.
- Assemble filtration line(s).
- Transfer raw serum to cleanroom. Verify cleanroom temperature is between 0 and 5˚C.
- Aseptically pool all raw serum and filter to specification.
- Monitor filtration to ensure proper line pressure throughout process.
- Collect filtrate in sterile, disposable manufacturing bladder.
- Purge all material into bladder to minimize hold-up volumes/maximize product yield.
- Perform line clearance.
- Recirculate filtrate in bladder to achieve and maintain product homogeneity throughout dispense process.
- Verify coldroom temperature is between 0 and 5˚C.
- Perform environmental monitoring for Class 100 (ISO 5) cleanroom.
- Verify sterility of all dispense train components (disposable tubing, fittings, etc.) and PPE.
- Assemble dispense line(s).
- Prepare and stage sterile PETG bottles.
- Perform calibration checks on balances to be used for fill-volume assurance.
- Program and calibrate dispensing pump(s).
- Aseptically dispense finished serum into sterile, capped PETG bottles.
- Collect QC samples for in-house and third-party analyses.
- Label and heat-shrink all finished product. Box and store at or below -20˚C.
- Tabulate and record process yields.
- Perform environmental monitoring for Class 100 (ISO 5) cleanroom.
- Perform line clearance and sanitize Class 100 (ISO5) cleanroom.
- Perform or cause to be performed all quality analyses required for finished product. Collect results and prepare Certificate of Analysis.
- Perform QA review of Batch Record, assemble Workpapers and prepare Manufacturing Report.

Manufacturing Report Workpaper File Contents:

PM-CF004 *Label Request Form*(s)

PM-CF001 *Raw Serum Receiving Form*

Raw Material Receiving Documents from Carrier

Raw Material Certificate(s) of Origin

Affidavits for USDA (from raw material supplier)

QC-CF002 *Thaw List Form*

QC-CF003 *Thaw Record*

QC-CF001 *Environmental Monitoring Form*(s)

QC-CF008 *Bottle Closure Torque Monitoring Form*

QA-AF005 *QA/QC Sample Collection Form*

PM-CF007 *Yield Record*

QA-AF004 *Observation Report*(s), if any

Sample Submission Forms for Outsourced Analyses & Shipping Receipts

QA-AF002 *Sterility Testing Results Form*

QA-AF003 *Osmolality & pH Test Results Form*

QA-AF001 *Serum Hemoglobin Test Results Form*

EM-UL007 *Yamato SM510 Autoclave Usage Log* and/or EM-UL012 *Yamato SM830 Autoclave Usage Log*

Endotoxin results

Blood chemistry panel results

Protein electrophoretic panel results

9CFR viral panel results

Mycoplasma results

NVSL testing results, if applicable

IgG results

Hormone panel results

Specialized test results, if any

Material Safety Data Sheet for FBS

QA-RF002 *Fetal Bovine Serum Release Form*

Certificate of Analysis

Bottles/Containers

Manufacturer	Size	Type	# of Cases Used	Mfr Lot Number(s)
Vendor	60mL	PETG	x (200/cs)	xxxxxxx
Vendor	500mL	PETG	x (40/cs)	

Finished Product Volumes

Fill Size	Quantity	Total Volume
51mL	x	xL
502mL	x	xL

QA/QC Samples

Assay	Sample Volume	Approved Lab
pH	xL	Axenia BioLogix
Osmo	xL	Axenia BioLogix
Hb	xL	Axenia BioLogix
Mycoplasma	xL	Qualified 3rd Party Lab
9CFR Viral	xL	Qualified 3rd Party Lab
Biochem/PEPS	xL	Qualified 3rd Party Lab
Endotoxin	xL	Qualified 3rd Party Lab
Hormone Panel	xL	Qualified 3rd Party Lab
IgG	xL	Qualified 3rd Party Lab
Iron Panel	xL	Qualified 3rd Party Lab
Tetracyclines	xL	Qualified 3rd Party Lab
MTT Assay	xL	Qualified 3rd Party Lab
Origin Verif.	xL	Oritain Pty Ltd

Yield Calculation

Declared raw volume (estimated)	x.xxxL
Finished Volume Dispensed	x.xxxL
QA/QC Volume Dispensed	x.xxxL
Volume Recovered in Process	x.xxxL
Volume Retained in Process	x.x%
Finished Product Yield	xx.x%

Report Certification

This report provides an accurate record and overview of our customer-directed manufacturing process, from raw materials receipt to finished product delivery.

Thank you for this opportunity to be of service to you.

Chief Executive Officer Date

Quality Director Date

End of Report