Axenia BioLogix Custom Serum Manufacturing Report

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
**Axenia BioLogix for**

**Customer**

City, ST zip

Confidential

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**Bottles/Containers**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Size</th>
<th>Type</th>
<th># of Cases Used</th>
<th>Mfr Lot Number(s)</th>
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</thead>
<tbody>
<tr>
<td>Vendor</td>
<td>60mL</td>
<td>PETG</td>
<td>x (200/cs)</td>
<td>xxxxxxx</td>
</tr>
<tr>
<td>Vendor</td>
<td>500mL</td>
<td>PETG</td>
<td>x (40/cs)</td>
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</tbody>
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**Finished Product Volumes**

<table>
<thead>
<tr>
<th>Fill Size</th>
<th>Quantity</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>51mL</td>
<td>x</td>
<td>xL</td>
</tr>
<tr>
<td>502mL</td>
<td>x</td>
<td>xL</td>
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**QA/QC Samples**

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<thead>
<tr>
<th>Assay</th>
<th>Sample Volume</th>
<th>Approved Lab</th>
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<tbody>
<tr>
<td>pH</td>
<td>xL</td>
<td>Axenia BioLogix</td>
</tr>
<tr>
<td>Osmo</td>
<td>xL</td>
<td>Axenia BioLogix</td>
</tr>
<tr>
<td>Hb</td>
<td>xL</td>
<td>Axenia BioLogix</td>
</tr>
<tr>
<td>Mycoplasma</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>9CFR Viral</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Biochem/PEPS</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Hormone Panel</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>IgG</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Iron Panel</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>xL</td>
<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>MTT Assay</td>
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<td>Qualified 3rd Party Lab</td>
</tr>
<tr>
<td>Origin Verif.</td>
<td>xL</td>
<td>Origin Pty Ltd</td>
</tr>
</tbody>
</table>

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**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