Applicable Sites: St Louis USA

Affected Area: Lab

Legal Entity Name: MO Bio Labs

BATCH PRODUCTION RECORD – ISSUE APPROVAL	
Issued By:	**Date:**

TABLE OF CONTENTS

1.0 General SOP References

Title	Reference #
N/A	N/A

2.0 Bill of Materials

Description	Material Master Number	Common Name / Intended use	Recommended Quantity
Latex gloves	XXXXXX	Latex gloves	2
95% ethanol	XXXXXX	95% ethanol	1
Isopropanol	XXXXXX	Isopropanol	1
50 mL sterile pipette	XXXXXX	50 mL pipette	2
5 mL sterile pipette	XXXXXX	5 mL pipette	2
500 mL flask	XXXXXX	500 mL flask	1
1.5 mL microcentrifuge tube	XXXXXX	1.5 mL tube	1
Transfer pipette	XXXXXX	Transfer pipette	1
Media	XXXXXX	Media	300 mL

3.0 Equipment

3.1 Serological pipette (aka Pipette Aid)

3.2 Incubator

3.3 Cell Counter

3.4 Biosafety Cabinet

4.0 EHS Information

Identifier	Pictogram/ Signal Word	Hazard/Precaution Statement
MEDIA Description	**CONSULT EHS**	**CONSULT EHS**

5.0 Operational Instructions

5.1	Cell Culture	Initial / Date	
		Performer	Verifier
5.1.1	Put on gloves. Spray gloves with IPA and rub hands together. Allow gloves to dry		
5.1.2	Spray the biosafety cabinet (BSC) with IPA and wipe down.		
5.1.3	Gather the sample flask from the incubator, a new 500 mL flask, and pipette aid. Clean all items with IPA before placing them in the BSC.		
5.1.4	Open sample flask. Slowly pipette out 1 mL of culture and put it in an empty tube. Cap the tube.		
5.1.5	Place the tube outside the BSC. Take the sample to the counter and measure the cell count. **Cell count** **8.7 x 10^6** **Equipment#** **n/a** **Calibration Date** **n/a**		

5.1	Cell Culture	Initial / Date	
		Performer	Verifier
5.1.6	The final concentration will be 0.3 x 10^6 cells/mL in 200mL working volume. Calculate how much media and cell culture is needed to reach the final concentration at the 200 mL working volume using the following formula: C1V1 = C2V2 **C2** **V2** (volume of cells/cell culture in mL) **Volume of media (mL)**		
5.1.7	In a new flask, add volume of media first and then the cell culture. Close the flask. Mix by gently rocking the flask back and forth. Write the name of the cell line and date on the flask, and your initials.		
5.1.8	Place the flask in the designated incubator. **Temperature** **Thermometer Calibration Date**		
5.1.9	Properly dispose of all materials and clean the BSC.		

END of this protocol.

Appendix A.

SAP Material Verification: ☐ N/A	Production Supervisor Review:	QA Review:

	Time Collected	General Location for Storage	Additional Comments
Sample 1			
Sample 2			

6.0 COMMENTS LOG

Comment Number	Step Number	Time (hhmm)	Comment

7.0 MANUFACTURING REVIEW

SAP Final Confirmation/ Clear Reservation (COR6)	
Signature / Date	

SAP Review and TECO – COOISPI-(Review of material consumption) AND COR2- (final closure in SAP)	
Signature / Date	

Manufacturing Batch Record Review	
As a Manufacturing representative responsible for the review of this Batch Record, my signature indicates that the record has been reviewed.	
Comments [ ] N/A	
Signature / Date	

SAP Material Verification: ☐ N/A	Production Supervisor Review:	QA Review:

8.0 REVISION HISTORY

not included in this protocol