BIOLOGICS PILOT PLANT BATCH DOCUMENT

Material Code: _____ Material Description: _____

Batch No.: _____

MODULE: 50L Production Bioreactor Template: _____ **Rev:** _____

PREP STEP

1.1 Media Supplementation (Growth Phase)

Instructions / Input	Performed by Initials / Date	Verified By Initials / Date
1. Indicate if FSPM and FSQSM containers are moved to media warming or 2-8°C storage. **Description** / **Input** FSPM Container: ☐ Media Warming ☐ 2-8°C Storage FSQSM Container: ☐ Media Warming ☐ 2-8°C Storage 2. For FSPM moved to: Media warming proceed to section 2.5. N/A steps 2.4.4 – 2.4.6. 2-8 °C storage proceed to step 2.4.4. 3. For FSQSM moved to: Media warming proceed to section 2.5. N/A steps 2.4.4 – 2.4.6. 2-8 °C storage proceed to step 2.4.4.		
	Performed By Initials & Date	**Verified By Initials & Date**
4. For FSPM container(s) are stored at 2-8°C, record the 2-8°C storage start time, 2-8°C storage location (CTU), and 2-8°C storage end time below. 5. Record information in the table below. **Description** / **Input** FSPM 2-8°C Storage Start Date / Time (Step 2.4.5.a) FSPM Storage CTU Tag FSPM 2-8°C Storage End Date / Time (Step 2.4.5.b) _____		
	Performed by Initials / Date	**Verified By Initials / Date**
6. After removing FSPM from 2-8°C storage e. Confirm FSPM is within expiry storage (Ref 2.4.23) and proceed to section 2.5 Media Warming. f. If FSPM is not with expiry contact Process Lead and Quality, and record actions taken in Process Notes Section 1.9		

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Instructions / Input	Performed By Initials & Date	Verified By Initials & Date
7. For FSQSM container(s) are stored at 2-8°C, record the 2-8°C storage start time, 2-8°C storage location (CTU), and 2-8°C storage end time below. N/A rows/table below if not used 8. Record information in the table below.		

Description	Input
FSQSM 2-8°C Storage Start Date / Time (Step 2.4.41.a)	
FSQSM Storage CTU Tag	
FSQSM 2-8°C Storage End Date / Time (Step 2.4.41.b)	

	Performed by Initials / Date	Verified By Initials / Date
9. After removing FSQSM from 2-8°C storage. g. Confirm FSQSM is within expiry (Ref 2.4.33), and proceed to section 2.5 Media Warming h. If FSQSM is not with expiry contact Process Lead and Quality, and record actions taken in Process Notes Section 1.9		

1.2 Media Warming (Growth Phase)

NOTE(s): For Filtered Supplemented Production Media (FSPM), step (2.5.3.a) Production Warming Start time must occur ≥ 12 hours, but ≤ 72 hours prior to FSPM use (Ref 4.1.1). For Filtered supplemented QS Media (FSQSM), step (2.5.8.a) FSQSM Warming Start time must occur ≥ 12 hours, but ≤ 72 hours prior to FSQSM use (Ref 5.2.4).

Instructions / Inputs	Performed By Initials & Date	Verified By Initials / Date
1. Obtain the FSPM container for warming. System: ☐ Lot Number: Container: 2. Place container at room temperature for warming 12-72 hours prior to use.		

	Performed By Initials & Date	Verified By Initials & Date
3. Record information in the table below.		

Description	Input
FSPM Warming Start Date / Time (Step 2.5.3.a)	
FSPM Warming End Date / Time (Step 2.5.3.b)	

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	Performed By Initials & Date	Verified By Initials / Date
4. Calculate the minimum media warm date/time required prior to use.		
5. Calculate the maximum media warm date/time allowed prior to use.		

Description	Input
FSPM Warming Start Date / Time (Ref 2.5.3.a)	
[+] Minimum Media Warming Duration Prior to Use	12 hrs
[=]Minimum FSPM Use Start Date/Time Calculated DateTime (Step 2.5.4.a)	

Description	Input
FSPM Warming Start Date / Time (Ref 2.5.3.a)	
[+] Maximum Media Warming Duration Prior to Use	72 hrs
[=]Maximum FSPM Use Start Date/Time Calculated DateTime: (Step 2.5.5.a)	