

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								
<p>1. Indicate if FSPM and FSQSM containers are moved to media warming or 2-8°C storage.</p> <table><thead><tr><th>Description</th><th>Input</th></tr></thead><tbody><tr><td rowspan="2">FSPM Container</td><td><input type="checkbox"/> Media Warming</td></tr><tr><td><input type="checkbox"/> 2-8°C Storage</td></tr><tr><td rowspan="2">FSQSM Container</td><td><input type="checkbox"/> Media Warming</td></tr><tr><td><input type="checkbox"/> 2-8°C Storage</td></tr></tbody></table>		Description	Input	FSPM Container	<input type="checkbox"/> Media Warming	<input type="checkbox"/> 2-8°C Storage	FSQSM Container	<input type="checkbox"/> Media Warming	<input type="checkbox"/> 2-8°C Storage		
Description	Input										
FSPM Container	<input type="checkbox"/> Media Warming										
	<input type="checkbox"/> 2-8°C Storage										
FSQSM Container	<input type="checkbox"/> Media Warming										
	<input type="checkbox"/> 2-8°C Storage										
<p>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.</p> <p>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.</p>											
		Performed By Initials & Date	Verified By Initials & Date								
<p>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.</p> <p>5. Record information in the table below.</p> <table><thead><tr><th>Description</th><th>Input</th></tr></thead><tbody><tr><td>FSPM 2-8°C Storage Start Date / Time (Step 2.4.5.a)</td><td></td></tr><tr><td>FSPM Storage CTU Tag</td><td></td></tr><tr><td>FSPM 2-8°C Storage End Date / Time (Step 2.4.5.b)</td><td>_____</td></tr></tbody></table>		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)	_____		
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								
<p>6. After removing FSPM from 2-8°C storage</p> <p>e. Confirm FSPM is within expiry storage (Ref 2.4.23) and proceed to section 2.5 Media Warming.</p> <p>f. If FSPM is not with expiry contact Process Lead and Quality, and record actions taken in Process Notes Section 1.9</p>											

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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.			
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.										
<table><tr><th>Description</th><th>Input</th></tr><tr><td>FSPM Warming Start Date / Time (Ref 2.5.3.a)</td><td></td></tr><tr><td>[+] Minimum Media Warming Duration Prior to Use</td><td>12 hrs</td></tr><tr><td>[=]Minimum FSPM Use Start Date/Time Calculated DateTime (Step 2.5.4.a)</td><td></td></tr></table>	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)										
[+] Minimum Media Warming Duration Prior to Use	12 hrs									
[=]Minimum FSPM Use Start Date/Time Calculated DateTime (Step 2.5.4.a)										
5. Calculate the maximum media warm date/time allowed prior to use.										
<table><tr><th>Description</th><th>Input</th></tr><tr><td>FSPM Warming Start Date / Time (Ref 2.5.3.a)</td><td></td></tr><tr><td>[+] Maximum Media Warming Duration Prior to Use</td><td>72 hrs</td></tr><tr><td>[=]Maximum FSPM Use Start Date/Time Calculated DateTime: (Step 2.5.5.a)</td><td></td></tr></table>	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)			
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)										