Manufacturing Record			
Passage 5 Through Harvest of	REC-000335		
Document Number	Version	Status	Effective Date
MMD-000123092	19.0	Effective	Thu Jul 21 06:07:48 UTC 2022

PROCEDURE FOR ROCKER PARAMETER CHECK					
Parameter Control Actual Performed Checked Initials/Date Initials/Date					
Rocker Agitation Mode	1				
Rocker Speed Setpoint	10 RPM	RPM			

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
5. Passage 5 Seed Bottle #1 used	Record Label			
6. Transfer of Seed Bottle #1 Contents Date/Time	Record	/		
7. Pump Speed	300 RPM (280 – 350 RPM)	RPM		
8. Final Rocker Weight	23.1 kg (22.6 – 23.6 kg)	kg		



CONTINUE HyPerforma Rocker Mixing until CS10s #14.

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	Control	Actual	Performed Initials/Date	Checked Initials/Date
Rocker Angle Setpoint	6.0 °	o		

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
Mixing after Seed Bottle Addition Start Date/Time	Record	/		

MFG Page Review	QA Page Review	
Initials / Date	Initials / Date	

Manufacturing Record			
Passage 5 Through Harvest of	REC-000335		
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PROCEDURE FOR ROCKER PARAMETER CHECK					
Parameter Control Actual Performed Checked Initials/Date Initials/Date					
Rocker Agitation Mode	1				
Rocker Speed Setpoint	10 RPM	RPM			

PROCEDURE FOR TRANSFER TO ROCKER BPC #2					
Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date	
5. Passage 5 Seed Bottle #2 used	Record Label				
6. Transfer of Seed Bottle #2 Contents Date/Time	Record	/			
7. Pump Speed	300 RPM (280-350 RPM)	RPM			
8. Final Rocker Weight	23.1 kg (22.6 – 23.6 kg)	kg			



CONTINUE HyPerforma Rocker Mixing until CS10 #34 is filled.

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER					
Parameter	Control	Actual	Performed Initials/Date	Checked Initials/Date	
Rocker Angle Setpoint	6.0 °	o			

PROCEDURE FOR TRANSFER TO ROCKER BPC #2				
Parameter Control Actual Performed Initials/Date Unitials/Date				
9. Mixing after Seed Bottle Addition Start Date/Time	Record	/		

MFG Page Review	QA Page Review	
Initials / Date	Initials / Date	

Manufacturing Record			
Passage 5 Through Harvest of	REC-000335		
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MMD-000123092	19.0	Effective	Thu Jul 21 06:07:48 UTC 2022

1.1.7 INOCULATION AND INCUBATION OF CS10 #21-40 (WI-000129569)

PROCEDURE FOR TRANSFER TO ROCKER BPC #2					
Parameter	Parameter Control Actual		Performed Initials/Date	Witnessed Initials/Date	
1. Pump ID	Record				
Pump Speed for Cell Transfer	300 RPM				
	(280 – 350 RPM)	RPM			
3. Seeding Start CS10 #21 Date/Time	Record	/			
Parameter	Control	Actual	Performed Initials/Date	Checked Initials/Date	
HyPerforma Rocker Mix Time prior to seeding	10 – 90 min	min			
		Section 1.1.7 Step 3 – Section 1.1.6 Step 9			



RECORD weight of Cell Suspension transferred to each CS10 in Attachment 1.

Manufacturing Record			
Passage 5 Through Harvest of	REC-000335		
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2.1.3 TRANSFECTION MATERIAL (WI-000129565)

AMBIENT MATERIALS FOR TRANSFECTION							
Material Name	Material Number	Qty Needed	Qty Used	Batch	Expiry	Performed Initials/Date	Checked Initials/Date
3L Spinner Flask	110129	4					
Spinner Flask Diptube	411682	4					
Spinner Flask Transfer Cap	112259	4					
Plasmid Transfer Tubing Assembly	□ 412259 □ 413135	4					
Mobius In/Out Tubing assembly	□ 412253 □ 413166	4					
CS10 feed Manifold	□ 412251 □ 413169	10					
20L Rocker BPC	115557	4					
AQG 3/8" ID Tee Connector 3/8" AQG Wye Connector	□ 113987 □ 114052	4					
AQG to MPC Insert	□ 114084 □ 113154 □ 413167 □ 113520	4					
1L PETG Bottle	□ 110042 □ 115348	4					
1L WFI	411723	4					
AQG Reducer w/Plug	413166	4					

MFG Page Review	QA Page Review	
Initials / Date	Initials / Date	