Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1234-25

Step	Procedure			Performed by / Date	Checked by / Date
1.	Perform a room inspection and clearance of the Prep Room (Room 107) per **PRD.SOP.003**.				
			Day 1	CSB 15 May 25	BM 15 May 25
			Day 2	CSB 16 May 25	BM 16 May 25
			Day 3		
2.	Obtain the required number of previously cleaned tray bottoms and tray lids. Record the associated tray ASC #.		Tray ASC #		
		Day 1	4036	CSB 15 May 25	BM 15 May 25
		Day 2	4036	CSB 16 May 25	BM 16 May 25
		Day 3			
3.	Load trays into the Ultrasonic Cleaner for cleaning cycle per **PRD.SOP.810**.		# of tray sets cleaned		
		Day 1	60	CSB 15 May 25	BM 15 May 25
		Day 2	60	CSB 16 May 25	BM 16 May 25
		Day 3			

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Step	Procedure			Performed by / Date	Checked by / Date
4.	Perform a room inspection and clearance of the Prep Room (Room 107) per **PRD.SOP.003**.				
			Day 1	CSB 15 May 25	BM 15 May 25
			Day 2	CSB 16 May 25	BM 16 May 25
			Day 3		
5.	Remove vials from inventory, completing the *Production Materials Summary* form per **PRD.SOP.002** and the relevant inventory card as removed, per **PRD.SOP.002.**		Vials removed from inventory		
		Day 1	5700	CSB 15 May 25	BM 15 May 25
		Day 2	5700	CSB 16 May 25	BM 16 May 25
		Day 3			
6.	If the Gruenberg Oven Load Pattern designated on page 1 details a Soak Time other than 4hrs (240min), verify a Service Order has been initiated per **QUA.SOP.650**. N/A if Soak Time is 4hrs (240min).		Service Order #		
		Day 1	N/A	CSB 15 May 25	BM 15 May 25
		Day 2	N/A	CSB 16 May 25	BM 16 May 25
		Day 3			

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Step	Procedure			Performed by / Date	Checked by / Date
7.	Perform a single wash cycle using the Cozzoli Washer per **FAC.SOP.310** and **PRD.SOP.200.** Complete *Vial Wash Data Sheet* per **PRD.SOP.200.** For batches consisting of multiple shifts, the materials should be secured at the end of each shift. A new *Vial Wash Data Sheet* should be completed for each shift. Reject any vials that are damaged or defective in any way. If damaged vials or broken glass is observed it should be documented. Place rejected vials in a designated reject container, labeled as such and with the lot number and production date. Note: Holding times for wetted vials are detailed in **PRD.SPC.001.**				
8.	Load vials into vial trays as designated by the Vial Configuration on page 1 per **PRD.SPC.002**. Any discrepancies in the number of vials per tray should be reported to a supervisor immediately.		Vial Configuration #		
		Day 1	01	CSB15May25	BM15May25
		Day 2	01	CSB16May25	BM16May25
		Day 3			
9.	Document the total number of vials processed below.				
		# of vials / tray	# of trays	Total # of vials	
	Day 1	100	54	5400	CSB15May25 / BM15May25
	Day 2	100	54	5400	CSB16May25 / BM16May25
	Day 3				
	Total number of vials processed:			10800 ~~5400~~	CSB16May25 ~~CSB15May25~~ EECSB16May25
					BM16May25 ~~BM15May25~~

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Step	Procedure			Performed by / Date	Checked by / Date
10.	Ensure the Soak Time has been adjusted by the associated Service Order (see step 6), if necessary, and the Service Order is posted on the Gruenberg Oven. N/A if Soak time is 4hrs (240min).		Day 1	N/A	N/A
			Day 2	N/A	N/A
			Day 3		
11.	If partial flats of vials are to be disposed of and not returned to inventory, record the quantity of vials each day.		# Vials not returned		
		Day 1	0	CSB 15 May 25	BM 15 May 25
		Day 2	10	CSB 16 May 25	BM 16 May 25
		Day 3			
12.	Record the number of rejected vials at the end of processing each day.		# of rejects		
		Day 1	10	CSB 15 May 25	BM 15 May 25
		Day 2	10	CSB 16 May 25	BM 16 May 25
		Day 3			

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Step	Procedure			Performed by / Date	Checked by / Date
13.	Return any unused vials to inventory, as applicable, recording the information on the relevant inventory card, per **PRD.SOP.002.**		# of vials returned		
		Day 1	290	CSB 15 May 25	BM 15 May 25
		Day 2	270	CSB 16 May 25	BM 16 May 25
		Day 3			

Step	Procedure								Performed by / Date	Checked by / Date
14.	Calculate daily vial reconciliation. Investigate inventory discrepancy if reconciliation is less than 99% or greater than 100%.									
	Day	# vials manufactured from step 9 **(A)**	# of vials not returned from step 11 **(B)**	# vials rejected from step 12 **(C)**	# of vials returned to inventory from Step 13 **(D)**	Total # of vials **E=A+B+C+D**	# vials removed from inventory from step 5 **(F)**	% Yield **(E/F)*100**		
	1	5400	0	10	290	5700	5700	100.00	CSB 15 May 25	BM 15 May 25
	2	5400	10	10	270	5700	5700	100.00	CSB 16 May 25	BM 16 May 25
	3									
15.	Run the oven per **FAC.SOP.203** according to **FAC.SPC.200** according to the Load Pattern on page 1.									

Batch Record Review (Quality Assurance): _____ Date: _____