CSB - UNCONTROLLED

Production System

PRD.BAT.425.05

Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1334-25

Step	Procedure			Performed by / Date	Checked by / Date
-	Perform a room inspection and clearance of the Prep Room (Room 107) per PRD.SOP.003.				
			Day 1	CSBISMEYZS	BMISMLYZS
			Day 2	25B16May 25	BMICMEYES
			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	(5815 May 35	BMISMUY2S
		Day 2	4036	(SBILUMAY2)	BMILMLY 25
		Day 3			
3.	Load trays into the Ultrasonic Cleaner for cleaning cycle per PRD,SOP.810.		# of tray sets cleaned		
		Day 1	09	CSBISMAY2S	BMIS May 35
·		Day 2	9	(SBILMWA)S	BMILMAJSS
		Day 3			

Afton Scientific

CSB - UNCONTROLLED

Production System

PRD.BAT.425.05

Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1234-25

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.	OP.003.			
			Day 1	CSB15/MWy25	BMIS MENDS
			Day 2	(5816,May 25	BM 16 MW 25
			Day 3		
5.	Remove vials from inventory, completing the <i>Production Materials Summary</i> form per PRD.SOP.002 and the relevant inventory card as removed, per		Vials removed from inventory		
	TKD.SOF.002.	Day 1	0015	(SBISMayas	Stynkslm.
		Day 2	\$700	25B16 May 25	BMILMMY 25
		Day 3		•	
9	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		Service Order#		
	QUA.SOP.650.	Day 1	NIA	15B151Mey 25	BMISMAY 35
	N/A if Soak Time is 4hrs (240min).	Day 2	NA	25BIC May 25	BMIGMENDS
		Day 3			

CSB - UNCONTROLLED

Production System

PRD.BAT.425.05

Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1234-25

	\vdash					Performed by /	Checked by /
Step	Procedure					Date	Date
7.	Perform a s Wash Data at the end o	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.	e Cozzoli Washer per FAC.SOP.310 and PRD.SOP.200. Complete Vial . For batches consisting of multiple shifts, the materials should be secured Vash Data Sheet should be completed for each shift.	and PRD.SOP.	200. Complete Vial ils should be secured		
	Reject any should be d number and	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.	defective in any way. If damaged vials or broken glass is observed it d vials in a designated reject container, labeled as such and with the l	s or broken gla , labeled as suc	ss is observed it h and with the lot		
	Note: Hold	Note: Holding times for wetted vials are detaile	are detailed in PRD.SPC.001.				
∞i	Load vials	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 chould be reported to a supervisor immediately	/ial Configuration on n the number of vials per		Vial Configuration #		
	uay suouid	octobolica to a supervisor minima		Day 1	01	(51315 May 25	SEKTW SIWY
				Day 2	10	(SB 16 May 25	B.M.Lemay 25
				Day 3			
9.	Document	Document the total number of vials processed below.	below.				
	L.	# of vials / tray	# of trays		Total # of vials		
	Day 1	001	hS		0045	25BISM423	BMISMAYDS
	Day 2	001	48		Sybo	(5BloMAY 25	3MILMEY 25
	Day 3						
			Total number of vials processed:	,	00801	25/10/10/15/25	BAISMAYSS
				-			

Afton Scientific

RECSIBIL MAY 25

CSB - UNCONTROLLED

Production System

PRD.BAT.425.05

Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1234-25

i da					
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.	tep 6), if	Day 1	NIA	NIA
	N/A if Soak time is 4hrs (240min).		Day 2	NIA	N/A
			Day 3		,
Ë	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	15B1SM472S	SMISMLY 35
		Day 2	70	CSB16May 35	BMILE MUJ 25
		Day 3		,	
12.	Record the number of rejected vials at the end of processing each day.		# of rejects		
		Day 1	01	258is May 25	BMISM435
		Day 2	0/	CSB16M4735	3 MILOMAY 25
		Day 3			

CSB - UNCONTROLLED

Production System

PRD.BAT.425.05

Vial Processing/Depyrogenation for the 2030 Manufacturing Facility

LOT#: 1234-25

Step	Procedure	lure							Performed by / Date	Checked by / Date
13.	Return	any unused via ation on the rele	Return any unused vials to inventory, a information on the relevant inventory c	as applicable, recording the card, per PRD.SOP.002.	ecording the SOP.002.	4	#	# of vials returned		
						Day 1		240	SELMANSISS)	BMISMY 25
						Da	Day 2	270	(SB16 M4)25	BMIGM4725
						Da	Day 3			
14.	Calculi	Calculate daily vial regreater than 100%.	Calculate daily vial reconciliation. Investigate inventory discrepancy if reconciliation is less than 99% or greater than 100%.	estigate invent	ory discrepancy	if reconciliatio	n is less tha	ın 99% or		
	Day	# vials manufactured from step 9 (A)	# of vials not returned from step 11	# vials rejected from step 12 (C)	# of vials returned to inventory from Step 13	Total # of vials E=A+B+C+D	# vials removed from inventory from step 5 (F)	om % Yield % (E/F)*100		
	-	3400	0	0/	290	\$700	0025	100.00	CSBISMAY 35	BMISMRYÐS
	2	Chors	20	0]	270	3700	5700	00.001	25.8160May 25	BMILEMEN 25
	3									
15.	Run th	e oven per FA	Run the oven per FAC,SOP.203 according to FAC.SPC.200 according to the Load Pattern on page 1.	rding to FAC.	SPC.200 accord	ling to the Load	Pattern on	page 1.		

Afton Scientific

Date:

Batch Record Review (Quality Assurance):