

COPY
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 |
|------|--|------------------------|------------------------|----------------------|
| 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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| 4. | Perform a room inspection and clearance of the Prep Room (Room 107) per PRD.SOP.003 . | | | |
| | | Day 1 | CSB15 May 25 | BM15 May 25 |
| | | Day 2 | CSB16 May 25 | BM16 May 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 PRD.SOP.002 . | Vials removed from inventory | | |
| | | Day 1 | 5700 CSB15 May 25 | BM15 May 25 |
| | | Day 2 | 5700 CSB16 May 25 | BM16 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 CSB15 May 25 | BM15 May 25 |
| | | Day 2 | N/A CSB16 May 25 | BM16 May 25 |
| | | Day 3 | | |

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Page 4 of 8

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|----------------------------------|--|---------------------|--------------------------|------------|------------------|-------|-----|-------|------|-------|-----|----|------|-------|--|--|--|----------------------------------|--|--|--------------------------|--|--|
| 7. | <p>Perform a single wash cycle using the Cozzoli Washer per FAC.SOP.310 and PRD.SOP.200. Complete <i>Vial Wash Data Sheet</i> per PRD.SOP.200. For batches consisting of multiple shifts, the materials should be secured at the end of each shift. A new <i>Vial Wash Data Sheet</i> should be completed for each shift.</p> <p>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.</p> <p>Note: Holding times for wetted vials are detailed in PRD.SPC.001.</p> | | | | | | | | | | | | | | | | | | | | | | |
| 8. | <p>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.</p> <table border="1"> <thead> <tr> <th></th><th>Vial Configuration #</th></tr> </thead> <tbody> <tr> <td>Day 1</td><td>01</td></tr> <tr> <td>Day 2</td><td>01</td></tr> <tr> <td>Day 3</td><td></td></tr> </tbody> </table> | | Vial Configuration # | Day 1 | 01 | Day 2 | 01 | Day 3 | | | | | | | | | | | | | | | |
| | Vial Configuration # | | | | | | | | | | | | | | | | | | | | | | |
| Day 1 | 01 | | | | | | | | | | | | | | | | | | | | | | |
| Day 2 | 01 | | | | | | | | | | | | | | | | | | | | | | |
| Day 3 | | | | | | | | | | | | | | | | | | | | | | | |
| 9. | <p>Document the total number of vials processed below.</p> <table border="1"> <thead> <tr> <th></th><th># of vials / tray</th><th># of trays</th><th>Total # of vials</th></tr> </thead> <tbody> <tr> <td>Day 1</td><td>100</td><td>54</td><td>5400</td></tr> <tr> <td>Day 2</td><td>100</td><td>54</td><td>5400</td></tr> <tr> <td>Day 3</td><td></td><td></td><td></td></tr> <tr> <td colspan="3">Total number of vials processed:</td><td>10800 5400</td></tr> </tbody> </table> | | # of vials / tray | # of trays | Total # of vials | Day 1 | 100 | 54 | 5400 | Day 2 | 100 | 54 | 5400 | Day 3 | | | | Total number of vials processed: | | | 10800 5400 | | |
| | # of vials / tray | # of trays | Total # of vials | | | | | | | | | | | | | | | | | | | | |
| Day 1 | 100 | 54 | 5400 | | | | | | | | | | | | | | | | | | | | |
| Day 2 | 100 | 54 | 5400 | | | | | | | | | | | | | | | | | | | | |
| Day 3 | | | | | | | | | | | | | | | | | | | | | | | |
| Total number of vials processed: | | | 10800 5400 | | | | | | | | | | | | | | | | | | | | |

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EECSB16May25

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|------|---|----------------------|------------------------|----------------------|
| 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 |
| | | Day 2 | 10 | CSB 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 |
| | | Day 2 | 10 | CSB 16 May 25 |
| | | Day 3 | | |

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Page 6 of 8

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|------|---|--------------------------------------|---|--|--|--|--|--|--|
| 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 | CSB15May25 BM15May25 | | | | | | |
| | Day 2 | 270 | CSB16May25 BM16May25 | | | | | | |
| | Day 3 | | | | | | | | |
| 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 | CSB15May25 BM15May25 | | | | | | |
| | 2 | 5400 | 10 | | | | | | |
| | | 10 | 270 | | | | | | |
| | | 5700 | 5700 | | | | | | |
| | | 100.00 | CSB16May25 BM16May25 | | | | | | |
| | 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: _____

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