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| **Section 1: Document Approval and Review** | |
| THIS RECORD IS A VERIFIED COPY OBTAINED FROM THE MASTER RECORD:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  MS By / Date | THE FINAL DISPOSITION  OF THIS RECORD IS:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Product Quality By / Date |
| Prepared and Issued by: |

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| **Section 2: General Information – Table of Contents** | |
| **Documents Contained in Completed Package** | **Number of Pages** |
| Product Specific Information Sheet (PSIS) |  |
| Environmental, Health and Safety Precautions |  |
| Work Order Pick List |  |
| Universal Packaging Batch Record |  |
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| **Total Number of Pages:** |  |

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| **Section 3: Reference Information – Referenced Documents** | |
| **Document Number** | **Document Title** |
| OTW-QA-0004 | Documentation and Inspection of Cleaning Equipment |
| OTW-MFG-0013 | Production Scales/Balances |
| OTW-DOC-0024 | Document Management, Retention, Destruction of Documents and Records |
| OTW-DOC-0010 | Proper Issuance, Use, and Control of Room, Equipment, and Cleaning Logs |
| OTW-PKG-0005 | Bottling Primary Packaging |
| OTW-PKG-0006 | Bottling Secondary Packaging |
| OTW-PKG-0007 | Serialization Overview |
| OTW-PKG-0008 | Bottle Label, Topsert, Sidesert, Insert, and Packaging Carton Control |
| OTW-PKG-0011 | Handling of Rejects and Ejects in Primary and Secondary Packaging |
| OTW-PKG-0012 | Videojet 1580 Printer |
| OTW-PKG-0013 | Tabletop Label Applicator |
| OTW-PKG-0015 | Packaging and Labeling Controls |
| OTW-PKG-0016 | Setup, Operation and Cleaning of the Pester PEWO-450 Shrink Bundler |
| OTW-PKG-0018 | Setup and Operation of the AZCO VIP Desiccant Inserter |
| OTW-PKG-0019 | Automatic Torque Tester |
| OTW-PKG-0020 | Setup, Operation and Cleaning of the ESS SC120 Horizontal Cartoner |
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| **Section 4: Primary Packaging Equipment List** | | |
| **Instructions:** Fill in the equipment number for all equipment being used. N/A for any equipment not used in batch. Record any additional equipment not listed in the spaces provided. | | |
| Equipment | Equipment Number | Verified By/Date |
| Bottle Unscrambler ILS-1 |  |  |
| Line Control Conveyor |  |  |
| IMA Uniline |  |  |
| SK600 Surekap Re-torquer |  |  |
| LM5412-T67 Induction Sealer |  |  |
| IMADA Torque Tester |  |  |
| Wipotec Weight Checker |  |  |
| Swiftcheck Tablet Capsule Counter |  |  |
| AZCO Sachet Desiccant Machine |  |  |
| Gram Scale |  |  |
| Gram Scale Printer |  |  |
| Mid-Range Scale |  |  |
| Mid-Range Scale Printer |  |  |
| Drum Scale |  |  |
| Drum Scale Printer |  |  |
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| **Section 5: Primary Packaging Operation** | | | | | |
| **Step** | **Instructions** | **Specification** | **Actual** | **Done By/Date** | **Check By/Date** |
| 1 | Ensure that the correct Health and Safety placard is posted on the room door. |  |  |  |  |
| 2 | Verify that all scales have been standardized and are within acceptable tolerances. |  |  |  |  |
| 3 | Verify the cleanliness of the room and equipment prior to beginning. Record the room number in the space provided. |  | Room No.: |  | **QA** |
| 4 | Verify that a Room Clearance Checklist has been completed following the recent GMP Clean, and that the clean has been documented in the Room Use Log. If this is not the first batch of the campaign, N/A this step. |  |  |  | **QA** |
| 5 | Record the batch number and quantity of bulk material to be packaged in the space provided. |  | Batch #: |  |  |
| Qty:  \_\_\_\_\_\_\_\_\_\_\_\_ g |
| 6 | Collect 100 capsules/tablets from the beginning, middle, and end of the bulk batch, and printweigh each (in grams) using the spaces provided.  **Note: All product used for the 100 ct. weights are to be returned to bulk product.** | 100-Count Weight – Beginning (g) | A. |  |  |
| 100-Count Weight –  Middle (g) | B. |
| 100-Count Weight –  End (g) | C. |
| 7 | Calculate the average capsule/tablet weight using the calculation below:  Step 6A + Step 6B + Step 6C = Step 7A  Step 7A ÷ 300 = Step 7B | Weight of 300 Capsules/Tablets (g) | A.  \_\_\_\_\_\_\_\_\_\_\_\_ g |  |  |
| Average Capsule/Tablet Weight (g) | B.  \_\_\_\_\_\_\_\_\_\_\_\_ g |
| 8 | Fill in the correct, specified values from the PSIS. | Fill Count per Bottle  *PSIS – Sec. X* | A. Fill Count |  |  |
| Total Bottles Required  *PSIS – Sec. X* | B. Total Bottles |
| 9 | Use the calculation below to determine the total quantity of capsules/tablets needed (kg).  *Do we need this? Will we not just run out the bulk? Also, calculations in current records don’t account for any scrap %, so we always end up with less than calculated.* |  |  |  |  |
| 10 | Verify that the Wipotec Scale has been standardized and properly set up, and select the correct recipe. Set the parameters into the Wipotec Scale tolerances. | Wipotec Product Recipe | *PSIS – Sec. X* |  |  |
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**Part I: Setup (Primary)**

**A. Primary Materials**

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| **Item No.** | Product | Theoretical Amount required |
| 10485  or  40555 | Alli Banding, 60mg | 739.28 kg / 4,000,000 capsules |

**B. Primary Packaging Materials**

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| --- | --- | --- | --- |
| **Item No.** | | **Material** | **Theoretical Amount required** |
| Circle Item #(s) | GS6445  and/or  GS6446 | 150 CC Pharmaceutical Round WH (Vendor Code #0150I1X100) | 33,000 |
| Circle Item #(s) | GS6531  and/or  GS6532 | 38 mm SAF-CP-III-A Closure with printed liner  (Vendor Code #201386 or 26733) | 33,000 |
| Circle Item #(s) | GS6358  and/or  GS6359 | CAN SILICA GEL 1G P02 4K/C  (Vendor Code #27293727648 or 31741427648) | 66,000 |

C. Primary Equipment List

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| --- | --- | --- |
| **Qty.** | **Equipment** | **Type** |
| 1 | Bottle Unscrambler | ILS-1 |
| 1 | Line Control | Conveyor |
| 1 | Uniline | IMA |
| 1 | Surekap Re-torquer | SK600 |
| 1 | Induction Sealer | LM5412-T67 |
| 1 | IMADA Torque Tester | N/A |
| 1 | Wipotec Weight Checker | N/A |
| 1 | Swiftcheck Tablet Capsule Counter | N/A |

**Environmental, Health and Safety Precautions**

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| **GHS Labeling: Signal Word: None** |
| **Waste Category:**   * Product waste is Non-hazardous * Solvent Waste is Hazardous * Rags with Solvent are Hazardous |
| **Potency Category:** **Category 1 of 4 (low potency compound)**   * Refer to SDS or OHC for more information |
| **Personal Protective Equipment:**   * Safety glasses * Jumpsuit or similar * Nitrile Gloves * ANSI Safety Shoes * Shoe covers |
| **Respiratory Protection:**   * PAPR, EVA or P100 Filter (purple) * RT3 Hood |
| **Respirator Required Task:**   * Raw material sampling/testing/preweigh of API * Charge/discharge of product (exception: coated beads) * Milling operations * Binder preparation and charging of binder prep tanks * Dry cleaning with air blow down * Swecoing (exception: coated beads) * Filter Bag/Bonnet change/dropping of filter bags |
| **Special Hazards:**  Harmful to aquatic life |

**Part II: Primary Packaging**

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| Step | A. Primary Packaging Line | | **Done By / Date** | **Check By / Date** |
|  | Ensure that the correct Health and Safety placard is posted on the room door. | |  |  |
|  | Verify that all scales have been standardized and are within acceptable tolerances. | |  |  |
|  | Verify the cleanliness of the room and equipment prior to beginning. Record the room number in the space provided. | Room No.: |  | QA |
|  | Verify that a Room Clearance Checklist has been completed by manufacturing and QA following the recent GMP clean. Also verify that the GMP clean has been documented in the Room Use Log. If this is not the first batch of the campaign, N/A this step. | |  | **QA** |
|  | Verify that the room relative humidity (RH) is NMT 65% and the temperature is NMT 75°F using a calibrated device (located no more than 5 feet from the Swiftpharm hopper) or the environmental monitoring system. If the RH and temperature are within ranges indicate **Pass** in the space provided and continue processing. If the RH or temperature are outside the specified ranges indicate **Does Not Pass** in the space provided, do not proceed with startup of the batch and ensure that all capsules are returned to the bulk drum and sealed. Once RH and temperature are back within specifications, resume processing. **Note: If at any point during the batch the RH% or temperature reaches alarm status, stop processing and return all capsules and desiccants back to their original bulk drums and to be sealed. Document the event on the Down Time/Adjustment Verification Sheet, page 12. Once RH and temperature are back within specifications, resume processing.** | Circle one:  Pass  or  Does Not Pass |  |  |
|  | Record the batch number and quantity of Alli Banding, 60 mg available in the spaces provided. | Batch #: |  |  |
| Qty. allocated to batch:  \_\_\_ \_\_\_ \_\_\_ . \_\_\_ \_\_\_kg |

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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | Collect one hundred (100) Alli Banding, 60 mg capsules from the beginning of the bulk product allocated for this batch and printweigh (in grams) using the space provided. Record the scale number in the space provided.  **Note: All product used for the 100 ct. weights are to be returned to bulk product.** | Scale #: |  |  |
| 100 capsules wt. (beginning)(grams): |
|  | Collect one hundred (100) Alli Banding, 60 mg capsules from the middle of the bulk product allocated for this batch and printweigh (in grams) using the space provided. Record the scale number in the space provided.  **Note: All product used for the 100 ct. weights are to be returned to bulk product.** | Scale #: |  |  |
| 100 capsules wt. (middle)(grams): |
|  | Collect one hundred (100) Alli Banding, 60 mg capsules from the end of the bulk product allocated for this batch and printweigh (in grams) using the space provided. Record the scale number in the space provided.  **Note: All product used for the 100 ct. weights are to be returned to bulk product.** | Scale #: |  |  |
| 100 capsules wt. (end)(grams): |
|  | Use the following calculations to determine the average capsule weight and the weight of 120 capsules:  \_\_ \_\_.\_\_ \_\_ \_\_ g + \_\_ \_\_.\_\_ \_\_ \_\_ g + \_\_ \_\_.\_\_ \_\_ \_\_ g = \_\_ \_\_.\_\_ \_\_ \_\_ g  Step 7 Step 8 Step 9 A. Wt. of 300 capsules  \_\_ \_\_.\_\_ \_\_ \_\_ g ÷ 300 = \_\_ .\_\_ \_\_ \_\_ \_\_ g ( **Range:** 0.1792-0.1904 g)  A. Wt. of 300 B. Avg. capsule wt.  capsules  \_\_ .\_\_ \_\_ \_\_ \_\_ g x 120 = \_\_ \_\_ .\_\_ \_\_ \_\_ g  B. Avg. capsules wt. C. Wt. of 120 capsules | |  |  |

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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | Use the calculations below to determine either the total amount of capsules needed (kg) or the total number of bottles needed. If a bottle count is available and the total weight of capsules needed is what needs to be determined use the calculation below.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Wt. of 120 capsules  (Step 10C) | x | Bottle count | ÷ | g/kg | = | Total Weight of capsules needed (kg)  (round to two decimal places) | | \_\_ \_\_ .\_\_ \_\_ \_\_ g | x |  | ÷ | 1000 | = | \_\_ \_\_ \_\_. \_\_ \_\_ kg | | |  |  |
| If the total weight of capsules (kg) to be used is available and the bottle count is to be determined, use the calculation below.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Total Weight of capsules on hand (Step 6) (kg) | x | g/kg | ÷ | Wt. of 120 capsules (Step 10C) | = | Bottle count | | \_\_ \_\_ \_\_. \_\_ \_\_ kg | x | 1000 | ÷ | \_\_ \_\_ .\_\_ \_\_ \_\_ g | = |  |   N/A the calculation not needed. | |
|  | Using the space provided, printweigh 10 kg of capsules into a clean, tared, double polyethylene liner. Record the scale number in the space provided. Prepare the material to complete the EFS Learn per the example below.  **Example of prepared capsules: Remove quantity of banded capsules from the bulk containers. Manipulating the bag in a manner that is cGMP compliant as to separate any conjoined capsules before charging into the fill hopper of the Swiftpharm.**  **Note: Perform a 100% inspection on the 10 kg of prepared capsules to ensure that there are no defects found as a result of the manipulation prior to charging (e.g. incomplete band/crack in band, scrape marks on band twinned capsules). Any defect found prior to the introduction of the product to the batch does not count toward the defect allowance for the batch. The prepared capsules should also be inspected for foreign matter (e.g. pieces of the liner) that could be introduced as a result of the manipulation. This material will be used for processing once the EFS Learn is complete.** | Scale #: |  |  |
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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | Printweigh any defects found during the inspection of the prepared capsules from step 12. Record the scale number in the space provided. If no defects are found, enter none in the space provided. | Scale #: |  |  |
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|  | Verify Wipotec Scale has been standardized and properly set up. Set the parameters into the Wipotec Scale tolerances. | Wipotec Recipe:  GSK\_Alli\_60mg\_120ct |  |  |
|  | Once the scale setup is complete, place 10 empty bottles on the line and run through the scale to ensure they are rejected. Circle pass or fail.  **If the bottles are not rejected, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle one:  Pass  Fail |  |  |
|  | Stop the machine, place 10 bottles filled with two desiccant and 120 capsules on the line and run through the scale to ensure they pass. Circle pass or fail.  **If the bottles do not pass, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle one:  Pass  Fail |  |  |

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| Step | **A. Primary Packaging Line (cont.)** | | | **Done By / Date** | **Check By / Date** |
|  | Stop the machine, place 10 bottles filled with two desiccants and approximately 200 capsules on the line and run through the scale to ensure they are rejected. Circle pass or fail.  **If the bottles are not rejected, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle one:  Pass  Fail | |  |  |
|  | Ensure that the capsules utilized in the challenge test in step 16 and step 17 have been placed back into the bulk product. Reference SOP OTW-PKG-0011. | | |  |  |
|  | Prepare properly labeled containers for the waste bottles, waste closures and spillage waste. | | |  |  |
|  | Verify that the Induction Sealer has been set up properly to ensure a complete seal per SOP OTW-PKG-0014-J11. Target Range: 60-65% and sealing gap of 3-4 mm. Record the Induction Sealer and sealing gap setting in the spaces provided. | | Induction Sealer setting:  % |  |  |
| Sealing Gap:  mm |
|  | On the Induction Sealer:  Select:   * Data * Bottle Counts * Reset Counts   This completes the set-up process. | | |  |  |

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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | Remove the foil from 10 closures and place the closures back onto the bottles. Run the 10 bottles through the induction sealer to ensure they are rejected.  Circle pass or fail.  **If the bottles are not rejected, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle One:  Pass  Fail |  |  |
|  | Verify that the Surekap Re-torque machine is set to the closure requirements: Target: 21.5 in-lb (Range: 17-26 in-lb)  Select:   * Setup * Reset Report * Batch Number   This completes the set-up process. | |  |  |

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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
| **Operator Notes: Ensure hopper gate is closed before charging.**  The 10 kg of prepared capsules weighed in step 12 must be used in the performance of the following EFS Learn procedure since “twinning” is inherent to this process. If excessive “twinning” is observed during processing, a visual inspection of the product prior to charging to the vibratory tray will be completed. Add materials to their respective hoppers and continue to fill the hoppers throughout the process as needed. As each box of desiccants, closures or bottles is brought in the room, document the quantity in the box, the item number, lot number, and box number on the Bottle Usage Log (pages 14-17), Closure Usage Log (pages 18-19) and Desiccant Usage Log (page 20). In the event that the room temperature or RH% reaches alarm status, or active production is stopped for ≥ 6 hours, all banded capsules that remain in the Swiftpharm hopper and all desiccants in the desiccant hopper are to be returned to their original containers and re-sealed. Document the event on the Down Time/Adjustment Verification Sheet, page 13. | | | | |
|  | Select the recipe on the Bottle Unscrambler. Ensure bottles are in the upright position then press start and allow the bottles to fill the line. | Recipe:  150CC Round 38 mm |  |  |
|  | Ensure that the bottles are properly oriented on the conveyor belt. | |  |  |
|  | Select and load the appropriate recipe on the Uniline HMI then perform the following actions: | Recipe:  GSK\_Alli\_60mg\_120ct |  | **QA** |
| Select   * Production Screen * Batch Control * Enter lot number * Press Start Batch   Confirm to start batch. | |
|  | Access the Counter Screen on the Uniline HMI under the recipe tab and verify the count is set to 120. | |  | **QA** |
|  | Adjust the product hopper gate height to ensure optimal flow. Visually inspect for broken/dented capsules prior to charging. | |  |  |
|  | Verify that the closure torque is set to 17 in-lbs. (Range: 15-19 in-lbs.) Enter the recipe, choose Uniline and then choose Capper 1 to verify. | |  | **QA** |
|  | Access the “configuration’ icon 1024px-Red_Silhouette_-_Gears. Click on the “Overrides” tab and then press the bottle transport override button to enable. | |  |  |
|  | Access the “counter” icon Abacus-2-548x552 . Click on the EFS learn and press the “start counter” start-button-305427_960_720 . When all columns have turned to green, press save. | |  |  |

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| Step | **A. Primary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | Press Test, choose Optical, the Optical Tab and select “Copy to Product”. | |  |  |
|  | Record the Last Change Time and Learn Time before Learn Start in the spaces provided. | Last Change Time: |  |  |
| Learn Time: |
|  | Click on the “Test Screens” icon MTVU9 . Access the EFS test and verify that all pulse rows have a range of 2 or less across all 12 heads. | |  | **QA** |
|  | Access the “Run” screen and set BPM to 40 prior to starting.  **Note: This is for startup only and will be adjusted after initial startup.** | |  |  |
|  | If needed, home the capper, gate and transport. Place in automatic mode. | |  |  |
|  | Access the “Run” screen on the Uniline. Monitor the E-Stop and visually inspect the first set of transport teeth for clearances. | |  |  |
|  | Perform the EFS Challenge on page 21. | |  |  |
|  | Perform the Filled Bottle Count Challenge on page 22. | |  |  |
|  | After set-up is complete, allow equipment to bottle approximately 50 bottles, then perform QA First Piece Inspection on four (4) consecutive bottles. Record the results on page 23. If all requirements are not met, an adjustment must be made, and the QA First Piece (2nd) will be performed. All bottles produced prior to the second inspection must be re-worked per SOP OTW-PKG-0011. | |  |  |
|  | After first piece inspection has passed, start the equipment and begin primary packaging. | |  |  |
|  | In-Process readings are required at approximately every 30 minutes. Four (4) bottles are to be pulled from the outfeed of the Re-torquer and documented as one line item. Record all in-process data on pages 24-26. | |  |  |
|  | At approximately 50 bottles from the end of process, perform the QA Last Piece Inspection on four (4) consecutive bottles. Record the results on page 23. | |  |  |

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| **Step** | **A. Primary Packaging Line (cont.)** | | | **Done By / Date** | **Check By / Date** |
|  | To end the batch, go to the Uniline Control, select Production Screen, press End Batch, Confirm and save the report. | | |  |  |
|  | Using the space provided, printweigh the remaining capsules from the partial/full containers of product and return to inventory. Record the scale number in the space provided. If no material is collected, enter none in the space provided. | | Scale #: |  |  |
| Amt. of capsules returned to inventory: |
|  | Any spilled capsules will be reconciled as waste. Printweigh all capsule waste in the space provided.  Record the scale number in the space provided. If no material is collected enter none in the space provided. | | Scale #: |  |  |
|  |
|  | Return all unopened bottles and closures to inventory. | | |  |  |
|  | If necessary, prepare a properly labeled container for receiving the unlabeled, filled bottles as they proceed from the primary packaging line to the secondary packaging for labeling. N/A this step if not needed. | | |  |  |
|  | Review the Down Time/Adjustment Sheet (page 13) and document the number of temperature and RH% alarms documented in the space provided. In the space provided, indicate Yes or No if capsules/desiccants were returned to their original drums and re-sealed after an alarm. If No, contact a Supervisor and QA immediately. If no alarms were documented, enter None in the spaces provided. | No. of Temp./RH alarms: | |  |  |
| Were capsules/desiccants returned to drums and re-sealed following alarms?: | |

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| **Down Time/Adjustment Verification Sheet**  **Note: This sheet is to record any down time/adjustments made during the processing of the batch. Record all down time using this sheet. Check either the non-mechanical or mechanical section.**  **A non-mechanical down time does not require a description, please N/A space.**  **Mechanical stops are interruptions due to issues with any equipment or any facility issues including RH or temperature alarms. Non-Mechanical stops are interruptions due to other issues (i.e. breaks, scheduling, order product, etc.).** | | | | | |
| **Process Stop Time** | **Process Start Time** | **Non-**  **Mechanical** | **Mechanical** | **Brief Description of Adjustment or Repair** | **Done By /**  **Date** |
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| Bottle Usage Log | |  |  | |  | |  | |
|  | **Item #**  **Lot #**  **Box #** | | | **Number of bottles issued to batch** | | **Done By / Date** | | **Check By / Date** |
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| **Calculate the total quantity of bottles issued and record in the space provided on page 17A.** | | | | | | | | |

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| Bottle Usage Log | | | | | | |
|  | **Item #** | **Lot #** | **Box #** | **Number of bottles issued to batch** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of bottles issued and record in the space provided on page 17A.** | | | | | | |

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| Bottle Usage Log | | | | | | |
|  | **Item #** | **Lot #** | **Box #** | **Number of bottles issued to batch** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of bottles issued and record in the space provided on page 17A.** | | | | | | |

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|  | Bottle Usage Log |  | |  | |  |
|  | **Item #**  **Lot #**  **Box #** | | **Number of bottles issued to batch** | **Done By / Date** | | **Check By / Date** |
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| **Calculate the total quantity of bottles issued and record in the space provided.** | | | A. | |  |  |
| **Document the number of bottles returned to inventory in the space provided.** | | | B. | |  |  |

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| Closure Usage Log | | | | | | |
|  | **Item #** | **Lot #** | **Box #** | **Number of closures issued to batch** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of closures issued and record in the space provided on page 19A.** | | | | | | |

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| Closure Usage Log | | | | | | |
|  | **Item #** | **Lot #** | **Box #** | **Number of closures issued to batch** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of closures issued and record in the space provided.** | | | | A. |  |  |
| **Document the number of closures returned to inventory in the space provided.** | | | | B. |  |  |

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| Desiccant Usage Log | | | | | | |
|  | **Item #** | **Lot #** | **Bag #** | **Number of desiccants issued to batch** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of desiccants issued and record in the space provided.** | | | | A. |  |  |

**EFS Learn Test Log**

**Double Product:**

* Number 4 bottles and place at the infeed of the Uniline.
* Use 8 capsules to form (4) sets of double capsules.
* Place a pair of doubles on each of the following tracks in the front tray: #2, #5, #8, and #11.
* Run the Uniline to fill the four marked bottles, and ensure the bottles are marked for rejection.
* Stop the Uniline and remove the four marked bottles.
* Reconcile the doubles and all other product in the marked bottles as waste; keep the marked bottles to continue testing.

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| **Date** | **Time** | **Period of testing (start of shift, start of batch, etc.)** | **EFS Learn Complete?**  **(Circle One:)** | **Number of Bottles Rejected** | **Done By** | **Check By** | **Date** | **Time** | **Period of testing (start of shift, start of batch, etc.)** | **EFS Learn Complete?**  **(Circle One:)** | **Number of Bottles Rejected** | **Done By** | **Check By** |
|  |  |  | Yes / No |  |  |  |  |  |  | Yes / No |  |  |  |
|  |  |  | Yes / No |  |  |  |  |  |  | Yes / No |  |  |  |
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**Broken Product:**

* Place the marked bottles at the infeed of the Uniline.
* Form broken product:
  + For capsules: open (4) capsules and remove some of the beads, ensuring capsules are 47% of the original capsule weight or smaller. Weigh up beads as waste.
* Place broken piece on each of the following tracks in the front tray: #2, #5, #8, and #11.
* Run the Uniline to fill the four marked bottles, and ensure the bottles are marked for rejection.
* Stop the Uniline and remove the four marked bottles. Remove the broken capsule from each of the bottles.
* Reconcile the broken capsules and marked bottles as waste.

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| **Date** | **Time** | **Period of testing (start of shift, start of batch, etc.)** | **EFS Learn Complete?**  **(Circle One:)** | **Number of Bottles Rejected** | **Done By** | **Check By** | **Date** | **Time** | **Period of testing (start of shift, start of batch, etc.)** | **EFS Learn Complete?**  **(Circle One:)** | **Number of Bottles Rejected** | **Done By** | **Check By** |
|  |  |  | Yes / No |  |  |  |  |  |  | Yes / No |  |  |  |
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**If at any time one of the marked bottles is not rejected:**

1. Ensure the indicated bottle contains the double capsule or the broken capsule as applicable.
2. If the bottle does not have the bad product in it, run the Uniline again, ensuring the unacceptable product is in a location in the front tray where it will drop into the bottle.
3. If the bottle does have the bad product in it and it was still not marked for rejection, remove all marked bottles and unacceptable product from the line. Re-perform the EFS learn, and then repeat the EFS challenge steps.

**Filled Bottle Count Challenge Test Log**

* After completion of EFS Learn Test Log, run 8 bottles through the filling process.
* Retrieve the 8 bottles prior to induction sealer.
* Perform the count inspection (confirm that each bottle contains 120-122 capsules) and document the results in the table below.
* If any of the results are unacceptable, repeat the EFS Learn Test process and repeat bullet points 1-3.

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| **Date:** | | **Time:** | | | **Uniline Speed: BPM \_\_\_\_\_\_\_\_\_** | |
| **Bottle No.** | **Count**  **(120-122 Capsules/ Bottle)**  **(Circle one)** | | **Comments** | **Done By** | | **QA Check By** |
| **1** | **A U** | |  |  | | **QA** |
| **2** | **A U** | |  |  | | **QA** |
| **3** | **A U** | |  |  | | **QA** |
| **4** | **A U** | |  |  | | **QA** |
| **5** | **A U** | |  |  | | **QA** |
| **6** | **A U** | |  |  | | **QA** |
| **7** | **A U** | |  |  | | **QA** |
| **8** | **A U** | |  |  | | **QA** |

**Note: All acceptable capsules are to be re-introduced to the capsule hopper.**

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| **QA First Piece / Last Piece Inspection (Primary Packaging): Document 1st Piece and Last Piece Results in the appropriate column. N/A “1st Piece (2nd)” if initial 1st Piece is successful.**  **Key: A = Acceptable U = Unacceptable N/A = Not Applicable** | | | | |
| **1st Piece** | **1st Piece (2nd)** | **Last Piece** | **Requirements** | **Comments** |
|  |  |  | **Correct Drug Product:** Verify w/ product description on page 1 of the batch record |  |
|  |  |  | **Correct Bottle Size per job:** Compare item number to the item number on the batch record |  |
|  |  |  | **Correct Closure size/style:** Compare item number to the item number on the batch record |  |
|  |  |  | **Correct Desiccants** Compare item number to the item number on the batch record |  |
|  |  |  | **Correct Product Count:** Verify the correct product count of 120-122 capsules on page 1 of the batch record. |  |
|  |  |  | **Induction Seal:** Verify a complete seal with no signs of burnt or weak seals. |  |
|  |  |  | **Closure Removal Torque:** Verify it is within the specified range from the Re-torquer. Target of 10.5 in-lbs. (Range of 6-15 in-lbs.). |  |
|  |  |  | **Done By/Date** |  |

**Note: All Primary Samples are to be removed from the line downstream from the Surekap Re-torquer. All four (4) samples will be tested simultaneously and documented as one line item.**

**Note: All acceptable capsules are to be re-introduced to the capsule hopper.**

**Note: QA will notify the Supervisor in the instance of last piece failure.**

**In-Process Verification (Packaging)**

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| **No.** | **Date** | **Time** | **Bottle**  **(Circle one)** | **Closure**  **(Circle one)** | **Closure Removal Torque**  Target 10.5 in-lbs.)  (Range: 6-15 in-lbs.) | | | | **\*120-122 acceptable capsules/**  **bottle)**  **(Circle one)** | **Uniline Speed (40-50 BPM)** | **Seal (Circle one)** | **Two Desiccants**  **(Circle one)** | **Unscrambler Air Pressure (4.0-6.0 bar)** | **Uniline**  **Total Good Bottles** | **Comments** | **Done By** | **Check By** |
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**A = Acceptable U – Unacceptable**

**Notes: Perform in-process testing approximately every 30 minutes. All primary samples are to be removed from the line downstream from the Surekap Re-torquer and each sample of four (4) documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded. All acceptable capsules are to be re-introduced to the capsule hopper.**

**\* Acceptable capsules show no indication of damage, overfilling (greater than 122), underfilling or foreign material.**

**In-Process Verification (Packaging)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **No.** | **Date** | **Time** | **Bottle**  **(Circle one)** | **Closure**  **(Circle one)** | **Closure Removal Torque**  Target 10.5 in-lbs.)  (Range: 6-15 in-lbs.) | | | | **\*120-122 acceptable capsules/**  **bottle)**  **(Circle one)** | **Uniline Speed (40-50 BPM)** | **Seal (Circle one)** | **Two Desiccants**  **(Circle one)** | **Unscrambler Air Pressure (4.0-6.0 bar)** | **Uniline**  **Total Good Bottles** | **Comments** | **Done By** | **Check By** |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
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**A = Acceptable U – Unacceptable**

**Notes: Perform in-process testing approximately every 30 minutes. All primary samples are to be removed from the line downstream from the Surekap Re-torquer and each sample of four (4) documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded. All acceptable capsules are to be re-introduced to the capsule hopper.**

**\* Acceptable capsules show no indication of damage, overfilling (greater than 122), underfilling or foreign material.**

**In-Process Verification (Packaging)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** | **Date** | **Time** | **Bottle**  **(Circle one)** | **Closure**  **(Circle one)** | **Closure Removal Torque**  Target 10.5 in-lbs.)  (Range: 6-15 in-lbs.) | | | | **\*120-122 acceptable capsules/**  **bottle)**  **(Circle one)** | **Uniline Speed (40-50 BPM)** | **Seal (Circle one)** | **Two Desiccants**  **(Circle one)** | **Unscrambler Air Pressure (4.0-6.0 bar)** | **Uniline**  **Total Good Bottles** | **Comments** | **Done By** | **Check By** |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |
|  |  |  | **A U** | **A U** |  |  |  |  | **A U** |  | **A U** | **A U** |  |  |  |  |  |

**A = Acceptable U – Unacceptable**

**Notes: Perform in-process testing approximately every 30 minutes. All primary samples are to be removed from the line downstream from the Surekap Re-torquer and each sample of four (4) documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded. All acceptable capsules are to be re-introduced to the capsule hopper.**

**\*Acceptable capsules show no indication of damage, overfilling (greater than 122), underfilling or foreign material.**

**Part III: Setup Secondary**

**A. Secondary Packaging Materials**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item No.** | | **Material** | **Theoretical Amount required** |
| Circle Item #(s) | GS6714 and/or  GS6715 | Bottle Label 120 ct US (Item Code #1001166) | 33,000 |
| Circle Item #(s) | GS6557  and/or  GS6558 | 5 Carton, 0.016” SBS Seal End 120CT (Item Code #1001167) | 33,000 |
| Circle Item #(s) | GS6477  and/or  GS6478 | Shipper Box US (Vendor code #21077/21078) | 5,502 |
| Circle Item #(s) | GS6549  and/or  GS6550 | Tamper Label (with text 104528XA) | 66,000 |
| Circle Item #(s) | GS6547  and/or  GS6548 | Insert Folded “RMF” Brochure (Artwork file 8021191) | 33,000 |

B. Equipment List

|  |  |  |
| --- | --- | --- |
| **Qty.** | **Equipment** | **Type** |
| 1 | LineMaster | Optel |
| 1 | PharmaProof #1 | Optel BottleTracker |
| 1 | PharmaProof #2 | Optel LabelTracker |
| 1 | PharmaProof #3 | Optel CartonTracker |
| 1 | Cartoner | ESS SC120 Horizontal |
| 1 | Rotary Labeler | Weiler |
| 1 | Case Erecter | Wexxar Bell |

**C. Templates**

|  |  |
| --- | --- |
| **Bottle Label** | **Tamper Evident Label** |
|  |  |
| **Shipper** | |
|  | |
| **Carton** | |
|  | |



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**Part IV: Secondary Packaging**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line | | **Done By / Date** | **Check By / Date** |
|  | Ensure that the correct Health and Safety placard is posted on the room door. | |  |  |
|  | Verify that all scales have been standardized and are within acceptable tolerances. | |  |  |
|  | Verify the cleanliness of the room and equipment prior to beginning. Record the room number in the space provided. | Room No.: |  | QA |
|  | Verify that a Room Clearance Checklist has been completed by manufacturing and QA following the recent GMP clean. Also verify that the GMP clean has been documented in the Room Use Log. If this is not the first batch of the campaign, N/A this step. | |  | **QA** |
|  | **A.** Collect 10 cartons and printweigh in the space provided. Record the scale number and lot number in the spaces provided.  Reference the Carton Usage Log on pages 55-62. | Scale #: |  |  |
| Lot #: |
|  |
| **B.** Use the following calculation to determine the average weight of one carton:  \_\_\_ \_\_\_ \_\_\_ . \_\_\_ \_\_\_ g ÷ 10 = \_\_\_ \_\_\_ . \_\_\_ \_\_\_g  Wt. of 10 cartons Avg. Wt of one carton | |
|  | **A.** Collect 10 inserts and printweigh in the space provided. Record the scale number and lot number in the spaces provided.  Reference the Insert Usage Log on page 54. | Scale #: |  |  |
| Lot #: |
|  |
| **B.** Use the following calculation to determine the average weight of one labeled insert:  \_\_\_ \_\_\_ . \_\_\_g ÷ 10 = \_\_\_ . \_\_\_g Wt. of 10 inserts Avg. Wt of one insert | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | **Done By / Date** | **Check By / Date** |
|  | Record the shipper lot number in the space provided. | Lot #: |  |  |
|  |  |  |  |  |
|  | * Enter in Lot # associated with this packaging work order and press the NEXT button * Select the recipe: Enter Recipe Name (OTW-GS151-30433) * Press NEXT button | |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | | **Done By / Date** | **Check By / Date** |
|  | Determine the manufacturing date of each drug product used in the capsules by performing the following bullet points:   * Determine the batch number of Alli Banding, 60mg and obtain the executed batch record. * Determine the batch number of Alli Encapsulation, 60 mg and obtain the executed batch record. * Determine the batch number of the Alli Blend, 60 mg and obtain the executed batch record. * Determine the batch number of the Alli Granulation, 60 mg and obtain the executed batch record. * Record the batch numbers in the table below * Determine and record the manufacturing date in the table below.   The manufacturing date is the earliest date that the API (Orlistat) is charged to the VG-1500.  **N/A any unused spaces.** | | | | |
|  | **Batch Number** | **Manufacturing Date** |  |  |
| Alli Granulation, 60 mg |  | (YYYY/MM) | **SPVSR** | **QA** |
| Alli Blend, 60 mg |  |  | **SPVSR** | **QA** |
| Alli Encapsulation, 60 mg |  |  | **SPVSR** | **QA** |
| Alli Banding, 60mg |  |  | **SPVSR** | **QA** |
|  | Verify that the expiration date is 23 months from date of manufacture (Refer to Step 59). Record the expiration date in the space provided.  Expiration date: Step 59 + 23 months = Expiration date  Example: If the manufacturing date from Step 59 is 2022/04, then the calculated expiration date should be recorded as 2024/03. | | Expiration date:  (YYYY/MM) | **SPVSR** | **QA** |
|  |  | | |  |  |
|  | * Select the recipe: * Enter the Expiration Date (MMYYYY) and press NEXT. | | Recipe Name:  OTW-GS151-30433 |  |  |
|  | * ENTER the following information into the Optel Line Master: * EXPIRY DATE: MMYYYY format * Then press NEXT * Press the USER CONFIRM BATCH button | | |  |  |
|  | * Team Lead/Supervisor Log In to re-enter and re-confirm batch parameters * Enter Batch ID (Lot Number). | | |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | **Done By / Date** | **Check By / Date** |
|  | Once the information has been entered into Line Master and confirmed, move to PP1 bottle track and Log in.   * Press NEXT button on Batch Confirmation if status is “OK” for all information. * Press YES to stay Logged In prompt. If NO is selected, User will need to Log In. | |  |  |
|  | Select “Shipper” tab and press the “Re-Print Shipper Label” button. Attach the Label Specimen to page 75. |  |  | **QA** |
|  | Ensure that the shipper label specimen attached to the Printed Label Sheet (page 75) have been verified and signed. Signatures on the Printed Label Sheets from both Production and QA should be present indicating the label meets requirements. | |  |  |
|  | PHARMA PROOF 1  Select “Start-Up” and Log in. | |  |  |
|  | Select “Quick Set-Up”. | |  |  |
|  | Inspect Image, press “Accept” if Image is correct. | |  |  |
|  | Inspect Frames and press “Accept” if frames are properly aligned. | |  |  |
|  | Select “Build Reference” and pass 10 bottles through the bottle tracker. | |  |  |
|  | Verify on the PharmaProof 1 HMI that the Lot Number is correct. | |  |  |
|  | Run bottles through the bottle tracker until you can confirm that the correct tracking code has been applied to the bottom of the bottle. | |  |  |

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| --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | **Done By / Date** | **Check By / Date** |
|  | Using a permanent marker black out the bottom of the bottle. Pass the bottles through the bottle tracker and ensure the 10 bottles are rejected. Circle pass or fail.  **If the bottles are not rejected, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle one:  Pass  Fail |  |  |
|  | WEILER LABELER  Log In and select the correct Recipe. Ensure labeler count is set to zero. | Recipe:  150CC Round-Alli |  | **QA** |
|  | Press STARTUP to login to Label Tracker using a Team Lead or Supervisor or higher USER NAME and PASSWORD. | |  |  |
|  | Press the **ACCEPT WARNING** Button on the HMI to acknowledge alarm, if present.  Press the **QUICK SETUP** button.  Press the **QUICK** button.  **Note: The conveyor will start up. All labels and bottles used for building image references will be rejected.**  Feed a bottle into the labeler in the correct orientation and press the **Accept Image** button once the print looks acceptable.  Press the **Frames** and press **NEXT** to scroll through all the frames, when frames are properly centered, they are displayed with green frames on Label Tracker HMI.  Press the **Accept Frames** button to accept image.  Press the **Build Reference** button to build a reference on LabelTracker. | |  |  |

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| --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | **Done By / Date** | **Check By / Date** |
|  | Once complete, turn Camera 2.1 back to enabled. | |  |  |
|  | Access Quick Settings, disable “Label head run mode”. | |  |  |
|  | Print a bottle label from the Optel. Verify That the following items are correct.   * Verify the packaging lot number is correct and preceded by LOT. Circle yes or no. The lot number is listed on the header of this batch record with the prefix LOT.   Example: “LOT 1234567”. Record the packaging lot number in the space provided.   * Verify the packaging expiration date is correct and is preceded by EXP. Circle yes or no. The expiration is as indicated in step 60 of this batch record with prefix EXP. Example: “EXP YYYY/MM”. Record the expiration date in the space provided.   If any of the above requirements are not met, contact a Supervisor or above to perform any adjustments needed. Do not continue to the next step until all requirements are met. Attach the label to page 77. | Packaging Lot #: |  | **QA** |
| Circle one:  **Yes or No** |
|  |  | EXP Date: |  |  |
| Circle one:  **Yes or No** |
|  | Jog the label head until a passing label inspected by Camera 2.1 is obtained and “Clear Web” appears. Print a bottle label using the label tracker.  **Optel Line Setup is now complete.** | |  |  |
|  | From the Quick setting Screen, enable the “Label Head Run Mode”. | |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Step** | **A. Secondary Packaging Line (cont.)** | | | **Done By / Date** | **Check By / Date** |
|  | Using a permanent marker, mark a straight line through 5 labels on the web. Jog labels past camera 2:1 and verify that the labels are rejected. Circle pass or fail.  **If the labels are not rejected, stop and contact a Supervisor or above to perform any adjustments needed.**  **Note: Upon completion of the label reject challenge place the label head into jog mode and pass the 5 labels through as to not create wasted bottles.**  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Circle one:  Pass  Fail | |  |  |
|  | Log in to the cartoner HMI. | | |  |  |
|  | Verify the servos are home on the HMI main screen. Home if needed. | | |  |  |
|  | Press the HMI e-stop. Select the correct recipe on the **Setup-Settings** and load it into the cartoner. Record the recipe name in the space provided. | | Recipe: |  |  |
|  | Set up the cartoner per SOP OTW-PKG-0020 using materials listed in the Secondary Packaging list. Turn on the glue system if needed. | | |  |  |
|  | Set up all cartoner infeed and outfeed conveyors to match the bottle and carton in use. | | |  |  |
|  | Set up the cartoner in the Dry Run mode and allow to cycle for NLT 1 minute. Verify a smooth cycle. | | |  |  |
|  | Allow NLT 5 bottles to be loaded, formed, filled and sealed by turning Dry Run OFF. | | |  |  |
|  | Once NLT 5 bottles have been loaded, turn Dry Run back ON. | | |  |  |

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| --- | --- | --- | --- | --- | --- |
| **Step** | **A. Secondary Packaging Line (cont.)** | | | **Done By / Date** | **Check By / Date** |
|  | Remove NLT 5 completed cartons from the CartonTracker outfeed for inspection. Verify that the following are correct (carton will need to be opened for some items):   * Carton is properly closed and sealed * Bottle is present and properly oriented * Insert is present and properly oriented * Any other required components are present and properly oriented * External seals or labels are applied in correct location. * Verify the packaging lot number is correct and preceded by LOT. Circle Yes or No. The lot number is listed in the header of this batch record with prefix LOT. Example: “LOT 1234567”. Record the packaging lot number in the space provided. * Verify the packaging expiration date is correct and is preceded by “EXP”. Circle Yes or No. The expiration is as indicated in step 60 of this batch record.   Example: “EXP YYYY/MM”. Record the expiration date in the space provided.  Indicate in the space provided if inspection is a Pass or Fail. If any failures are found, contact a Supervisor or above to perform any adjustments needed. Do not continue to the next step until all requirements are met. Once all have been verified, include five printed cartons from this inspection with the batch record. | | General Inspection Results (Circle one):  Pass  or  Fail |  | **QA** |
| Packaging Lot #: |
| Circle one:  Yes or No |
| EXP Date: |
| Circle one:  Yes or No |
|  | Gather any reusable components (bottles, leaflets, etc.) and return to appropriate location for rework per SOP OTW-PKG-0011. | | |  |  |
|  | Ensure the inspected cartons are rejected.  **Note: Cartons cannot be reworked.** | | |  |  |
| 1. Pa | If seals or labels are applied to the carton, perform a challenge of the vision system. Pass 5 cartons through the camera system with NLT 1 seal/label missing per carton. Verify all 5 cartons are rejected. Indicate in the space provided if inspection is a Pass or Fail. If any failures are found contact a Supervisor or above to perform any adjustments as needed.  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Inspection Results (Circle one):  **Pass**  **or**  **Fail** | |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **A. Secondary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | If inserts are required, perform a challenge of the insert barcode scanner. Place a line through the barcode on 8 inserts (2 in each magazine) and allow the cartoner to load through the line. Verify that all 8 inserts are rejected by the cartoner prior to loading in the carton. Indicate in the space if inspection is a pass or fail. If any failures are found contact a Supervisor or above to perform any adjustments as needed.  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Inspection Results (Circle one):  **Pass**  **or**  **Fail** |  |  |
|  | If inserts are required, perform a challenge of the insert present sensor. Pull the inserts in each magazine back such that they will not pick. Cycle NLT 5 cartons without inserts. All 5 cartons should be rejected at the exit of cartoner. Indicate in the space if inspection is a pass or fail. If any failures are found contact a Supervisor or above to perform any adjustments as needed.  **Note: If any unexpected downtime occurs that causes the batch to stop for an extended period of time, the challenge should be performed again and documented on the Down Time/Adjustment Sheet, page 13, prior to restarting the batch.** | Inspection Results (Circle one):  **Pass**  **or**  **Fail** |  |  |
|  | Ensure 6 cartons go into each shipper and are closed by the case erector. | |  |  |
|  | Zero production counts on the HMI main screen. | |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | **A. Secondary Packaging Line (cont.)** | | **Done By / Date** | **Check By / Date** |
|  | After secondary packaging set-up is complete, allow equipment to complete approximately 5 shippers, then perform the following:  A. Perform QA First Piece Inspection Part 1 on four (4) consecutive bottles pulled from the outfeed of the labeler. Record the results on page 48.  B. Perform QA First Piece Inspection Part 2 on one (1) shipper. Record the results on page 49.  If all requirements are not met, an adjustment must be made, and the QA First Piece (2nd) will be performed. All shippers produced prior to the second inspection must be reworked per OTW-PKG-0011. | |  |  |
|  | After first piece inspection has passed, start the equipment and begin secondary packaging. | |  |  |
|  | Place completed shippers on a pallet in a 4x4 layout for a total of 16 shippers per layer with 6 layers. **Note: Partial shippers cannot be generated for this process.** | |  |  |
|  |  |  |  |  |
|  |
|  | In-Process readings are required at approximately every 30 minutes. Four (4) bottles are to be pulled from the outfeed of the labeler and recorded as one line item. Record all in process data for Part 1 on pages 50-51. One (1) shipper is to be pulled from the outfeed of the Case Erector and documented as one line item. Record all in-process data for Part 2 on pages 52-53. | |  |  |
|  | Perform all rework per OTW-PKG-0011.  **Note: Prior to passing labeled bottles to primary, count the number of labels applied and record on page 73, step C.** | |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | | | **Done By / Date** | **Check By / Date** | |
| Collect the following samples from the outfeed of the carton tracker (PharmaProof #3):   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Batch Size** | **AQL and Count Check Composite** | | | | **Catalent Reserve Sample** | | | **Leak Testing Sample** | | | **Micro Sample** | | | **QC Sample** | | | | **Location** | | | **Total Qty. Cartoned Bottles** | **Location** | | | **Location** | | | **Location** | | | **Location** | | | | Beg. | Middle | End | Beg. | Mid. | End | Beg. | Mid. | End | Beg. | Mid. | End | Beg. | Mid. | End | | **501-1200** | 27 | 26 | 27 | 80 | 42 | 42 | 42 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 4 | 4 | | **1201-3200** | 42 | 41 | 42 | 125 | | **3201-10000** | 67 | 66 | 67 | 200 | | **10001-35000** | 105 | 105 | 105 | 315 | | **35001-150000** | 166 | 167 | 166 | 500 | | **Label** | Initials/Date, Count, Sample Name | | | | | | | | | | | | | | | | | **Deliver To** | QA Lab | | | | | | | Sample Drop Point | | | | | | | | | | | | | | | |
|  | Record the number of bottles collected for the AQL beginning of the batch sample in the space provided. | Target #: | Beginning of batch: |  | |  |
| Record the number of bottles collected for the AQL middle of the batch sample in the space provided. | Target #: | Middle of batch: |  | |  |
| Record the number of bottles collected for the AQL end of the batch sample in the space provided. | Target #: | End of batch: |  | |  |
|  | Record the number of bottles collected for the Catalent Reserve beginning of the batch in the space provided. | Target #:  42 | Beginning of batch: |  | |  |
| Record the number of bottles collected for the Catalent Reserve middle of the batch in the space provided. | Target #:  42 | Middle of batch: |  | |  |
| Record the number of bottles collected for the Catalent Reserve end of the batch in the space provided. | Target #:  42 | End of batch: |  | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Step** | A. Secondary Packaging Line (cont.) | | | | **Done By / Date** | **Check By / Date** |
|  | **Note: Results need to be recorded on page 71.**  Record the number of bottles collected for the Leak Testing Sample beginning of the batch in the space provided. | Target #:  4 | | Beginning of batch: |  |  |
| Record the number of bottles collected for the Leak Testing Sample middle of the batch in the space provided. | Target #:  4 | | Middle of batch: |  |  |
| Record the number of bottles collected for the Leak Testing Sample end of the batch in the space provided. | Target #:  4 | | End of batch: |  |  |
|  | Record the number of bottles collected for the Micro Sample beginning of the batch in the space provided. | Target #:  3 | | Beginning of batch: |  |  |
| Record the number of bottles collected for the Micro Sample middle of the batch in the space provided. | Target #:  3 | | Middle of batch: |  |  |
| Record the number of bottles collected for the Micro Sample end of the batch in the space provided. | Target #:  3 | | End of batch: |  |  |
|  | Record the number of bottles collected for the QC Sample beginning of the batch in the space provided. | | Target #:  4 | Beginning of batch: |  |  |
| Record the number of bottles collected for the QC Sample middle of the batch in the space provided. | | Target #:  4 | Middle of batch: |  |  |
| Record the number of bottles collected for the QC Sample end of the batch in the space provided. | | Target #:  4 | End of batch: |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step** | A. Secondary Packaging Line (cont.) | | **Done By / Date** | **Check By / Date** |
|  | At approximately 5 shippers remaining from the end of process, perform the following:  A. Perform QA Last Piece Inspection Part 1 on four (4) consecutive bottles pulled from the outfeed of the labeler. Record the results on page 48.  B. Perform QA Last Piece Inspection Part 2 on one (1) shipper. Record the results on page 49. | |  |  |
|  | Notify QA to initiate the Reserve Sample Form. | |  | **QA** |
|  | Print Last bottle label and shipper case label. (Last labels to be attached to pages 76 and 77). Include the last carton with the batch record. | |  |  |
|  | Press the End Batch Button. | |  |  |
|  |  |  |  |  |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| Step | A. Secondary Packaging Line (cont.) | **Done By / Date** | **Check By / Date** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Step | B. Material Reconciliation | | | **Done By / Date** | **Check By / Date** |
|  | Reconcile the bulk product as follows: | | |  |  |
| Type | **Location** | **Amount** |
| A. Number of cartoned bottles | Page 65, Step B | bottles |
| B. Number of sampled cartoned bottles | Steps 104 + 105 + 106 +107 + 108 | bottles |
| C. Net wt. of useable packaged bulk product | [(A + B) x Step 10C] ÷ 1000 | kg |
| D. Net wt. of bulk product waste | Steps 13 + 46 | kg |
| E. Net wt. of bulk product returned to inventory | Step 45 | kg |
| F. Net wt. of bulk product issued to batch | Step 6 | kg |
| G. Useable Yield | [C / (F - E)] x 100 | % |
| H. Accountable Yield | [(C + D + E) / F]  x 100 | % |
| The allowable Accountable Yield limits are 95-102%.If the results are outside of these limits, notify the Supervisor and QA immediately and initiate an Investigation per site procedure. | | |
| **Primary Technician or Above Review:**  I have reviewed this record and find it complete and accurate.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

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| Step | C. Carton Reconciliation | | | **Done By / Date** | **Check By / Date** |
|  | Reconcile the cartons as follows: | | |  |  |
| Type | **Location** | **Amount** |
| A. Number of cartoned bottles | Step 116A | bottles |
| B. Number of sampled cartoned bottles | Step 116B | bottles |
| C. Number of waste cartons | Step 114A | cartons |
| D. Number of cartons issued to batch | Page 62, Step A –  Page 62, Step B | cartons |
| E. Accountable Yield | [(A + B + C) ÷ D] x 100 | % |
| The allowable Accountable Yield limits are 99-101%. If the Accountable Yield limits results are outside of these limits, notify the Supervisor and QA immediately and initiate an Investigation per site procedure. | | |
| **Primary Technician or Above Review:**  I have reviewed this record and find it complete and accurate.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

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| Step | D. Insert Reconciliation | | | **Done By / Date** | **Check By / Date** |
|  | Reconcile the inserts as follows: | | |  |  |
| Type | **Location** | **Amount** |
| A. Number of cartoned bottles | Step 116A | bottles |
| B. Number of sampled cartoned bottles | Step 116B | bottles |
| C. Number of waste inserts | Step 115A | inserts |
| D. Number of inserts issued to batch | Page 54, Step A –  Page 54, Step B | inserts |
| E. Accountable Yield | [(A + B + C) ÷ D] x 100 | % |
| The allowable Accountable Yield limits are 99-101%. If the Accountable Yield limits results are outside of these limits, notify the Supervisor and QA immediately and initiate an Investigation per site procedure. | | |
| **Primary Technician or Above Review:**  I have reviewed this record and find it complete and accurate.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

**Part 1 checks are to be performed on four (4) consecutive bottles pulled form the outfeed of the labeler.**

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| **QA First Piece / Last Piece Inspection Part 1 (Secondary Packaging): Document 1st Piece and Last Piece Results in the appropriate column. N/A “1st Piece (2nd)” if initial 1st Piece is successful.**  **Key: A = Acceptable U = Unacceptable N/A = Not Applicable** | | | | |
| **1st Piece** | **1st Piece (2nd)** | **Last Piece** | **Requirements** | **Comments** |
|  |  |  | **Correct Bottle Label:** Verify with product description on the batch record and confirm artwork #1001166 |  |
|  |  |  | **Label Appearance:** Straight, no wrinkles. Label legible with not smearing. |  |
|  |  |  | **Correct Lot Number and Expiration Date (step 79)**  **Correct Lot Number:** The Lot number is as listed on the header of this batch record with the prefix LOT.  Example: “LOT 1234567”  **Correct Exp:** The expiration is as listed as indicated on  **step 60** of the batch record with the prefix EXP.  Example: “EXP YYYY/MM” |  |
|  |  |  | **Done By/Date** |  |

Note: All four (4) samples will be tested simultaneously and documented as one line item. Passing/acceptable bottles will be reintroduced into the packaging line downstream from the rotary labeler.

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| **QA First Piece / Last Piece Inspection Part 2 (Secondary Packaging): Document 1st Piece and Last Piece Results in the appropriate column. N/A “1st Piece (2nd)” if initial 1st Piece is successful.**  **Key: A = Acceptable U = Unacceptable N/A = Not Applicable** | | | | |
| **1st Piece** | **1st Piece (2nd)** | **Last Piece** | **Requirements** | **Comments** |
|  |  |  | **Correct number of cartons in case (6)** |  |
|  |  |  | **Correct carton and confirm artwork #1001167** |  |
|  |  |  | **Correct Case Label:** Contains accurate information and in proper location |  |
|  |  |  | **Correct insert in carton and confirm artwork #8021191** |  |
|  |  |  | **Correct bottle in carton** |  |
|  |  |  | **Correct TE label with text 104528XA** |  |
|  |  |  | **Carton filled and closed correctly** |  |
|  |  |  | **Correct Lot Number and Expiration Date (step 91)**  **Correct Lot Number: The Lot number is as listed on the header of this batch record with the prefix LOT.**  **Example: “LOT 1234567”**  **Correct Exp: The expiration is as listed on**  **step 60 of the batch record with the prefix EXP.**  **Example: “EXP YYYY/MM”** |  |
|  |  |  | **Done By/Date** |  |

**Part 2 checks are to be performed on one (1) shipper case.**

Note: Passing/acceptable bottles and application inserts will be reintroduced into the packaging line downstream from the rotary labeler.

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| **In-Process Verification Part 1 (Secondary Packaging)**  Key: A = Acceptable U = Unacceptable N/A = Not Applicable | | | | | |
|  | **Date** | **Time** | **Bottle Label (#1001166) (Circle one)** | **Done By** | **Check By** |
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**A = Acceptable U – Unacceptable**

**Note: Perform in-process testing approximately every 30 minutes.** **All Part 1 secondary samples are to be pulled from the** **outfeed of the labeler and each sample of bottles documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded.**

**Note: Acceptable bottle labels will meet the same requirement criteria as the first piece/last piece inspection, page 48. Passing/acceptable in-process bottles will be re-introduced into the packaging downstream from the rotary labeler.**

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| **In-Process Verification Part 1 (Secondary Packaging)**  Key: A = Acceptable U = Unacceptable N/A = Not Applicable | | | | | |
|  | **Date** | **Time** | **Bottle Label (#1001166) (Circle one)** | **Done By** | **Check By** |
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**A = Acceptable U – Unacceptable**

**Note: Perform in-process testing approximately every 30 minutes. All Part 1 secondary samples are to be pulled from the outfeed of the labeler and each sample of bottles documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded.**

**Note: Acceptable bottle labels will meet the same requirement criteria as the first piece/last piece inspection, page 48. Passing/acceptable in-process bottles will be re-introduced into the packaging downstream from the rotary labeler.**

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| **In-Process Verification Part 2 (Secondary Packaging)**  Key: A = Acceptable U = Unacceptable N/A = Not Applicable | | | | | | | |
|  | **Date** | **Time** | **Shipper Count (6)**  **(Circle one)** | **Shipper Label Check**  **(Circle one)** | **Correct Cartons**  **(Circle one)** | **Done By** | **Check By** |
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**A = Acceptable U – Unacceptable**

**Note: Perform in-process testing approximately every 30 minutes. All Part 2 secondary samples are to be pulled from the line downstream from the Carton Tracker and each sample of one shipper documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded.**

**Note: Acceptable shipper labels will contain accurate information (lot number, expiration date, product count, etc.) and be placed in the proper location. Acceptable cartons will meet the same requirement criteria as the first piece/last piece inspection, page 49 and have the correct lot number, correct expiration date, appropriate artwork number (1001167), correct TE label with text 104528XA, and be closed correctly.**

**Note: Passing/acceptable bottles and application inserts will be re-introduced into the packaging line downstream from the rotary labeler.**

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| **In-Process Verification Part 2 (Secondary Packaging)**  Key: A = Acceptable U = Unacceptable N/A = Not Applicable | | | | | | | |
|  | **Date** | **Time** | **Shipper Count (6)**  **(Circle one)** | **Shipper Label Check**  **(Circle one)** | **Correct Cartons**  **(Circle one)** | **Done By** | **Check By** |
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**A = Acceptable U – Unacceptable**

**Note: Perform in-process testing approximately every 30 minutes. All Part 2 secondary samples are to be pulled from the line downstream from the Carton Tracker and each sample of one shipper documented as one line item. Notify QA and a Supervisor if any out of range value or unacceptable condition is recorded.**

**Note: Acceptable shipper labels will contain accurate information (lot number, expiration date, product count, etc.) and be placed in the proper location. Acceptable cartons will meet the same requirement criteria as the first piece/last piece inspection, page 49 and have the correct lot number, correct expiration date, appropriate artwork number (1001167), correct TE label with text 104528XA, and be closed correctly.**

**Note: Passing/acceptable bottles and application inserts will be re-introduced into the packaging line downstream from the rotary labeler.**

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| Insert Usage Log | | | | | | | |
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| **Calculate the total quantity of inserts and record in the space provided.** | | | | A. |  |  | |
| **Document the number of inserts returned to inventory in the space provided.** | | | | B. |  |  | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- |
| Carton Usage Log | | | | | | |
|  | Item # | Lot # | Box # | Number of cartons in the box | Done By / Date | Check By / Date |
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| **Calculate the total quantity of cartons issued and record in the space provided on page 62A.** | | | | | | |

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| Carton Usage Log | | | | | | | |
|  | Item # | Lot # | Box # | Number of cartons in the box | Done By / Date | | Check By / Date |
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| **Calculate the total quantity of cartons and record in the space provided.** | | | | A. |  |  | |
| **Document the number of cartons returned to inventory in the space provided.** | | | | B. |  |  | |

**Pallet Tally Sheet**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Pallet Completion Date** | **License Plate Number** | **Shipper count** | **Cartoned Bottle Count** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of bottles and shippers and record in the space provided on page 65A.** | | | | | | |

**Pallet Tally Sheet**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Pallet Completion Date** | **License Plate Number** | **Shipper count** | **Cartoned Bottle Count** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of bottles and shippers and record in the space provided on page 65A.** | | | | | | |

**Pallet Tally Sheet**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Pallet Completion Date** | **License Plate Number** | **Shipper count** | **Cartoned Bottle Count** | **Done By / Date** | **Check By / Date** |
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| **Calculate the total quantity of shippers and cartoned bottles and record in the spaces provided.** | | | **A.** | **B.** |  |  |

#### OTW QUALITY ASSURANCE AQL FOR CARTONED BOTTLES

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Instructions:**   1. **AQL inspections are to be performed on finished product testing samples from the end of processing based on batch record.** 2. **Indicate the applicable section. N/A all the sections that are not applicable to the finished product.** 3. Perform the inspection of the sample and record the defects in the appropriate column below. 4. The defects are summarized below and the disposition, Pass/Fail, is made. 5. All Major defects for each component are to be marked on the data sheets then summed together per component and compared to the AQL Accept/Reject. 6. Note: If the combined major/minor defect total from AQL Summary exceeds the minor acceptance level, Production and QA management should be notified to evaluate the defects. 7. **For any foreign material found (regardless of defect level) an investigation should be initiated per site procedure.** | | | | | | | | | | | |
| **Batch Size** | | | | | **AQL Inspection**  **(Beg, Mid, End)** | | | | | | |
| **501-1200** | | | | | 80 (27, 26, 27) | | | | | | |
| **1201-3200** | | | | | 125 (42, 41, 42) | | | | | | |
| **3201-10000** | | | | | 200 (67, 66, 67) | | | | | | |
| **10001-35000** | | | | | 315 (105, 105, 105) | | | | | | |
| **35001-150000** | | | | | 500 (166, 167, 166) | | | | | | |
| **Accept/Reject Defect Levels** | | | | | | | | | | | |
| **Number of cartoned bottles sampled** | **80** | | **125** | | | **200** | | **315** | | **500** | |
| **Category** | **Accept** | **Reject** | **Accept** | **Reject** | | **Accept** | **Reject** | **Accept** | **Reject** | **Accept** | **Reject** |
| **Critical I-Safety Defects** | **0** | **1** | **0** | **1** | | **0** | **1** | **0** | **1** | **0** | **1** |
| **Critical II-Procedural Defects** | **0** | **1** | **0** | **1** | | **0** | **1** | **0** | **1** | **0** | **1** |
| **Major I** | **1** | **2** | **2** | **3** | | **3** | **4** | **5** | **6** | **7** | **8** |
| **Major II** | **5** | **6** | **7** | **8** | | **10** | **11** | **14** | **15** | **21** | **22** |
| **Minor** | **7** | **8** | **10** | **11** | | **14** | **15** | **21** | **22** | **21** | **22** |
| Overfill (Fill is More Than Specification  (120-122) | **5** | **6** | **7** | **8** | | **10** | **11** | **14** | **15** | **21** | **22** |
| Underfill (˂ 90% of label claim, 0-107 capsules) | **0** | **1** | **0** | **1** | | **1** | **2** | **1** | **2** | **3** | **4** |
| Underfill (≥ 90% of label claim, 108-119 capsules) | **2** | **3** | **3** | **4** | | **5** | **6** | **7** | **8** | **10** | **11** |
| **The Accept/Reject criteria is applicable to the number of bottles the defects are found in.** | | | | | | | | | | | |

**OTW QUALITY ASSURANCE AQL FOR CARTONED BOTTLES**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sample Interval** | **Beginning** | | **Middle** | | **End** |
| Sample Size **(amount from table on page 66)** | **\_\_\_\_** | | **\_\_\_\_** | | **\_\_\_\_** |
| **Critical I Safety Defects AQL (Accept: 0 Reject: 1)**  ***May be injurious to the customer or consumer.*** |  | |  | |  |
| **Bottle, Label and Carton** |  | |  | |  |
| Foreign capsule |  | |  | |  |
| Foreign material in bottle |  | |  | |  |
| Foreign material in or on bottle, label or carton (includes metal, glass, insect parts) |  | |  | |  |
| Foreign material inside or outside cap (includes metal, glass, insect parts) |  | |  | |  |
| Bottle or closure has dangerous flash or sharp edges |  | |  | |  |
| Missing or damaged tamper evident feature (two are required) |  | |  | |  |
| Partial/No Induction Seal |  | |  | |  |
| Safety closure not functioning properly |  | |  | |  |
| **Summary Total (Beginning + Middle + End)** |  | | | | |
| **Critical II Procedural Defects AQL= 0.065**  ***Would constitute a procedural violation of the law.* (Accept: 0 Reject: 1)** |  | |  | |  |
| **Bottle, Label and Carton** |  | |  | |  |
| Missing desiccants (two are required) |  | |  | |  |
| Incorrect bottle, closure or carton (size, shape or color) |  | |  | |  |
| Missing closure, loose/low torque closures |  | |  | |  |
| Incorrect or missing label |  | |  | |  |
| Incorrect components used in packaging |  | |  | |  |
| Missing bottle in carton (empty carton) |  | |  | |  |
| Defective material (bottle, closure, etc.) |  | |  | |  |
| Illegible regulated text on bottle label or carton label |  | |  | |  |
| Multiple labels applied to one bottle causing regulated text illegibility |  | |  | |  |
| Finished product lot code and/or expiry date missing, illegible, or incorrect for bottle or carton. |  | |  | |  |
| Label is falling off or easily removed intact, without residue left on bottle. |  | |  | |  |
| **Insert** |  | |  | |  |
| Incorrect or missing insert |  | |  | |  |
| Foreign insert |  | |  | |  |
| **Summary Total (Beginning + Middle + End)** |  | | | | |
| **Count (Underfills to be counted with Major I defects, overfills with Major II)** |  |  | |  | |
| Overfill (Fill is More Than Specification (120-122) **AQL=2.5 (Accept: \_\_\_ Reject:\_\_\_)** |  |  | |  | |
| Underfill (˂ 90% of label claim, 0-107 capsules) **AQL=0.15 (Accept: \_\_\_ Reject: \_\_\_)** |  |  | |  | |
| Underfill (≥ 90% of label claim, 108-119 capsules) **AQL=1.0 (Accept: \_\_\_Reject:\_\_\_)** |  |  | |  | |
| **Summary Total (Beginning + Middle + End)** |  | | | | |
| **Major I\* Defects AQL=0.65 (Accept: \_\_\_ Reject: \_\_\_)**  ***Will prevent use or performance of the product in its intended manner or would be repulsive to the customer or consumer.*** |  | |  | |  |
| **Bottle, Label and Carton** |  | |  | |  |
| Damaged bottle (Bottle cracked, crushed or punctured) |  | |  | |  |
| Unseated closure. Cocked or not fully threaded on bottle. |  | |  | |  |
| Label not properly oriented. |  | |  | |  |
| Burnt induction seal |  | |  | |  |
| **Summary Total (Beginning + Middle + End)** |  | | | | |
| **Note: For any foreign material found (regardless of defect level) an investigation should be initiated per site procedure.** | | | | | |

#### AQL for Packed Bottles continued on the next page.

**OTW QUALITY ASSURANCE AQL FOR CARTONED BOTTLES (cont.)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sample Interval** | Beginning | Middle | End |
| **Sample Size (amount from table on page 66)** | \_\_\_\_ | \_\_\_\_ | \_\_\_\_ |
| **Major II Defects AQL= 2.5 (Accept: \_\_\_ Reject: \_\_\_)**  ***May or may not be objectionable to the customer or consumer but will not prevent the use and will likely not prevent repurchase.*** |  |  |  |
| **Bottle, Label and Carton** |  |  |  |
| Defective material (bottle has rocker bottom, closure, etc.) |  |  |  |
| Damaged capsules (affecting functionality) |  |  |  |
| Smeared but legible print on label |  |  |  |
| Closure or bottle damaged (dents and scratches) |  |  |  |
| Illegible non-regulated text on label (overall visual check, not word by word) |  |  |  |
| Carton is scuffed, dented, torn, etc. |  |  |  |
| Carton flaps are not closed correctly |  |  |  |
| **Summary Total (Beginning + Middle + End)** |  | | |
| **Insert** |  |  |  |
| Damaged insert |  |  |  |
| Misaligned insert |  |  |  |
| Double insert |  |  |  |
| **Summary Total (Beginning + Middle + End)** |  | | |
| **Minor Defects AQL = 4.0 (Accept: \_\_\_ Reject: \_\_\_)**  ***Will not reduce the usability of the product nor significantly affect the product appearance. A slight deviation from the design intent.*** |  |  |  |
| **Bottle, Label and Carton** |  |  |  |
| Cosmetic defect on closure (scuffs, scratches, minor dents on cap surface visible at arm’s length.) |  |  |  |
| Foreign material on outside of closure (dirt, grease, glue etc. that are inherent to packaging process) |  |  |  |
| Cosmetic defect on bottle (scuffs, bubbles, minor dents on bottle surface visible at arm’s length.) |  |  |  |
| Broken/cracked parts |  |  |  |
| Closure under- or over-torqued |  |  |  |
| Severely dented, damaged or crushed capsules (dents damage that extend greater than 40% of the circumference of the capsule) |  |  |  |
| Burnt induction seal |  |  |  |
| Closure (lid) scratched on exterior |  |  |  |
| Foreign material on inside or outside of label (dirt, grease, glue etc. that are inherent to packaging process) |  |  |  |
| Label appears to visually overlap bottle shoulder |  |  |  |
| Double label, folded label, skewed label or bubbled label |  |  |  |
| Blurred but legible essential text |  |  |  |
| Finished product lot code and/or expiry date/best by on carton is legible but faint, crooked or smeared |  |  |  |
| Carton flaps open with little or no fiber tear |  |  |  |
| **Summary Total (Beginning + Middle + End** |  | | |
| AQL Summary (Pass/Fail\*) |  |  |  |
| Done By/Date |  |  |  |
| **Note: For any foreign material found (regardless of defect level) an investigation should be initiated per site procedure.**  **If the combined major/minor defect total from AQL Summary exceeds the minor acceptance level, Production and QA management should be notified to evaluate the defects.** | | | |

**Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Shipper/Shipper Label AQL**

Instructions:

1. **Perform the inspection of the sample and record the defects in the appropriate column below in the Packaging suite.**
2. The defects are summarized below and the disposition, Pass/Fail, is made.
3. **Shipper AQL samples are to be resealed and replaced on pallet once AQL is complete.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Shipper (6 bottles )** | | **AQL Inspection** | | |
| **Total Number of Shippers** | **Sample Size** | **Beginning** | **Middle** | **End** |
| **Less than** 90 Shippers | **13** | **4** | **5** | **4** |
| 91-150 Shippers | **20** | **7** | **6** | **7** |
| 151-280 Shippers | **32** | **11** | **10** | **11** |
| 281-500 Shippers | **50** | **17** | **16** | **17** |
| 501-1200 Shippers | **80** | **27** | **26** | **27** |
| 1201-3200 Shippers | **125** | **42** | **41** | **42** |
| 3201-10000 Shippers | **200** | **66** | **67** | **66** |
| 10001-35000 Shippers | **315** | **105** | **105** | **105** |

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| **Number of Shipper Sampled** | | | | | | | | | | | | | | | | |
|  | **13 Shippers** | | **20 Shippers** | | **32 Shippers** | | **50 Shippers** | | **80** **Shippers** | | **125** **Shippers** | | **200 Shippers** | | **315 Shippers** | |
| **Category** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** | **Acc.** | **Rej.** |
| **Critical I-Safety Defects** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** |
| **Critical II-Procedural Defects** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** |
| **Major I** | **0** | **1** | **0** | **1** | **0** | **1** | **0** | **1** | **1** | **2** | **2** | **3** | **3** | **4** | **5** | **6** |
| **Major II** | **0** | **1** | **1** | **2** | **2** | **3** | **3** | **4** | **5** | **6** | **7** | **8** | **10** | **11** | **14** | **15** |
| **Minor** | **1** | **2** | **2** | **3** | **3** | **4** | **5** | **6** | **7** | **8** | **10** | **11** | **14** | **15** | **21** | **22** |
| **The Accept/Reject criteria is applicable to the number of bottles the defects are found in.** | | | | | | | | | | | | | | | | |

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| --- | --- | --- | --- |
| **Number Sampled :** |  |  |  |
| **Critical I Safety Defects AQL Accept: 0 Reject: 1**  ***May be injurious to the customer.*** |  |  |  |
| Foreign Material inside or outside Shipper (includes metal, glass, insect parts) |  |  |  |
| **Summary Total (Beginning + Middle + End)** |  | | |
| Critical II Procedural Defects AQL= 0.065 Accept: 0 Reject: 1 *Would constitute a procedural violation of the law.* |  |  |  |
| Wrong Shipper |  |  |  |
| Finished Product Lot Code, Product Description, Expiration Date, Count, UPC barcode and human readables are incorrect, missing, or illegible on any shipper/shipper label. |  |  |  |
| Summary Total (Beginning + Middle + End) |  | | |
| **Major I Defects AQL= 0.65 Accept: \_\_\_ Reject: \_\_\_** *May or may not be objectionable to the customer or consumer but will not prevent the use and will likely not prevent repurchase.* |  |  |  |
| Torn or punctured shipper |  |  |  |
| Shipper Flaps are open (not taped closed) |  |  |  |
| Incorrect carton count in shipper (short fill), if applicable |  |  |  |
| Bottle or carton inside of shipper is upside down |  |  |  |
| Incorrect bundle format (bundle material is not present, incorrect number of cartons in the bundled unit, bundle is not functional or intact). |  |  |  |
| Incorrect bottle count in bulk shipper, if applicable. |  |  |  |
| Summary Total (Beginning + Middle + End) |  | | |

#### AQL for shippers continued on the next page.

**Shipper/Shipper Label AQL (cont.)**

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| --- | --- | --- | --- |
| **Minor Defects AQL= 4.0 Accept: \_\_\_ Reject: \_\_\_**  ***May or may not be objectionable to the customer or consumer but will not prevent the use and will likely not prevent repurchase.*** |  |  |  |
| Finished Product Lot Code, Product Description, Expiration Date, Count, UPC barcode and human readable are legible but faint, crooked or smeared on any shipper/shipper label |  |  |  |
| Shipper or shipper label has Foreign Material on Inside or Outside that is not potentially injurious to customer (dirt, grease, glue etc. that are inherent to packaging process) |  |  |  |
| **Summary Total (Beginning + Middle + End)** |  | | |
| **AQL Summary (Pass/Fail\*)** |  | | |
| **Done By/Date** |  |  |  |
| **Note: If the combined major/minor defect total from AQL Summary exceeds the minor acceptance level, Production and QA management should be notified to evaluate the defects.** | | | |

**Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| Step | Leak Test Results Data Sheet | **Done By / Date** | **Check By / Date** |
|  | **Beginning Samples**  Vacuum Gauge EN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Laboratory Notebook Reference:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Method: Catalent Method 220011 |  |  |
|  | Specification: No blue color or wetness observed in any bottle.  Results:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | **Middle Samples**  Vacuum Gauge EN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Laboratory Notebook Reference:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Method: Catalent Method 220011 |  |  |
|  | Specification: No blue color or wetness observed in any bottle.  Results:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | **End Samples**  Vacuum Gauge EN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Laboratory Notebook Reference:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Method: Catalent Method 220011 |  |  |
|  | Specification: No blue color or wetness observed in any bottle.  Results:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

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| --- | --- | --- | --- | --- | --- |
| **Down Time/Adjustment Verification Sheet**  **Note: This sheet is to record any down time/adjustments made during the processing of the batch. Record all down time using this sheet. Check either the non-mechanical or mechanical section.**  **A non-mechanical down time does not require a description, please N/A space.**  **Mechanical stops are interruptions due to issues with any equipment or any facility issues.**  **Non-Mechanical stops are interruptions due to other issues (i.e. breaks, scheduling, order product, etc.).** | | | | | |
| **Start Downtime** | **Stop Downtime** | **Non-**  **Mechanical** | **Mechanical** | **Brief Description of Adjustment or Repair** | **Done By /**  **Date** |
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**Bottle Label Reconciliation & Information Verification Log**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Calculation / Location | Results | Done By / Date | Checked By / Date |
| 1. Number of Labels Issued | Line A from “Label Counting  Sheet (page 74)” |  |  |  |
| 1. Number of Labels on Acceptable Bottles | Step 116A |  |  |  |
| 1. Number of Labeled Bottles Rejected | Manual Count |  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| 1. Label waste from roll setup | Unused label page |  |  |  |
| 1. Number of Samples Pulled | Step 116B |  |  |  |
| 1. Number of Labels affixed to the Printed Label Sheet | Page 77 |  |  |  |
| 1. Number of Unused Labels | Remaining Label Rolls in Portable Label Lock Box |  |  |  |
| 1. Accountable Yield (Target: 99-101%) | (B+C+D+E+F) / (A-G) x 100 |  |  |  |
| The allowable Accountable Yield limits are 99-101%. If the Accountable Yield limits results are outside of these limits, notify the Supervisor and QA immediately and initiate an Investigation per site procedure. | | | | |
| **Primary Technician or Above Review:**  I have reviewed this record and find it complete and accurate.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |

**BOTTLE LABEL COUNTING SHEET**

**Instructions: For each roll of labels to be issued to production, record the lot indicated on the core of the label roll in the table below. Warehouse personnel are to place each roll on the automated label counter while Production personnel observe. Perform Standardization by setting the counter to unwind 20 labels and manually count the number of labels to verify the number of labels actually unwound matches the set value and document the results. Document the number of labels on each roll in the table below using the label counter readout. Warehouse personnel must sign for the Done By and Production personnel sign as the Check By. N/A any unused lines.**

**Standardization Results:** Expected Result: 20 Actual Result: \_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ Check By / Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Label Counter EN:** \_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | |  |  |  |
| Label Lot Number | Number of Labels on Roll | Comments | Done By / Date  (Warehouse) | Check By / Date (Production) |
|  |  |  |  |  |
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|  |  |  |  |  |
| A. Total Number of Labels Issued to Production |  |  |  |  |

**Printed Label Sheet**

**Instructions: Attach the first label printed for the batch in the space below. Verify that the printed data is accurate and sign the associated steps (step 65) in the batch record.**

|  |  |
| --- | --- |
| **Shipper Label 1st** | |
| **Done By/Date:** | **QA Check By:** |

**Printed Label Sheet**

**Instructions: Attach the last label printed for the batch in the space below. Verify that the printed data is accurate and sign the associated steps (step 112) in the batch record.**

|  |  |
| --- | --- |
| **Shipper Label Last** | |
|  | |
| **Done By/Date:** | **QA Check By:** |

**Printed Label Sheet**

**Instructions: Attach the first and last labels printed for the batch in the space below. Verify that the printed data is accurate and sign the associated steps 79 and 112 in the batch record.**

|  |  |
| --- | --- |
| **First Bottle Labels** | |
|  | **Done By/Date:** |
| **QA Check By:** |
| **Last Bottle Labels** | |
|  | **Done By/Date:** |
| **QA Check By:** |

**LABEL RECONCILIATION SHEET**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **NO.** | **Done By/ Date** | **Check By/ Date** | **Final Check By/Date\*\*** |
| A | Number of labels issued/verified (Count and text accuracy): |  | **\*** | **\*** |  |
| B | Number of labels used (applied to correct lot): |  |  |  |  |
| C | Number of labels attached to Label Reconciliation Sheet of batch record: | **1** | **\*** | **\*** |  |
| D | Number of unused labels attached to the Unused Label Page: (if none, enter 0, initial/date) |  |  |  |  |
| E | Total Usage: (Sum B + C + D) Does E=A? If not, initiate an Investigation per site procedure. |  |  |

\*Must be performed by Manufacturing Services Reviewer **or** QA Reviewer **upon creation and before floor issuance**.

\*\*Must be performed by a Primary Technician or above prior to record entering Production Suite.

**Attach Sample of Label:**

Diagram

Description automatically generated with medium confidence

LABEL RECONCILIATION SHEET

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **NO.** | **Done By/ Date** | **Check By/ Date** | **Final Check By/Date\*\*** |
| A | Number of labels issued/verified (Count and text accuracy): |  | **\*** | **\*** |  |
| B | Number of labels used (applied to correct lot): |  |  |  |  |
| C | Number of labels attached to Label Reconciliation Sheet of batch record: | **1** | **\*** | **\*** |  |
| D | Number of unused labels attached to the Unused Label Page: (if none, enter 0, initial/date) |  |  |  |  |
| E | Total Usage: (Sum B + C + D) Does E=A? If not, initiate an Investigation per site procedure. |  |  |

\*Must be performed by Manufacturing Services Reviewer **or** QA Reviewer **upon creation and before floor issuance**.

\*\*Must be performed by a Primary Technician or above prior to record entering Production Suite.

**Attach Sample of Label:**

Table

Description automatically generated

**Primary General Equipment Use and Cleaning Log**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date: | | | | | Process Start Time: | | | | | Process Number: **GS151** | | | | | |
| Equip.  No. | Equipment | Room  No. | Cleaning/Sanitization  (Equipment Status Label) | | | Cleaning Checked By  QA | Equipment  # Verified By | Equip.  No. | Equipment | | Room  No. | Cleaning/Sanitization  (Equipment Status Label) | | Cleaning Checked By  QA | Equipment  # Verified By |
| Time | Initials/Date | | Initials/Date | Initials | Time | Initials/Date | Initials/Date | Initials |
|  | Bottle Unscrambler |  |  |  | |  |  |  | Surekap  Re-torquer | |  |  |  |  |  |
|  | Line Control Conveyor |  |  |  | |  |  |  | Induction Sealer | |  |  |  |  |  |
|  | IMA Uniline |  |  |  | |  |  |  | Wipotec Weight Checker | |  |  |  |  |  |
|  | IMADA Torque Tester |  |  |  | |  |  |  | Removal Torque | |  |  |  |  |  |
|  | Swiftcheck Tablet Capsule Counter |  |  |  | |  |  |  |  | |  |  |  |  |  |

Fill in # of items complete: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**9 items are required. If any item is not used, mark equipment usage space N/A and provide footnoted explanation to explain why the equipment was not required.**

**If additional equipment is required, record them on the next page under the Miscellaneous Equipment section.**

**Primary General Equipment Use and Cleaning Log (cont.)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Miscellaneous Equipment | | | | | | | | | | | | | |
| Equip.  No. \* | Equipment \* | Room  No. \* | Cleaning/Sanitization  (Equipment Status Label) \* | | Cleaning Checked By QA\* | Equipment  # Verified By \* | Equip.  No.\* | Equipment\* | Room  No. \* | Cleaning/Sanitization  (Equipment Status Label) \* | | Cleaning Checked By  QA\* | Equipment  # Verified By \* |
| Time | Initials/Date | Initials/Date | Initials | Time | Initials/Date | Initials/Date | Initials |
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\* N/A equipment usage spaces if equipment is not used.

Fill in # of items complete: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Secondary General Equipment Use and Cleaning Log**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date: | | | | | Process Start Time: | | | | | Process Number: **GS151** | | | | | |
| Equip.  No. | Equipment | Room  No. | Cleaning/Sanitization  (Equipment Status Label) | | | Cleaning Checked By  QA | Equipment  # Verified By | Equip.  No. | Equipment | | Room  No. | Cleaning/Sanitization  (Equipment Status Label) | | Cleaning Checked By  QA | Equipment  # Verified By |
| Time | Initials/Date | | Initials/Date | Initials | Time | Initials/Date | Initials/Date | Initials |
|  | LineMaster |  |  |  | |  |  |  | Case Erecter | |  |  |  |  |  |
|  | Shrink Wrap Bundler |  |  |  | |  |  |  | Rotary Labeler | |  |  |  |  |  |
|  | PharmaProof #1 |  |  |  | |  |  |  | PharmaProof #3 | |  |  |  |  |  |
|  | PharmaProof #2 |  |  |  | |  |  |  | Cartoner | |  |  |  |  |  |

Fill in # of items complete: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**8 items are required. If any item is not used, mark equipment usage space N/A and provide footnoted explanation to explain why the equipment was not required.**

**If additional equipment is required, record them on the next page under the Miscellaneous Equipment section.**

**Secondary General Equipment Use and Cleaning Log (cont.)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Miscellaneous Equipment | | | | | | | | | | | | | |
| Equip.  No. \* | Equipment \* | Room  No. \* | Cleaning/Sanitization  (Equipment Status Label) \* | | Cleaning Checked By QA\* | Equipment  # Verified By \* | Equip.  No.\* | Equipment\* | Room  No. \* | Cleaning/Sanitization  (Equipment Status Label) \* | | Cleaning Checked By  QA\* | Equipment  # Verified By \* |
| Time | Initials/Date | Initials/Date | Initials | Time | Initials/Date | Initials/Date | Initials |
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\* N/A equipment usage spaces if equipment is not used.

Fill in # of items complete: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Repaired Equipment/Maintenance Record | | | | | | | |
| Equipment Number | Equipment Description | Maintenance Performed By | | | Checked By QA | | Comments |
| Time | Initials | Date | Initials / Date | Clean  Required?  Yes or No |
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**Ingredient Weight Record**

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| --- | --- |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |

**Ingredient Weight Record**

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| --- | --- |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |

**Ingredient Weight Record**

|  |  |
| --- | --- |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |
| **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Step #: \_\_\_\_\_\_ Material: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Scale #: \_\_\_\_\_\_ Lot/Container ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Done By / Date:** | **Done By / Date:** |
| **Check By / Date:** | **Check By / Date:** |

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.

**UNUSED LABEL PAGE**

Number of labels attached: \_\_\_\_\_\_\_\_\_\_ Done By / Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Labels should be applied so that the type can be identified, and the count can be verified.