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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.** |  | A. Fill Count |  |  |
|  | 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 |  |  |  |
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**Part I: Setup (Primary)**

**A. Primary Materials**

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| --- | --- | --- |
| **Item No.** | Product | Theoretical Amount required |
|  |  |  |

**B. Primary Packaging Materials**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item No.** | | **Material** | **Theoretical Amount required** |
| Circle Item #(s) |  |  |  |
| Circle Item #(s) |  |  |  |
| Circle Item #(s) |  |  |  |

C. Primary Equipment List

|  |  |  |
| --- | --- | --- |
| **Qty.** | **Equipment** | **Type** |
|  |  |  |

**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**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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  Fail |  |  |
|  |  | Batch #: |  |  |
| Qty. allocated to batch:  \_\_\_ \_\_\_ \_\_\_ . \_\_\_ \_\_\_kg |

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| --- | --- | --- | --- | --- |
| Step | A. Primary Packaging Line (cont.) | | Done  By/  Date | Check  By/  Date |
| 7 |  | Scale #: |  |  |
|  |
| 8 |  | Scale #: |  |  |
|  |
| 9 |  | Scale #: |  |  |
|  |
| 10 |  | |  |  |

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| --- | --- | --- | --- | --- |
| Step | A. Primary Packaging Line (cont.) | | Done  By/  Date | Check  By/  Date |
| 11 | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 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 | | |  |  |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 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. | |  |  |
| 12 | 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 #: |  |  |
|  |