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| **1. Product Details** |  |
| Description | Tongkat Ali 250mg Tablet  Colour: Pale  Shape: Round/ Biconvex |
| Batch Quantity | Batch size: 53 kg  Approx No. tablets: \_\_\_\_\_\_\_\_\_\_\_ |
| Packaging | Bottle of 60’s |
| Storage Conditions | Ambient - conditions, store in tight container protected from light and moisture |

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| Prepared by :  Approved by : | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Production Manager**    **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **QA Manager** |  |  |  |  | **0**    Effective Date :  **1 January 2016** |

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| **2. Production Batch Record Issuance** | | |
| **Issued By –** Issuer has reviewed the Batch Record to ensure that the copy is a complete, accurate copy of the Master Batch Record. | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Print) Issued By – Quality Assurance Signature Date | | |
| **Issued To –** Production has reviewed the Batch Record to ensure that the copy is a complete and correct. Production is responsible for the Batch Record following issuance. | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Print) Issued By – Quality Assurance | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| **3. Reference Documents** | | |
| **SOP – 002:** Non conformances | | |
| **SOP – 007:** Line Clearance | | |
| **SOP – 010:** Temperature and Humidity Monitoring | | |
| **SOP – 012:** Facility Cleaning Procedures | | |
| **SOP – 015:** Material Weighing and Dispensing | | |
| **SOP – 017:** Batch Manufacturing Records | | |
| **SOP – 019:** Tray Oven | | |
| **SOP – 021:** Grinding and Milling Machine | | |
| **SOP – 022:** Cadmill | | |
| **SOP – 023:** Cube Mixer | | |
| Batch No:  **TT 1606001** | Manufacturing Date : **10 July 2016** | Expiry Date : **9 July 2017** |

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| **SOP – 028:** Ribbon Mixer |
| **SOP – 032:** B2 Strokes Tablet Press |

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| **4. Raw Materials** |  |  |  |  |  |  |  |
| Description | Part  Number | Quantity  Required  (kg) | Lot No. | Qty Staged | Exp/ Retest | Performed By / Date | Verified By / Date |
| Eurycoma  Longifolia | R-0122 | 25.00 |  |  |  |  |  |
| Lactose  Monohydrate | R-2323 | 19.34 |  |  |  |  |  |
| Gelatin | R-7896 | 4.80 |  |  |  |  |  |
| Corn Starch | R-5858 | 2.40 |  |  |  |  |  |
| Methocel | R-0326 | 1.00 |  |  |  |  |  |
| Magnesium  Stearate BP/USP | R-9696 | 0.46 |  |  |  |  |  |

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| **5. Processing Equipments** | |  |  |  |  |
| Equipment Description | ID No. | Previous Calibration | Calibration Required | Performed By / Date | Verified By / Date |
| Weighing Balance 150 kg | WB-01 |  |  |  |  |
| Tray Oven | OT-01 |  |  |  |  |
| Grinding and Milling Machine | GM-01 |  |  |  |  |
| Cube Mixer | MX-03 |  |  |  |  |
| Ribbon Mixer | MX-02 |  |  |  |  |
| Cadmill | GM-02 |  |  |  |  |
| B2 Strokes Tablet Press | TP-01 |  |  |  |  |
| Stainless Steel Container | CS-03 |  |  |  |  |
| Mechanical Sieve (Mesh No: 12) | SM-01 |  |  |  |  |

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| **6. Area Clearance** |  |  |
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| Batch No:  **TT 1606001** | Manufacturing Date : **10 July 2016** | Expiry Date : **9 July 2017** |

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| Prepared by :  Approved by : | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Production Manager**    **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **QA Manager** |  |  |  |  | **0**    Effective Date :  **1 January 2016** |

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| Step |  | Performed By / Date | Verified By / Date |
| 1. | GMP Processing Area(s):    Room: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 2. | Review the GMP Processing Area Logbook(s) and ensure that the Logbook(s) is (are) complete, and up-to-date. |  |  |
| 3. | Review all applicable GMP Processing Area Logbook(s) and verify that  Cleaning has been performed according to *Facility Cleaning Procedures* (SOP-011)  Date Cleaning Complete: \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 4. | Review Section 4: Raw Materials, and ensure that it is complete, accurate, and that all necessary materials are present for the GMP operation. |  |  |
| 5. | Ensure that all GMP Materials are Released, Approved and have sufficient time to the Expiry Date. |  |  |
| 6. | Review Section 5: Processing Equipment, and ensure that it is complete, accurate, and that all necessary equipment is present, cleaned and calibrated, as appropriate. |  |  |
| 7. Review the Logbook for each piece of Equipment, and ensure that the Logbooks are correctly filled out.  Tray Oven (OT-01) : \_\_\_\_\_\_\_\_\_\_\_  Grinding and Milling Machine (GM-01) : \_\_\_\_\_\_\_\_\_\_\_  Cube Mixer (MX-03) : \_\_\_\_\_\_\_\_\_\_\_  Ribbon Mixer (MX-02) : \_\_\_\_\_\_\_\_\_\_\_ B2 Strokes Tablet Press (TP-01) : \_\_\_\_\_\_\_\_\_\_\_ | |  |  |
| 8. Verify that the Production Area does not contain any items from previous batches or cleaning activities and that no items unrelated to the current batch are present. | |  |  |
| 9. Area Clearance Complete.    QA shall Complete the Area Clearance Sign (SOP-007, Attachment 1) and affix it to the GMP Processing Area entrance. | |  |  |

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| **7. Production Procedure** | | | |  |  |
| **Processing Step** | | | | Performed By / Date | Verified By / Date |
| **A.** | **Dispensing & Raw Material Preparation** Location: Dispensing Room 1 | | |  |  |
| 1. | Ensure room Temperature is within 22-24°C and Humidity is less than 65% | | |  |  |
| 2. | Weigh the ALL Raw Materials (RM) as mentioned in Part 4 separately into a suitable container/ plastic bags in.  Label each of the container/ bags with a) Name of RM  b) Lot No. | | |  |  |
| 3. | Wash Eurycoma longifolia (Tongkat Ali) with RO water and dry in Tray Oven (ID: OT-01) at 60°C for 8 hours.    Temperature: \_\_\_\_\_\_\_\_ °C Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ | | |  |  |
| 4. | Crush/powder the dry Eurycoma longifolia (Tongkat Ali) into fine powder with Grinding and Milling Machine (ID: GM-01). | | |  |  |
| **B. Mixing**  Location: Mixing Room 2     1. Ensure room Temperature is within 22-24°C and Humidity is less than 65%     Temperature: \_\_\_\_\_\_\_\_\_ Humidity: \_\_\_\_\_\_\_\_     1. Mix Eurycoma longifolia powder, Lactose and Corn Starch in Cube Mixer (ID: MX-03) for 5 mins.     Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ | | | |  |  |
| 1. Transfer all the contents of Cube Mixer (ID: MX-03) into a suitable container/ plastic bags.      1. Label the plastic bag with   a) “Tongkat Ali A Blend” | | | |  |  |
| Batch No:  **TT 1606001** | | Manufacturing Date : **10 July 2016** | Expiry Date : **9 July 2017** | | |

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| b) Batch No. |  |  |
| 1. “Transfer Tongkat Ali A Blend” into Ribbon Mixer (ID: MX-02).      1. Blend for 3 mins at speed no: 3.     Speed No: \_\_\_\_\_\_\_\_ Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ |  |  |
| 11. Dissolve Gelatin with hot water in a Stainless Steel Container (ID: CS03). |  |  |
| 12. Pour the “Dissolved Gelatin” into the powder, granulate for 5 mins at speed no: 3..    Speed No: \_\_\_\_\_\_\_\_ Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ |  |  |
| 13. Transfer all the contents of Ribbon Mixer (ID: MX-02) into Cadmill (ID: GM-02). Operate the machine according the SOP-022. |  |  |
| 14. Dry the granules at 60°C for 6 hours in Tray Oven (ID: OT-01).    Temperature: \_\_\_\_\_\_ °C Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ |  |  |
| 15. Sieve into fine powder with Mechanical Siever (Mesh No: 12) |  |  |
| 16. Transfer the fine powder into Cube Mixer (ID: MX-03), add in Magnesium Stearate and mix for 10 minutes at speed no: 3.    Speed No: \_\_\_\_\_\_\_\_ Time Start: \_\_\_\_\_\_\_\_ Time Stop: \_\_\_\_\_\_\_\_ |  |  |
| 1. Transfer the contents of the Cube Mixer into a suitable plastic bag.      1. Label the plastic bag    1. “Blend for Tableting: Tongkat Ali”    2. Batch No |  |  |
| **C. Tableting**    19. Ensure room Temperature is within 22-24°C and Humidity is less than 65%    Temperature: \_\_\_\_\_\_\_\_\_ Humidity: \_\_\_\_\_\_\_\_ |  |  |

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| Monitor both Temperature and Humidity every 30 mins until end of Tableting Process     |  |  |  | | --- | --- | --- | | **Time** | **Temperature (°C)** | **Humidity (%)** | |  |  |  | |  |  |  | |  |  |  |      1. Set-up the tablet press with the hopper and feed frame as described in SOP-032. Use Punches and Dies ID: 123456     Punches and Dies ID: \_\_\_\_\_\_\_\_\_\_     1. Ensure that the gap between the feed frame and the die table is paper thick |  |  |
| 1. Carefully pour the material (Blend for Tableting: Tongkat Ali) into the feed frame of the tablet press.      1. Manually operate/rotate the tablet press to ensure that the feed frame is evenly filled with the granules and flow well onto the die table and die cavity. |  |  |
| 1. Continue the rotation to produce a couple of tablets - ensure that all the parts of the press are working (SOP-032).   Target weight: 250 mg; Target weight range: 240 – 460mg     1. Set machine at speed no: 2. |  |  |
| 26. Turn on the tablet press (as described in SOP-032) and allow the machine to stabilize i.e. discard first 5 tablets and check the weight of the next 2 tablets.  Target weight: 250 mg; Target weight range: 240 – 460mg |  |  |
| 1. Collect tablets until the end of production. Transfer these tablets into containers and label “Tongkat Ali Tablet”      1. At the end of the run perform cleaning according the SOP-012. |  |  |
| **D. Film Coating** |  |  |

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| …Cont… |  |  |
| **E. Packing & Labelling** |  |  |
| …Cont… |  |  |
| **8. Sampling, Material Transfer & Storage** | | |

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| Prepared by :  Approved by : | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Production Manager**    **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **QA Manager** |  |  |  |  | **0**    Effective Date :  **1 January 2016** |

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| **9. Yield Calculation** |
| **Yield**  **= 100 % x Weight of Tablets**  **Weight of Raw Materials**  = \_\_\_\_\_\_\_ (Specification: 95 - 100 %)    **Finished Product Yield**  **= 100% x No. of Goods produced at the end of process + Rejects + Samples + Returned**  **No. of Goods received at the start of process**  **= \_\_\_\_\_\_\_\_\_\_** (Specification: 90 - 100 %) |

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| **10. Post-Production Review** | | | |
| The complete Post-Production Batch Record has been reviewed for completeness and accuracy. All pages are complete and all entries conform to Good Documentation Practices. | | | |
|  | Name | Signature | Date |
| Production |  |  |  |
| Quality Assurance |  |  |  |

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| Prepared by :  Approved by : | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Production Manager**    **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **QA Manager** |  |  |  |  | **0**    Effective Date :  **1 January 2016** |

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| **11. Product Release** | | | |
| The material produced through the execution of this Batch Record shall be Dispositioned by QA according to *Product Release Procedure* (SOP-010).    The product conforms to *Finished Goods Specification: Tongkat Ali Tablet* (FG 0333).    COA No: \_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_    The Disposition shall be recorded below. | | | |
|  | Name | Signature | Date |
| Production |  |  |  |
| Quality Control |  |  |  |
| Quality Assuarance |  |  |  |



