 COMPANY NAME	BATCH MANUFACTURING RECORD			Page: 1 of 8
Department : Production	Title : Tongkat Ali Tablet			Batch Record : BMR-001
	Name	Signature	Date	Revision No. : 0 Effective Date : 1 January 2016
Prepared by :	_____			
	Production Manager			
Approved by :	_____			
	QA Manager			

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

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

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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Prepared by :		<hr/>			
		Production Manager			
Approved by :		<hr/>			
		QA Manager			

SOP – 028: Ribbon Mixer

SOP – 032: B2 Strokes Tablet Press

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					

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				


6. Area Clearance

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	Production Manager				
Approved by :	_____				
	QA Manager				

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 <i>Facility Cleaning Procedures</i> (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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Prepared by :		_____			
		Production Manager			
Approved by :		_____			
		QA Manager			

7. Production Procedure			
Processing Step	Performed By / Date	Verified By / Date	
A. <u>Dispensing & Raw Material Preparation</u> Location: <u>Dispensing Room 1</u> 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. <u>Mixing</u> Location: <u>Mixing Room 2</u> 5. Ensure room Temperature is within 22-24°C and Humidity is less than 65% Temperature: _____ Humidity: _____ 6. Mix Eurycoma longifolia powder, Lactose and Corn Starch in Cube Mixer (ID: MX-03) for 5 mins. Time Start: _____ Time Stop: _____			
7. Transfer all the contents of Cube Mixer (ID: MX-03) into a suitable container/ plastic bags. 8. Label the plastic bag with a) "Tongkat Ali A Blend"			

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Approved by :	_____				
	QA Manager				


b) Batch No.		
9. "Transfer Tongkat Ali A Blend" into Ribbon Mixer (ID: MX-02).		
10. 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: CS-03).		
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: _____		
17. Transfer the contents of the Cube Mixer into a suitable plastic bag.		
18. Label the plastic bag a) "Blend for Tableting: Tongkat Ali" b) Batch No		
C. <u>Tableting</u>		
19. Ensure room Temperature is within 22-24°C and Humidity is less than 65% Temperature: _____ Humidity: _____		

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	QA Manager			

<p>Monitor both Temperature and Humidity every 30 mins until end of Tableting Process</p> <table border="1"> <thead> <tr> <th>Time</th> <th>Temperature (°C)</th> <th>Humidity (%)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>		Time	Temperature (°C)	Humidity (%)											
Time	Temperature (°C)	Humidity (%)													
<p>20. Set-up the tablet press with the hopper and feed frame as described in SOP-032. Use Punches and Dies ID: 123456</p> <p>Punches and Dies ID: _____</p> <p>21. Ensure that the gap between the feed frame and the die table is paper thick</p>															
<p>22. Carefully pour the material (Blend for Tableting: Tongkat Ali) into the feed frame of the tablet press.</p> <p>23. 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.</p>															
<p>24. 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</p> <p>25. Set machine at speed no: 2.</p>															
<p>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</p>															
<p>27. Collect tablets until the end of production. Transfer these tablets into containers and label "Tongkat Ali Tablet"</p> <p>28. At the end of the run perform cleaning according the SOP-012.</p>															
D. <u>Film Coating</u>															

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...Cont...		
E. <u>Packing & Labelling</u>		
...Cont...		
8. Sampling, Material Transfer & Storage		

9. Yield Calculation
<p>Yield</p> $= 100 \% \times \frac{\text{Weight of Tablets}}{\text{Weight of Raw Materials}}$ <p>= _____ (Specification: 95 - 100 %)</p> <p>Finished Product Yield</p> $= 100\% \times \frac{\text{No. of Goods produced at the end of process + Rejects + Samples + Returned}}{\text{No. of Goods received at the start of process}}$ <p>= _____ (Specification: 90 - 100 %)</p>

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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	Production Manager			
Approved by :	_____			
	QA Manager			

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 Assurance			

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