

<b>BIOMOX PHARMACEUTICALS</b>			
<b>STANDARD OPERATING PROCEDURE</b>			
Version No.	11	Copy No.	
Supercedes No.	10	Effective Date:	25 February 2006
Page No.	5 of 5	Dated:	10 February 2006
	<b>Compiled by:</b>	<b>Approved by:</b>	<b>Controlled by:</b>
Name:	N.C. Maluleke	Prof R van Brummelen	J.M. Human
Signature:			
Date:	10 February 2006	10 February 2006	10 February 2006

## **SEE SOP FILE: B1 - PRODUCTION IN GENERAL**

- B/001/1 -Request for Production**
- B/001/2 -Ordering Procedures**
- B/001/4 -Raw Material Procedures**
- B/001/4.1 -Receival of Raw Materials from Suppliers**
- B/001/4.2 -Log: Suppliers Deliveries (Raw Material)**
- B/001/4.3 -Raw Material Check List: Receival**
- B/001/4.4 -Control of Certificate of Analysis**
- B/001/4.5 -Raw Material Holding Area**
- B/001/4.6 -Log: Stock Reconciliation (Raw Material)**
- B/001/4.7 -Release and issue of Raw Materials for Production**
- B/001/4.8 -Raw Material Check List: Release**
- B/001/4.9 -Raw Material suppliers inspection**
- B/001/4.10 -De-dusting Area for Raw Material**
- B/001/4.11 -Excel Forecasting on raw material**
- B/001/4.12 -Expired raw material**
- B/001/4.13 -Stock taking**
- B/001/5.1 -Manufacturing Procedures**
- B/001/5.2 -Handling of Sub-Batches**
- B/001/5.3 -In process capsule/tablet/tube weight Check**
- B/001/5.4 -Log: Manufacturing (Machine/Equipment)**
- B/001/5.5 -pre-Manufacturing**
- B/001/5.6 -Pre-Manufacturing area log**
- B/001/6.1 -Master Documentation**
- B/001/6.2 -Master Manufacturing Document of Capsule /Tablets**
- B/001/6.3 -Master Manufacturing Document of Creams**

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- B/001/6.4 -Calculating % Yield loss of Power after Mixing**
- B/001/6.5 -Calculation of Batch Yield Loss**
- B/001/6.6 -Control Updating of Master Document**
- B/001/6.7 -Checking of manufacturing document for Correctiveness**
- B/001/7.1 -Empty Capsule Procedures**
- B/001/7.2 -Receival of Empty Capsules from Suppliers**
- B/001/7.3 -Empty Capsules Checklist: Receival**
- B/001/7.4 -Log: Suppliers Deliveries (Empty Capsules)**
- B/001/7.5 -Log: Stock reconciliation (Empty Capsules)**
- B/001/7.6 -Release of Empty Capsules for Production**
- B/001/7.7 -Empty Capsules checklist: Release**
- B/001/7.8 -Issue and Receival of Empty capsules To /from production**
- B/001/8.1 -Packaging Procedures**
- B/001/8.2 -Line opening for Packaging**
- B/001/8.3 -Line Closing for Packaging**
- B/001/8.4 -Pre-Packaging Area**
- B/001/8.5 -Pre-Packaging Area Log**
- B/001/8.6 -Re-Packing Procedures**
- B/001/9.1 -Packaging Material Procedures**
- B/001/9.2 -Receival of Packaging Material from Suppliers**
- B/001/9.3 -packaging Material Checklist: Receival**
- B/001/9.4 -Suppliers Deliveries (Packaging Material)**
- B/001/9.5 -Stock Reconcialition (Packaging Material)**
- B/001/9.6 -Release of Packaging Material for Production**
- B/001/9.7 -Packaging Material Checklist: Release**
- B/001/10.1 -Printed material Procedures**

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**B/001/10.2 -Receival of Printed Material for Suppliers**

**B/001/10.3 -Printed Material Checklist: Receval**

**B/001/10.4 -Log: Printers/Client deliveries (Printed Material)**

**B/001/10.5 -Log: Stock Reconcialition(Printed Material)**

**B/001/10.6 -Control of Label Design**

**B/001/10.7 -Control of Label Design-Check List**

**B/001/10.8 -Control of package Insert Design**

**B/001/10.9 -Control of Package insert Design-checklist**

**B/001/10.10-Printed Material standard Reference File  
-Stamp of Approval/Rejection of Printed Material**

**-Client Approval/Rejection of Printed Material**

**B/001/10.11 -Release of Printed Material for Production**

**B/001/10.12 -printed Material Sampling**

**B/001/10.13 -Printed Material Checklist: Release**

**B/001/10.14 -Issue and Receival of Printed Material  
To/from Production**

**B/001/10.15 -Line Opening for Labelling**

**B/001/10.16 -Line Closing for Labelling**

**B/001/10.17 -Label Store**

**B/001/10.18 -Excel Forecasting system for Printed  
Packaging Material**

**B/001/11.1 -Sampling Procedures**

**B/001/11.2 -Sample Label**

**B/001/11.3 -Sampling Area**

**B/001/11.4 -Cleaning & Storage of Sampling  
Equipment**

**B/001/11.5 -Written Procedures for Resealing of Bulk  
Containers**

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- B/001/11.6 -Log: Raw Material Sampling**
- B/001/11.7 -Log: Empty Capsules Sampling**
- B/001/11.8 -Log: Packaging Material Sampling**
- B/001/11.9 -Log: Printed Material Sampling**
- B/001/11.10 -Log: Final Products (Retention Samples) Sampling**
- B/001/12.1 -Production Door Notice Board**
- B/001/12.2 -Production Door Notice Board Master**
- B/001/13.1 -Receival of final products from the Production**  
**-Area into the Final Holding Area**
- B/001/13.2 -Log: Final Container Weight Check list**
- B/001/13.3 -Receival of final Products from the Holding Area into the Release Area**
- B/001/13.4 -Despatch of Final Product**
- B/001/13.5 -Letter: Products Ready for Collection**
- B/001/13.6 -Log: Final Product Release/Despatch Stocklist**
- B/001/14.1 -Lactobacillus and Bifidobacterium Handling Procedure**
- B/001/14.2 -Store of Thermolabile Materials in Event Of Fridge failure**
- B/001/14.3 -Log: Refrigerator**
- B/001/14.4 -Cold Room Thermostat Information Leaflet**
- B/001/14.5 -Cleaning of Cold Room**
- B/001/14.6 -Temperature Control of Cold Room**
- B/001/14.7 -Temperature Log of the Cold Room**
- B/001/15 -Calculation of Standard Deviation**
- B/001/16 -Change Control**
- B/001/17.1 -Final Product Retention Sample Procedure**

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- B/001/17.2 -Collection of Production Forms to the lab**
- B/001/18 -Batch gun Exchange**
- B/001/19 -Post Staging Area Log**
- B/001/20.1 -Fire Drill**
- B/001/20.2 -Fire Drill Report**
- B/001/20.3 -Fire Incidence Report**
- B/001/20.4 -Fire Marshals**
- B/001/20.5 -Inspection of dry powder extinguishers**