STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Preparation, Checking, Review, Approval, BOM & Master Formula Records.

2.0 SCOPE:

This SOP is applicable for Preparation, Checking, Review, Approval, of BOM & Mater Formula Records at ……

3.0 RESPONSIBILITY:

Production (Officer/Executive): Preparation, Revision of BOM & MFR**.**

QA (Officer/Executive): Issuance, Control, Retrieval and Destruction of BOM & MFR.

QA Manager: Review, Approval, Training and effective implementation of this SOP.

Manager Production: Checking, Implementation and Execution of BOM & MFR.

4.0 ACCOUNTABILITY:

Head Production: Ensure Training and effective Implementation of SOP.

5.0 DEFINITION:

BOM: Not Applicable

MFR: MFR is one of key document in pharmaceutical. it is record or history for every Master Formula Record.

6.0 PROCEDURE:

6.1 PREPARATION BOM & MFR:

6.1.1 BOM & MFR shall be written in English Language by using Microsoft Word.

6.1.2 Production (Officer/Executive) Preparation, Revision & QA (Officer/Executive) Issuance, Control, Retrieval and Destruction of BOM & MFR review.

6.1.3 Master Formula Record (MFR) shall be prepared" as shown in **Annexure-I.** Bill of materials (BOM) shall be prepared as shown in **Annexure-II**

6.1.4 MFR shall cover all activities of Operation in proper sequence and mention the reference SOP and Annexure No.-1 & Annexure No.–2 for BOM wherever applicable.

6.1.5 Initiator shall prepare the draft of BOM & MFR as per all activities of the product and send to the Manager Production.

6.1.6 Production manager shall check the draft BOM & MFR Accuracy, Adequacy, Correctness and Completeness.

6.1.7 Upon receipt of the comments (if any), the same shall be incorporated by initiator in the draft MFR.

6.1.8 Production shall take the printout of MFR for signature in Prepared By.

6.1.9 Upon signature of Production Manager in checked by, signed off MFR shall be sent back to Head QA and Approved by, Master Index of BOM & MFR shall be maintained by QA Department.

6.1.10 Master list index of MFR shall be updated by QA once in a year or whenever required.

6.2 DESIGN OF MFR:

MFR Format Considerations:

6.2.1 All MFR shall contain Header, Body **"MFR Specimen Copy"** as shown in **Annexure-I**.

6.2.2 All pages shall contain **Format No.** in Footer.

6.2.3 All the points in the MFR shall be numbered sequentially.

6.2.4 Provide the proper space between the Rows of the tables for filling the details.

6.2.5 Font size of table Content may be Changeable in case of insufficient space but it should not be less than 9 Font.

6.2.6 All MFR contents shall be covered by Single Borderline with ½ Line Width.

6.2.7 MFR Header shall be covered by a borderline with 1 Line Width, Specimen of Header of MFR as per format **"MFR Format Specimen Copy"** as shown in **Annexure-I.**

6.2.8 Line Spacing and Font Size: The Line Spacing between two points or title & subtitle shall be Single/1.5 lines font style shall be Times New Roman 12 font. Font size may be less in case of Table and Remarks.

6.2.9 MFR (Master Copy) shall be printed on A4 size Off-white colored Executive Bond Paper using **"Times New Roman"** Font with Black Ink. Printing shall be done on one side of the paper only.

6.2.10 Paper Selection for Print: Paper 8.5" (Width), 11" / 11.5" (Height), Border Top 0.38",Left 1.25", Right 0.4", and Bottom 0.5", with A4 Size Scaling, Layout of header 0.5".

6.3 CONTENT OF HEADER PART:

6.3.1 Header of First Page:

6.3.1.1 The Header of MFR shall include the Name of Organization. Header shall have the Logo of Organization in Left corner on Top, and followed by "Master Formula Record " in center as shown in **Annexure-I.**

6.3.1.2 Product Name: Product Name should be Pre-printed.

6.3.1.3 Effective Date: Effective Date shall be written in the form of **DD/MM/YY** in respective column.

6.3.1.4 MFR No.: Mention the MFR No. as per respective SOP, Assign the MFR No. as per respective SOP, it shall be pre- printed.

Assignment of MFR Number:

XXX/YY/NNN

Where,

XXX : Denotes MFR

/ : Separator

YY : Denotes department/code "Master Formula Records Numbering System".

/ : Separator

NNN : Sequential Numbering (001,002 & so on)

For example,

Three piece line **: MFR/TP/001**

Dry powder line : **MFR/DP/001**

Liquid Ampoule line : **MFR/LA/001**

Liquid Vial line : **MFR/LV/001**

BOM Sequential Numbering **HMF/0001** (Healthcare Manufacturing Formula)

6.3.1.5 Page No.: The Page Number shall be mentioned in 'X of Y' Header. **For Example:** If a MFR contain 60 pages then the first page of the MFR shall be Start from 1 of 60, 2 of 60 and shall be pre-printed.

6.3.1.6 Stamping: COPY stamp shall be stamped in space provided in the Header part on the upper right hand side of the page.

6.4 CONTENT OF THE BODY:

6.4.1 First Page: First page shall contain, content as shown in **Annexure-I.**

6.4.2 Second Page of MFR: Second Page of MFR shall contain **"TABLE OF INDEX"** in the form of given table. Header Row of Table shall have gray 25 % Shading Colour.

6.4.3 Other than First & Second Page:

6.4.3.1 Main Contents of the MFR (but not limited to):

All Master Formula Record shall contain the following headings:

6.4.3.2 Quantitative Formula (Bill of Material) of RM & PM.

6.4.3.3 API Calculations

6.4.3.4 Specification and standard testing procedures of RM & PM.

6.4.3.5 List of Equipment's/Machines to be used for Manufacturing/Packing Process with Machine/Equipment ID No.

6.4.3.6 Manufacturing/Packing Processing Details with proper instructions (Separately)

6.4.3.7 Process flow chart.

6.4.3.8 Manufacturing/Packing Processing Details with steps wise (Separately)

6.4.3.9 Bulk & Finished Product Specification

6.4.3.10 Abbreviations

6.4.3.11 Sale Authorization (in MFR)

6.4.3.12 Revision History: "Revision History" shall be the last heading of Body part of MFR.

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Done By
00	NA	NA	NA		

6.5 CONTENT OF THIRD PAGE:

6.5.1 Prepared By: Prepared By shall be signed by Officer / Executive Production who initiates the MFR along with Name, Sign, Date.

6.5.2 Checked By: Checked by shall be signed by Production Manager and signed along with Name, Sign, Date.

6.5.3 Approved By: Approved by shall be signed by Head QA and signed along with Date and Name.

6.5.4 Sign: Concerned personnel shall sign off with Blue Ink Ball Point Pen.

***Note:* Do not use Gel / Fountain Pen for Signing / Filling the Documents.**

6.5.5 Date: Date shall be mentioned in the form of **DD/MM/YY**.

6.5.6 Name: Full Name of person shall be mentioned who signs the MFR.

6.6 FONT STYLE/SIZE OF HEADER & BODY CONTENTS OF MFR & BOM:

NAME OF CONTENT	FONT SIZE
HEADER PAGE:	
Name of the Organization and Location	14 Capital & Bold
Logo (On Left Hand Side Corner of The Page)	Height-0.75''& Width-0.63''
Master Formula Record	12 Capital & Bold
Product Name	12 Capital & Bold
MFR No.	12 Capital & Bold
Effective Date	12 Capital & Bold
Page No.	12 Capital & Bold
Format No.	09 Capital & Normal
BODY:	
Paragraph Main Heading & First Page Content	38 Bold & Capital
Subheading	Not less 18 Normal/Capital & Bold

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

NAME OF CONTENT	FONT SIZE
Table Heading and Header of the Table	11 Capital/Normal & Bold
Table Body Part Content	11 Normal

6.7 PREPARATION OF BOM & MASTER MFR, CONTROL, ISSUANCE AND RETRIEVAL:

6.7.1 After Approved, MFR shall be stamped as **"MASTER COPY"** with Blue colour ink in space provided in Header (on all the pages) and sign and date with **Blue Ink Ball Point Pen**.

6.7.2 Effective Date shall be entered in all pages of header column **(Effective date :)** with **Blue Ink Ball point Pen.**

6.7.3 Master copy of BOM & MFR shall be scan and save as password protected pdf copy.

6.7.4 Take the print out from this scanned password protected pdf copy (Master copy) and shall be shall be stamped as **"CONTROLLED COPY"** with green colour stamp (all pages) and sign and date with **Black Ink Ball Point Pen.**

6.7.5 MFR No. Shall be entered in all pages of header column with Pre Printed**.**

6.7.6 In case of change in MFR which had already been issued for the products as per earlier plan are returned through deviation as per QA SOP "Handling of Deviation" before issuance of MFR as per revised plan.

6.7.7 QA Officer/Executive shall mark the entry of the returned MFR in Issuance Record as reason shall be mentioned in the remark column' as per format "**MFR Issuance and Retrieval Record"** as shown in **Annexure-III** and returned MFR shall be destroyed by Paper shredder**.**

6.8 MFR Cover File:

6.8.1 MFR Cover file Printing Matter shall be as per format "**MFR Cover Page Format"** as shown in **Annexure-VI**. MFR Cover file Colour shall be different for different QA Blocks/Dosage Forms.

6.8.2 All cover file shall contain MFR documents check list printed on back side of front cover file.

6.8.3 Colour Codes for Cover File:

- **General Products:** Blue Colour

Note: **Printing on Cover File shall be done by Black Ink only**

6.9 STORAGE OF BOM & MFR (Master Copy/Soft Copy):

6.9.1 All Master Copy/Soft Copy of Approved BOM & MFR shall be stored in QA Department with Password Protected System and Data Backup shall be kept in Information Technology (IT) Department.

6.10 REVISION OF BOM & MFR:

6.10.1 Any change in BOM & MFR shall be done only after Approval of **"Change Control"**.

6.10.2 Revision No., Change Control No., Details of Changes, and Reason for Change shall be written under heading **Revision History** in **BOM & MFR.**

6.10.3 Previous version shall be made obsolete as per SOP**.**

7.0 ABBREVIATIONS:

BOM	Bill of Materials
MFR	Master Formula Record
QA	Quality Assurance
Exp. Date	Expiry Date
ID No.	Identification Number
IT	Information Technology
Ltd.	Limited
Mfg. Date	Manufacturing Date
MFR No.	Master Formula Record Number
MRP	Maximum Retail Price
No.	Number
Pvt.	Private
QA	Quality Assurance
S. No.	Serial Number
Sign	Signature
SOP	Standard Operating Procedure
WHO	World Health Organization
PPIC	Production Planning and Inventory Control

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	MFR Format	
Annexure-II	BOM Format	

9.0 DISTRIBUTION:

- Master Copy — Quality Assurance Department
- Controlled Copy No. 01 — Quality Assurance
- Controlled Copy No. 02 — Production
- Controlled Copy No. 03 — Information Technology

10.0 REFERENCES:

- A WHO Guide to Good Manufacturing Practice (GMP) Requirements, Part–I, Standard Operating Procedures and Master Formulae, WHO/VSQ/97.01.
- Quality Assurance of Pharmaceuticals a Compendium of Guidelines and related materials Volume 2, 2nd updated edition Good Manufacturing Practices and Inspection.
- 21 CFR, Part 211 Current Good Manufacturing, Practice for Finished Pharmaceuticals; Subpart J-Records and Reports, Sec. 211.1866 Batch production and control records.
- SOP, Titled **"Documentation and Data Control"**

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE– I
MFR FORMAT SPECIMEN COPY

	PHARMA DEVILS PRODUCTION DEPARTMENT	**MASTER FORMULA RECORD FOR**	**MFR No.:** **Effective Date:** **Page:**

S.No.	Title
1.0	**Approval**
2.0	**General Information**
MANUFACTURING PROCESS	
3.0	**Formula**
4.0	**Calculation**
5.0	**Specifications and Standard Testing Procedures**
6.0	**List of Equipment's/ Machines to be used for Manufacturing**
7.0	**Manufacturing Instructions**
8.0	**Process Flow Chart**
9.0	**Manufacturing Procedure**
10.0	**Bulk Solution Specification**
PACKAGING PROCESS	
11.0	**Bill of Packaging Materials**
12.0	**Packaging Material Specifications and Standard Test Procedures**
13.0	**List of Equipment's Required for Packing**
14.0	**Packing Instructions**
15.0	**Packing Procedure**
16.0	**Packing Style, Batch Yield**
17.0	**Finished Product Specification**
18.0	**Abbreviations**
19.0	**Approved Specimen of Printed Label**
20.0	**Approved Specimen of Printed Secondary materials**
21.0	**Approved specimen of Primary materials**

FORMAT No.: ……..

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Preparation, Review, Approval of BOM & MFR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE– II

BOM FORMAT SPECIMEN COPY

PHARMA DEVILS
PRODUCTION DEPARTMENT

BILL OF MATERIAL FOR RAW MATERIAL

PRODUCT NAME	**PACK SIZE:**	**STRENGTH:**	**BATCH SIZE**	
	MARKET:	**SHELF LIFE:**	**PRODUCT CODE**	
	REVISION No.	**EFFECTIVE DATE**	**PAGE No.**	

S. No.	Material Code	Material Name	Specification	Label Claim	Over-ages %	Qty. Required as per Standard Batch Size	UOM

Calculation:

Active Materials has been taken equivalent to its 100% Assay on as is basis considering the minimum Assay: NLT……% and maximum LOD/Water Content NMT……..%

Calculation: During Formulation Required Qty. of Active shall be taken equivalent to 100% Assay on as is basis considering the estimated Assay % & LOD % Water Content

	Prepared by Officer/Executive Production	Checked by		Approved by Head Quality Assurance
		Head Production	Head Quality Control	
Name				
Signature				
Date				

FORMAT No.: ……