DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation Checking, Review, Approval of master BMR & BPR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Preparation, Checking, Review, Approval, Batch Manufacturing Records and Batch Packing records.

2.0 SCOPE:

This SOP is applicable for Preparation, Checking, Review, Approval, of Batch Manufacturing Records and Batch Packing Records at ……

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Distribution (to Production) Revision, Retrieval an Destruction of this SOPs. Preparation, Issuance, Control, Retrieval and Destruction of BMP,BPR.

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

Manager Production: Checking, Implementation and Execution of BMR And BPR.

4.0 ACCOUNTABILITY:

Head QA: Approved of this SOP & ensure Training and effective Implementation of SOP approved and Archival of BMR and BPR.

Head Production: Review and Authorization of BMR & BPR.

5.0 DEFINITION:

BMR: BMR is one of key document in pharmaceutical. it is record or history for every Batch Manufacture.

BPR: BPR is one of key document in pharmaceutical. it is record or history for every Batch Packing.

6.0 PROCEDURE:

6.1 PREPARATION OF BMR & BPR:

6.1.1 BMR & BPR shall be written in English language by using Microsoft Word.

6.1.2 On the basis of MFR, Officer/Executive QA shall initiate the BMR & BPR.

6.1.3 Batch Manufacturing Record (BMR) and Batch Packing Record (BPR) shall be prepared separately as per format **"BMR and BPR Format Specimen Copy"** as shown in **Annexure-I.**

6.1.4 BMR & BPR shall cover all activities of Operation in proper sequence and mention the reference SOP No. wherever applicable.

6.1.5 Initiator shall prepare the draft of BMR & BPR as per respective approved MFR of the product and send to the Manager Production.

6.1.6 Production manager shall check the draft BMR/BPR for 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 BMR/BPR.

6.1.8 QA shall take the printout of BMR/BPR for signature in Prepared By production.

6.1.9 Upon signature of Production Manager in checked by, signed off BMR/BPR shall be sent back to Head QA and Approved by, Master Index of BMR/BPR shall be maintained by QA Department as per format "**Master BMR And BPR Index"** as shown in **Annexure-IV.** BMR and BPR List shall be maintained separately.

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

6.2 DESIGN OF BMR/BPR

BMR/BPR Format Considerations:

6.2.1 All BMR/BPR shall contain Header, Body and Footer. **"BMR and BPR Format 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 BMR/BPR 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 BMR/BPR contents shall be covered by Single Borderline with ½ Line Width.

6.2.7 BMR/BPR Header shall be covered by a borderline with 3 Line Width, Specimen of Header of BMR/BPR as per format **"BMR and BPR 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 BMR/BPR (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 0.32", Left 1", Right 0.7", and Bottom 0.6", with A4 Size Scaling, Layout of header 0.5" and footer 0.2"

6.3 CONTENT OF HEADER PART:

6.3.1 Header of First Page:

6.3.1.1 The Header of BMR/BPR shall include the Name of Organization (Including Name of Location). Header shall have the Logo of Organization in Left corner on Top, and followed by "Batch Manufacturing Record and Batch Packing Record" in center as shown in **Annexure-I.**

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

6.3.1.3 Product Code: Assign the product code as per respective SOP, it should be Pre-printed.

Assignment of Product code Number:

YY/NNN

Where,

YY **:** Denotes department/area code "Protocol and Report Numbering System" as per **SOP**

/ **:** separator

NNN **:** Sequential Number (001, 002 & so on)

For example,

Three piece line : **TP/001**

Dry powder line : **DP/001**

Ampoule line -1 & line-2 **:** **LA/001**

Liquid vial line : **LV/001**

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

6.3.1.5 MFR No.: Mention the MFR No. as per respective SOP, it should be pre-printed.

6.3.1.6 Line Code (**LA** for Ampoule Line **A1 & A2, LV** for Vial Line, **TP** for Three Piece Line & **DP** for Dry powder injection).

6.3.1.7 BMR & BPR No.: Assign the BMR & BPR No. as per respective SOP, it shall be pre-printed.

Assignment of BMR & BPR Number:

XXX/YY/MM/NNN

Where,

XXX **:** Denotes BMR & BPR

/ **:** separator

YY **:** Denotes department/area code "Protocol and Report Numbering System" as per **SOP.**

/ **:** separator

NNN **:** Sequential Number (001, 002 & so on)

For example,

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

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

Ampoule line -1 & line-2 : **BMR/LA/001**

Liquid vial line : **BMR /LV/001**

6.3.1.8 Batch No.: Assign the Batch No. as per respective SOP.

6.3.1.9 Revision No. : The new Version of BMR/BPR shall be written, as '00'. If it is a revision then subsequent Revision No. shall be given as '01', '02' etc., it should be pre-printed.

6.3.1.10 Supersede BMR/BPR No.: Supersede BMR/BPR shall have the history of the previous Revision No. and shall start from NA, it shall be pre-printed.

6.3.1.11 Page No.: The Page Number shall be mentioned in 'X of Y' format. **For Example:** If a BMR/BPR contain 60 pages then the first page of the BMR/BPR shall be Start from 1 of 60, 2 of 60 …… and shall be pre-printed.

6.3.1.12 Square Space for Stamping: MASTER COPY stamp shall be stamped in space provided in the Header part on the 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 BMR/BPR: Second Page of BMR/BPR shall contain **"TABLE OF INDEX"** in the form of given table. Header Row of Table shall have gray 25 % Shading Color.

S.No.	Title	Page No.

6.4.3 Other than First & Second Page:

6.4.3.1 Main Contents of the BMR/BPR (but not limited to):

6.4.3.1.1 Line clearance checklist at all the stages of Manufacturing and Packing Operations.

6.4.3.1.2 Always provide the separate space for the affixing of status labels.

6.4.3.1.3 Always provide the sampling details of each stage with proper details.

6.4.3.2 All Batch Manufacturing Record and Batch Packing Record shall contain the following headings:

6.4.3.2.1 Quantitative Formula (Bill of Material)

6.4.3.2.2 API Calculations

6.4.3.2.3 Pre Dispensing/Manufacturing & Packing Instructions

6.4.3.2.4 Dispensing of Raw/Packing Materials

6.4.3.2.5 Verification of Dispensed Materials (On Production Floor).

6.4.3.2.6 List of Equipments/Machines to be used for Manufacturing/Packing Process with Machine /Equipment ID No.

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

6.4.3.2.8 Stereo Issuance, Retrieval and Destruction Record (in BPR)

6.4.3.2.9 Overprinting Details

6.4.3.2.10 Stage wise Yield Reconciliation

6.4.3.2.11 In-process checks during Manufacturing Packing

6.4.3.2.12 Environmental Monitoring details at the time of Manufacturing/Packing Process

6.4.3.2.13 Shipper Weightment Record (in BPR)

6.4.3.2.14 In-process Observations Sheet

6.4.3.2.15 Extra Material Return/Issuance Details (e.g. Packaging Material etc.)

6.4.3.2.16 Sale Authorization (in BPR)

6.4.3.2.17 **Revision History:** "Revision History" shall be the last heading of Body part of BMR & BPR as shown in following Table.

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

6.5 CONTENT OF FOOTER PART:

6.5.1 **Prepared By:** Prepared By shall be signed by Officer/Executive Production who initiates the BMR/BPR 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 Name, Sign & Date..

6.5.4 **Format No.:** 09 Normal & Capital font size printed on the left corner of the page after Footer, out of page border and shall be printed as SOP with Revision No. on all pages of the BMR/ BPR.

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

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

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

6.5.7 **Name:** Full Name of person shall be mentioned who signs the BMR.

6.6 FONT STYLE/SIZE OF HEADER, FOOTER & BODY CONTENTS:

NAME OF CONTENT	FONT SIZE
HEADER PAGE:	
Name of the Organization and Location	14 Capital & Bold

NAME OF CONTENT	FONT SIZE
Logo (On Left Hand Side Corner of The Page)	Height-0.75''& Width-0.63''
Batch Production and Control Record	12 Capital & Bold
Product Name	12 Capital & Bold
Product Code	12 Capital & Bold
MFR No.	12 Capital & Bold
Effective Date	12 Capital & Bold
(BMR/BPR) No.	12 Capital & Bold
Revision No.	12 Capital & Bold
Supersede BMR/BPR No.	12 Capital & Bold
Page No.	12 Capital & Bold
FOOTER PAGE:	
Prepared By, Checked By, Approved By	12 Running & Bold
Name, Signature & Date	12 Running & Bold
Format No.	09 Capital & Normal
BODY:	
Paragraph Main Heading & First Page Content	11 Bold & Capital
Subheading	11 Normal/Capital & Bold
Table Heading and Header of the Table	11 Capital/Normal & Bold
Table Body Part Content	11 Normal

6.7 PREPARATION OF MASTER BPR/BMR, CONTROL, ISSUANCE AND RETRIEVAL :

6.7.1 After Approved, BMR & BPR 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 BMR/BPR 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 Batch No. Shall be entered in all pages of header column with **Black Ink Ball Point Pen.**

6.7.6 After receiving Production Planning from PPIC Department, Production shall give request for issuing BMR and BPR to QA as per format "**BMR/BPR Requisition Form"** as shown in **Annexure-II**.

6.7.7 QA Officer/Executive shall prepare the number of copies of Batch Production Record/Batch Packing Record as per **"BMR/BPR Requisition Form".**

6.7.8 QA Officer/Executive shall issue the BMR/BPR to Production Officer/Executive, as per format **"BMR/BPR Issuance and Retrieval Record"** as shown in **Annexure-III.**

6.7.9 In case of additional pages are requested by Production Department (for recording additional entries, pages got spoiled etc.) same shall be issued by QA department after receiving the request as per **"Request cum Issuance form for Additional Pages"** as per SOP**.**

6.7.10 Additional Page(s) shall be issued only after approval by Head QA upon receipt of Request form for Additional Page(s).

6.7.11 QA Officer/Executive shall record the issuance of Additional Page as per format **"Additional Page Issuance Record"** as shown in **Annexure-V** and stamped as **"ADDITIONAL PAGE"** and signed with **Black Ink Ball Point Pen**.

6.7.12 After completion of Batch, BMR/BPR shall further be reviewed for its completeness as per format **"Batch Production Record and Batch Packing Record Document Checklist"** as shown in **Annexure-VII.**

6.7.13 Head QA shall ensure closure of Deviation, Incident before batch release.

6.7.14 After completion of Batch, BMR/BPR shall be submitted by the Production Department to QA Department. QA shall maintain the record as per format "**BMR/BPR Issuance and Retrieval Record"** as shown in **Annexure-III.**

6.7.15 In case of discontinuation of the existing same BMR/BPR No. shall not be allotted to any other BMR/BPR.

6.7.16 In case of change in production plan, ensure that the BMR/BPR 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 BMR/BPR as per revised plan.

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

6.8 BMR/BPR Cover File:

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

6.8.2 All cover file shall contain BMR/BPR Documents check list printed on back side of front cover file.

6.8.3 **"Batch Production Record and Batch Packing Record Documents Check List"** is provided at the back side of BMR/BPR Cover as shown in **Annexure-VII**. Write the particulars as per the dosage form requirement.

6.8.4 **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 BMR/BPR (Master Copy/Soft Copy):

6.9.1 All Master Copy/Soft Copy of Approved BMR/BPR 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 BMR/BPR:

6.10.1 Any change in BMR/BPR 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 **BMR** & **BPR.**

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

6.11 ARCHIVAL AND DESTRUCTION OF BMR/BPR:

6.11.1 All the Obsolete/Discontinued hard copy of Master BMR/BPR shall be scanned and retained in soft copy with back up facility for life cycle from the date of Obsolete/Discontinued and the hard copy shall be stored for Five years and the destruction shall be done as per format shown in **SOP.**

6.11.2 After five year, Obsolete/Discontinued document shall be destroyed through paper shredder.

6.11.3 QA Officer/Executive shall destroy all the executed BMR/BPR after one year from the Date of Expiry of Product through paper shredder.

6.11.4 QA Officer/Executive shall take the approval of QA Head as per Format **"BMR/BPR Destruction Record"** as shown in **Annexure-VIII**.

6.11.5 Retain the records of batches for which legal samples are taken by any Regulatory Authority or Market Complaints are under investigation till the matter get cleared.

6.11.6 QA Officer/Executive shall prepare a list of Batch Records, which are due for Destruction as per format **"BMR/BPR Destruction Note"** as shown in **Annexure-IX** for every three months.

7.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
BPR	Batch Packing 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

8.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	BMR and BPR Format Specimen Copy	
Annexure-II	BMR and BPR Requisition Form	
Annexure-III	BMR and BPR Issuance and Retrieval Record	
Annexure-IV	Master BMR/BPR Index	
Annexure-V	Additional Page Issuance Record	
Annexure-VI	BMR and BPR Cover Page Format (Specimen Copy)	
Annexure-VII	BMR and BPR Documents Check List	
Annexure-VIII	BMR and BPR Destruction Record	
Annexure-IX	BMR and BPR Destruction Note	

9.0 DISTRIBUTION:

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

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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		

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ANNEXURE– I

BMR AND BPR FORMAT SPECIMEN COPY

BMR FORMAT

Page-01

BATCH MANUFACTURING RECORD			
PRODUCT NAME	**PRODUCT CODE**	**EFFECTIVE DATE**	**Space for Master Copy Stamp**
MFR No.	**BMR No.**	**BATCH No.**	
REVISION No.	**SUPERSEDES BMR No.**	**PAGE No.**	

(BODY OF THE FIRST PAGE):

BATCH MANUFACTURING RECORD

1. **PRODUCT NAME** :
2. **GENERIC NAME** :
3. **LABEL CLAIM** :
4. **MANUFACTURING LICENSE No.** :
5. **STANDARD BATCH SIZE** :
6. **ACTUAL BATCH SIZE** :
7. **PACK SIZE** :
8. **MANUFACTURING DATE** :
9. **EXPIRY DATE** :
10. **SHELF LIFE** :
11. **PRODUCTION LINE No.** :
12. **MARKET** : **Domestic/ Export**
13. **DATE OF COMMENCEMENT** :
14. **DATE OF COMPLETION** :
15. **BATCH YIELD (%)** :
16. **BMR ISSUED BY (QA)** :
17. **DATE** :

---	Prepared By Officer/Executive Production	Checked By Manager Production	Approved By Head Quality Assurance
Name			
Signature			
Date			

FORMAT No.: ……..

***Note:* Point No. 1- 5, 12 shall be Pre- printed.**

DECODING PHARMA

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BPR FORMAT

BATCH PACKING RECORD

PRODUCT NAME	**PRODUCT CODE**	**EFFECTIVE DATE**	**Space for Master Copy Stamp**
MFR No.	**BPR No.**	**BATCH No.**	
REVISION No.	**SUPERSEDE BPR No.**	**PAGE No.**	

(BODY OF THE FIRST PAGE):

BATCH PACKING RECORD

1. **PRODUCT NAME :**
2. **GENERIC NAME :**
3. **LABEL CLAIM :**
4. **MANUFACTURING LICENSE No.:**
5. **STANDARD BATCH SIZE :**
6. **ACTUAL BATCH SIZE :**
7. **SHELF LIFE :**
8. **MANUFACTURING DATE :**
9. **EXPIRY DATE :**
10. **PACKING STYLE :**
11. **MARKET :**
12. **MRP :**
13. **DATE OF COMMENCEMENT :**
14. **DATE OF COMPLETION :**
15. **BATCH YIELD (%) :**
16. **PRODUCT OF (Company Name)/Code:**
17. **BPR ISSUED BY (QA) :**
18. **DATE :**

---	Prepared By Officer/Executive Production	Checked By Manager Production	Approved By Head Quality Assurance
Name			
Signature			
Date			

FORMAT No.: ……..

Note: ***Point No. 1- 5, 11, shall be Pre- printed.***

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ANNEXURE – II

BMR/BPR REQUISITION FORM

Date:

To - QA Department
From - Production Department

Kindly issue us BMR/BPR for the following Products.

S.No.	Product Name	Batch No.	Batch Size	Mfg. Date	Exp. Date	Market		Remarks
						Sale	PS	

Request Prepared By:
Sign:
Date & Time:

Approved By:
Manager Production

FOR QA USE ONLY:

BMR/BPR Requisition Received By: **Date:** **Time:**
Sign:
BMR/BPR Issued On: **Date:** **Time:**
BMR/BPR Issued By: **Date:** **Time:**
Sign:
Received By (Production Officer/Executive) **Date:** **Time:**
Sign:

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ANNEXURE – III
BMR AND BPR ISSUANCE AND RETRIEVAL RECORD

Product Name: **Product Code:**

Manufactured for:

Batch Details					BMR/BPR Issuance				BMR/BPR Retrieval				Remarks
S.No.	Batch No.	Mfg. Date	Exp. Date	Batch Size	Issued By QA		Received By Production		Retrieved By Production		Received By QA		
					Sign	Date	Sign	Date	Sign	Date	Sign	Date	

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ANNEXURE–IV
MASTER BMR/BPR INDEX

HEADER:

Effective Date: **Revision No.:**

BODY:

S.No.	Product Name	Product Code	BMR/BPR No.	MFR No.	Revision No.	Effective Date	Remarks

FOOTER:

---	Prepared By Officer/Executive	Checked By Department Head	Approved By Head Quality assurance
Name			
Signature			
Date			

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ANNEXURE –V
ADDITIONAL PAGE ISSUANCE RECORD

Department: **Month/Year:**

S.No.	Date	Page Required	Product Name	Batch No.	No. of Pages	Issued By QA	Received By Production

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ANNEXURE –VI
BMR/BPR COVER PAGE FORMAT (SPECIMAN COPY)

BMR/BPR No…….

PRODUCT NAME : ……..
BATCH NO. : ……..
MFG. DATE : ……..
EXP. DATE : ……..
BATCH SIZE : ……..
MARKET : ……..
MANUFACTURED FOR : ……..

STANDARD OPERATING PROCEDURE	
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ANNEXURE–VII
BMR/BPR DOCUMENTS CHECK LIST

S.No.	Particulars	Checked By Production	Verified By IPQA
1.	Authorized Copy Batch Manufacturing Record		
2.	Line clearance Checklist – Dispensing		
3.	ERP Batch Sheet for Raw Material Dispensing		
4.	Weightment Record for Raw Material		
5.	Raw Material Dispensing Tags		
6.	Manufacturing Instructions		
7.	Rinse Water/Swab Release Report		
8.	Line Clearance Checklist/Mfg. …….		
9.	Release Report of Intermediate stage(s)		
10.	Authorized Copy of Batch Packing Record		
11.	SAP Batch Sheet for Packing Material Dispensing		
12.	Packaging Instructions		
13.	Line Clearance Checklist – Primary/Secondary Packing		
14.	Duly Signed Specimen of Overprinted Packing Material		
15.	Release Report of Finished product		
16.	Extra Material Issuance Record		
17.	Material Return Note/Online Rejection Note		
18.	Deviation/Planned Deviation		
19.	Incident(s)		
20.	Review of Environmental Monitoring data (micro)		
21.	Certificate of Analysis of Finished Products		
22.	Finished Goods Transfer Ticket (F.G.T.T.)		
23.	Any Other Document, Please Specify		
a)			
b)			
c)			

Note: Mark √, If Available **X, If Not Available** **NA, If Not Required**

----	Prepared By Officer/Executive	Checked By Department Head	Approved By Head Quality assurance
Name			
Signature			
Date			

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ANNEXURE–VIII
BMR/BPR DESTRUCTION RECORD

Month/Year:

S.No.	Product Name	Batch No.	Mfg. Date	Exp. Date	Destruction Due On	Remarks

Prepared By
QA Officer/Executive
Sign & Date

Approved By
QA Head
Sign & Date

STANDARD OPERATING PROCEDURE	
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Title: Preparation Checking, Review, Approval of master BMR & BPR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE – IX
BMR/BPR DESTRUCTION NOTE

Date:

DESTRUCTION NOTE No.:

PRODUCT NAME:

B. No.:

MFG. DATE:

EXP. DATE:

MANUFACTURED FOR:

MODE OF DESTRUCTION:

Prepared By
QA Officer / Executive

Checked By
Manager Production

Approved By
Head QA

DESTRUCTION VERIFICATION REPORT

BMR/BPR Destructed On:

Destructed By
QA Officer
Name:
Sign & Date:

Verified By
Head QA
Name:
Sign & Date