DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Preparation, Revision, Control and Issuance of BMR/BPR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for preparation, control and issuance of Batch Manufacturing Record (BMR) and Batch Packing Record (BPR).

2.0 SCOPE:

This procedure is specifically applicable for preparation, control and issuance of Batch Manufacturing Record (BMR) and Batch Packing Record (BPR) used in both manufacturing and packing operation.

3.0 RESPONSIBILITY:

QA Officer/QA Executive/QA Head – For preparation, revision, control and issuance of BMR/BPR

Manager –QA: To approve and ensure the compliance.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Preparation procedure:

5.1.1 For each new product, R&D will provide a master manufacturing formula to the QA department.

5.1.2 The BMR/BPR shall be prepared by the responsible in QA Officer.

5.1.3 Format of BMR/BPR with the following margins approximately:

Top: 0.9”, Bottom: 0.7”, Left: 0.7”, Right: 0.7”, Header: 0.7”, Footer: 0.7”.

5.1.4 The format for the BMR/BPR is prepared as per Annexure–I and Annexure–II.

5.1.5 Use A4 size (width 8.27” and height: 11.69”) white paper for the purpose of preparation of BMR/BPR.

5.1.6 All the contents in BMR/BPR shall be in “ARIAL” font.

5.1.7 BMR contents shall be incorporated sequentially including, but not limited to:

- Dispensing of materials
- Granulation area line clearance

- Recovery processing record
- Manufacturing process
- Yield reconciliation
- Process deviation sheet

5.1.8 BPR contents shall be incorporated sequentially including, but not limited to:

- Dispensing of materials
- Packaging process
- Finished good transfer
- Excess material return note
- Yield reconciliation

Process deviation sheet

5.1.9 In BMR/BPR at each critical stage, provision for line clearance and yield reconciliation shall be provided.

5.1.10 The draft copy of BMR/BPR shall be circulated to production and QA department for review by putting stamp “draft” and their comments along with master manufacturing formula.

5.1.11 The changes suggested by concerned persons shall be incorporated. After getting the approval from QA Manager and final printout shall be taken.

5.1.12 Final printout shall be signed by five persons, prepared by, checked by production, checked by QA, approved by Head, Production and finally by QA manager.

5.1.13 All pages of BMR/BPR shall be stamped as “MASTER COPY” in red ink at the top right corner.

5.1.14 One photocopy shall be taken from Master copy and shall be stamped as “CONTROLLED COPY” in red ink with department code of QA at the bottom center of pages.

5.1.15 Master copy of BMR/BPR shall not be used anywhere. For execution purpose, only controlled copy shall be used.

5.2 For revision of BMR/BPR:

5.2.1 Whenever any change occurred in process / formula / equipment, changes shall be done by following the change control procedure.

5.2.2 All the steps for existing BMR/BPR shall be followed from step 5.1 to 5.16.

5.3 For control and issuance of BMR/BPR:

5.3.1 As per production requirement, production department shall initiate the requisition as per Annexure-III with approval of plant Manager and QA Manager.

5.3.2 Based on requisition given by production department, the required number of copies of BMR/BPR shall be generated through photocopy from master copy by QA personnel.

5.3.3 The photocopies of BMR/BPR shall be stamped as ‘’CONTROLLED COPY’’ with the concerned department code sign and date with red colour ink on bottom center of each page by QA personnel and shall be stamped ‘ISSUED BY QA/DATE’ with blue colour ink on first page of BMR/BPR.

5.3.4 QA personnel shall write the batch number, manufacturing date, expiry date in the column provided in pages of BMR / BPR copy based on requisition slip.

5.3.5 QA personnel shall enter all the details as product / strength wise in BMR / BPR issuance register (as per Annexure –IV) and ensure the sign by production department as receipt of batch records.

5.3.6 The requisition slip shall be kept in separate file for future reference.

5.3.7 QA personnel shall hand over the Batch Manufacturing Record and Batch Packing Record to Production person after acknowledgement.

5.3.8 Incase of cancellation of batch due to change in manufacturing plan or any other reason, Production In-charge shall inform to QA and Stores through ‘BMR /BPR cancellation form’ as per Annexure-V and this cancellation form shall be checked by QA. Then BMR / BPR shall be returned to QA by production department. Issued BMR/BPR copy shall be destroyed by QA and same shall be recorded in remark column of issuance register. The returned material from production to stores shall be handled as per SOP.

5.3.9 In case of additional requirement of page(s) of BMR/BPR by production dept., the production personnel shall send the filled annexure-VI. Reason for requirement of additional pages shall be specified clearly on the requisition form.

5.3.10 After completion of manufacturing and packing, the executed BMR/BPR shall be returned to QA department.

5.3.11 QA personnel shall review the BMR/BPR and get it approved from plant Manager and QA manager.

5.3.12 QA personnel shall keep the BMR/BPR in document cell up to one year after expiry of

product.

5.3.13 For other outside requirement, the photocopy of master BMR/BPR shall be taken and shall be stamped 'UNCONTROLLED COPY' with black ink at right side bottom position of each page.

6.0 ABBREVIATION(S):

BMR : Batch Manufacturing Record

BPR : Batch Packaging Record

QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure – I: BMR Format

Annexure – II: BPR Format

Annexure – III: BMR/BPR Requisition Slip

Annexure – IV: BMR/BPR Issue Register

Annexure-V: BMR/BPR Cancellation form

Annexure-VI: Additional Pages Requisition Slip

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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Annexure I

BATCH MANUFACTURING RECORD		
Product:	**Generic Name:**	
BMR No. :	**B. No.:**	**Page No.:**

Annexure II

BATCH PACKAGING RECORD

Product:	**Generic Name:**	
BPR No.:	**B. No.:**	**Page No.:**

Annexure III

BMR/BPR REQUISITION SLIP

FROM: PRODUCTION DEPARTMENT **TO: QUALITY ASSURANCE DEPARTMENT**

Kindly issue the Batch Manufacturing Record/Batch Packing Record for the following products:

Product Name	Batch Size	Market	No. of Batches	Batch Numbers	Remarks

Prepared By (Production)	Date	Approved By (Head, Production)	Date	Authorized By (Head, QA)	Date

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Annexure IV

BMR/BPR ISSUANCE RECORD

S.No.	Product Name	Batch No.	Batch Size	Mfg. Date	Exp. Date	BMR Issued By/Date	BMR Recd. By/Date	BPR Issued By/Date	Executed BMR/ BPR Returned	Control Sample Collected	Batch Status (Released/ Rejected) By/Date	BMR/ BPR Archived By/Date	Remarks

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Annexure V

BMR/BPR CANCELLATION FORM

From: Production **To:** Quality Assurance

Please cancel the following BMR/BPR:

Product Name: **B. No.:**

Mfg Date: **Exp. Date:**

Reason For Cancellation:

Checked By (Production)/Date: **Checked By (Stores)/Date:**

Received By(QA)/Date: **Checked By(QA)/Date:**

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Annexure VI

ADDITIONAL PAGES REQUISITION SLIP

From: Production Department **To:** Quality Assurance Department

Kindly issue the following pages of Batch Manufacturing Record/Batch Packing Record for the following products:

Product Name	Batch Size	Market	Batch Number	Page Number(s) Required	Reason for Additional Requirement
Prepared By (Production)	**Sign/Date**	**Approved By (Head, Production)**	**Sign/Date**	**Authorized By (Head, QA)**	**Sign/Date**