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PROCEDURE FOR PREPARING, ISSUING, MOVEMENT, RETENTION AND DESTRUCTION OF BATCH HISTORY RECORD IN STERILE MANUFACTURING SITE

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ABSTRACT

Batch history record (BHR) is any written statement or proof of any activity in pharmaceuticals. BHR is to define the manufacturer's system of information and control, to minimize the risk of misinterpretation & errors inherent in oral or casually written communication, to provide unambiguous procedures to be followed to provide confirmation of performance, to allow calculations to be checked & to allow tracing of batch history. In this article it is clearly described on how a batch history record is Prepared and what are the prerequisites to be followed. Regulatory views on batch history records and the basic necessary checklist viewed during the development of the documents. This states to have an information or general procedure for Preparation, Approvals, and Maintenance of these records in the most of the pharmaceutical industry. These Documents are a mirror to show an actual image of any pharmaceutical company. Control of this document is also an important part of Good Documentation Practice (GDP) to reduce error and misuses of any documents. Every document should have an effective date, review date, and revision number. This record needs to be established for each Transitional and API/formulation and should consist of entire picture pertaining to exhibit, validation, and commercial batch.

KEYWORDS: Good Documentation Practice, Batch History Record.

INTRODUCTION[1-5]

This is to provide a written procedure for preparing, issuing, movement, checking, retention, archival and destruction of Batch Manufacturing Record (BMR) and Batch Packing Record (BPR), this whole together known as the Batch History Record (BHR), it is a integral part of the Good Documentation Practice which are the standards set by the Good Manufacturing Practices. These standards are legal requirements and observations if there is found to be deviating from the prescribed regulations. Main purpose of this records is to provide a step by step procedure and specifications for all the materials and methods of manufacturing, packing and necessary controls.[10,11]

Regulatory Views

- According to the 21 CFR Sec. 211.186 Master Production and control records[18]: States That the preparation of master production and control records shall be detailed in a written procedure and such established process or methodologies shall be followed.
- Good manufacturing practice describes the essential aspects of quality assurance system in designing, preparation, reviewing of documents, records. Followed by the approval, signature with date by suitable and authorized personnel.[6,19]

- TGA on Documentation: documentation is to describe organization details and control of producer's and to reduce probability of astigmatism, errors inborn with oral or written communication.[16]

- WHO GMP, PIC GMP and EU GMP Chapter 4[18]: Master Formula, states that there should be availability of approved, written master formula and processing instruction for each product and batch size to be manufactured.

- Health Canada GMP Guidelines[18]: tells documents must specify materials, procedures and precautions required to formulate a specified quantity of a finished goods as well as the instructions, including the in-process controls.

Important Definition

Master Formula Records: A document or set of documents specifying the starting materials with their quantities and packing materials, together with description of procedures and precautions to produce the specified quantity of the finished product as well as the processing instructions, including in process control. It is prepared by the R&D or F&D.

Batch Manufacturing Records: A batch manufacturing record is a document designed to provide a complete record of the manufacturing history of a batch of product. The terminology is widely applied within the pharmaceutical & chemical industries and is referenced in many of the pharmaceutical and food regulatory agency requirements. It is prepared by the QA department.

Batch Packing Records: A batch packing record should be kept for each batch or part batch processed. This document is based on packing operation. It should be based on the relevant parts of the packing instructions and the methods of preparation of such records should be designed to avoid transcription errors.

Documentum (DCM): It is software used to capture, manage, store, accessing, organizing, controlling, retrieving and archiving content and documents related to organizational processes.

System Application and Product (SAP)[15]: It is a software system delivers distinct solution for production of drugs in an automated approach. Economy management of pharmaceuticals effectively done through this software. Maintains workflow management of production process to take place in a constant order.

Laboratory Information Management System (LIMS) [21]: Is a software that allows you to effectively manage samples and associated data. It centralizes access and storage of quality control data.

Responsibility[13]: Functions or Role of the different department in most of the pharmaceutical industries involved in this process are as follows.

1. Quality Assurance: At the initial stage, most important work is to prepare and issuing of batch manufacturing and packing record by designated Quality Assurance Personnel. Later on, it will be reviewed and authorized by the head of the department or his designee for master copy. Finally, he/ she will be responsible for the retention, destruction and distribution of those records.
2. Production: Here the prepared records will be cross verified, reviewed and approved, once it is done by the QA head or designee and ensures the security of issued document during processing and shall raise the request for the issuance of records as per the planning.
3. Stores or Warehouse: Ensures the security of the issued document during dispensing. All these departments along with the related departments engage in verifying weather these records are in compliance with the standard operating procedure and is properly implemented at the site.
4. Packing and Development Cell: responsible for the approval and review of the master packaging record.

After all the review and approval records shall be checked fore the correct version number and the issued only as per the production planning.

General Note on Master Formual Record and Batch Records (Includes Packaging and Manufacturing)[20]

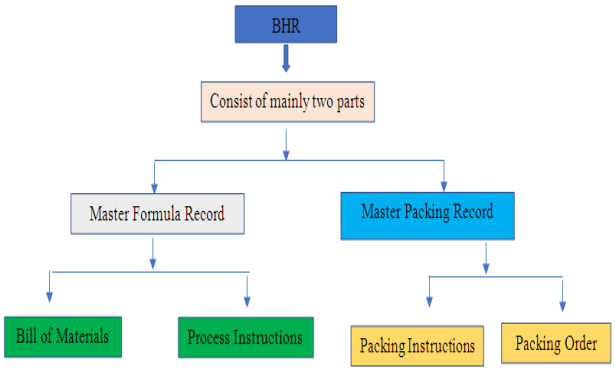
Master Formula Record

1. This intensify the prospective for compatible product Quality.
2. It proves that harmony is maintained in each individual in following the process.
3. It helps to evaluate the occurrence of any product quality or packaging quality deflections and provides a solid support for the development or upgradation.

Batch Records

1. These records are derived from the master formula records.
2. These records are used for the single manufacturing and packaging cycle.
3. Gives a specific explanation of all working operations and controls, when they are performed, by whom and where.

Skeleton of Batch History Record



Procedure for Bhr Preparation, Control and Issuance[7][8][9][12]

Receipt of Master Formula Record

The master formula records consist of two parts

- Part one – Bill of Materials (BOM)
- Part two- Process Instruction (PI)

➢ The MFR-BOM consists of Finished Product Information, Bill of Materials, Potency calculation with molecular weight details, Raw materials & Primary Packing materials information and stock solution preparation and process aids (materials of construction (MOC) of Filters and Tubing's without item codes) etc.

➢ The MFR-PI, consists of Product Specific requirements, precautions, critical process parameters (CPPs), Area requirements, recommended equipment, accessories & utilities, detailed manufacturing instructions, hold time & contact time recommendations and a schematic representation of process etc.,
➢ The master formula record (BOM & PI) prepared, reviewed and approved.
These master copies shall be under the control of R&D.
➢ Upon approval of MFR-BOM & MFR-PI, the same shall be distributed to the site by uploading the scanned master copy into documentum.
➢ Prior to initiation of the BMR preparation, production and QA personnel must ensure the availability of MFR-BOM & MFR-PI in the documentum.
➢ Both production and QA personnel must verify the MFR-BOM & MFR-PI for products code, process and supplier details and approve the document in DCM.
➢ After approval in documentum, QA personnel shall print controlled document of approved MFR-BOM & MFR-PI for initiation of BMR preparation.
➢ QA personnel shall prepare the BMR as per instructions mentioned in MFR-BOM & MFR-PI and store it in QA documentation room. Store the master BMR in QA record room along with the controlled copy of MFR-BOM & MFR-PI in master file.
➢ Once approved BMR is created at site, MFR-BOM shall be revised based on change control created by R&D for pre-approved products and Technical services (TS) for approve products for the changes as specified in procedure.
➢ Once approved BMR is created at site, MFR-PI shall not be revised by R&D and any changes to the process instructions shall be done at BMR level only by initiating a change control as per the change management system.
➢ Following are the changes (but not limited) shall require BMR updation without MFR-PI revision:
o Minor changes to the manufacturing process flow. (E.g. Change to WFI temperature, collection of additional WFI required for volume make-up etc.)
o Inclusion, exclusion and revision of the recommended hold- times and contact times.
o Changes to the product name or tittle. (e.g., inclusion of "USP" in product name or in other texts due to pharmacopieal updates).
o Batch size changes.
o Change in batch yield quantities.
o Change in equipment (e.g., using 100 L manufacturing vessel instead of 50 L vessel, change in autoclave etc.)
o Change in product shelf-life.
o Change in- process test parameters impacting BMR.
o Change in lyophilization cycle parameters.
o Change in terminal sterilization parameters.
o Change in fill volume range.
o Inclusion of filter and tubing item code from same type and supplier. (e.g. 2" filter to 5" filter, use of tubing with different ID/ OD etc.)
o Change in storage conditions.
o Change in critical process parameters, product specific instructions etc., based on process validation data.
o Any other changes required based on process validation.
o Change to source name arising out of AVL update.
o Typographical errors.
o Any other change required as per plant practices and requirement.

Preparation of Bmr

The draft BMR shall be prepared by QA personnel.
BMR shall be prepared in two parts.

- Part A – Product specific record (shall be prepared for individual product for each suite and batch size).
- Part B – Process specific record (common format to product) for individual suites and dosage forms.

Preparation of Part-A Bmr

The following shall be considered while preparing the BMR- (part-A), (but not limited to…)
➢ Product name, product code, label claim & storage conditions of the product as per the MFR-BOM and MFR-PI.
➢ Materials, item codes, MFR-PI & MFR-BOM number/ version & quantities are as per the MFR-PI & MFR-BOM.
➢ Calculations for assay/potency wherever applicable.
➢ Compounding steps and instructions as per MFR-PI and manufacturing line requirements.
➢ Provision for recording names and signatures of all personnel involved in product handling activity.
➢ Applicable equipment ID's, limits and reference SOP's as per process and suite requirement.
➢ Date of commencement is the date of dispensing first material and manufacturing date is the date of compounding for sterile products.
➢ Product specific instructions (wherever applicable), parameters, procedures and critical control points at all stages shall be specified in BMR.
➢ The personnel responsible for preparing and checking the document shall ensure the accuracy and authenticity of the draft BMR against in the MFR(PI), MFR-BOM.
➢ A checklist shall be generated along with draft BMR as a Table No:1.0, while preparation of BMR the person who prepares, reviews, checks, and shall tick on the applicable columns provided stating that the parameters have been verified against the checklist with the reference document.
➢ Circulate the draft BMR to respective Cross functional teams for review and comments if any.
➢ A copy of relevant change controls, or supporting documents as applicable, shall be circulated (if required) along with the draft batch record for reference purpose during review and approval process.
➢ Based on review and comments, the BMR shall be corrected and printed
➢ During master BMR signing and approval the personnel shall cross verify all the columns marked during draft BMR review in Table No: 1.0 along with the reference document.
➢ Master BMR shall be checked and approved by respective personnel on the columns as follows:

- Prepared By: QA personnel
- Checked By: Production Personnel
- Checked By: QA personnel
- Approved By: TS Personnel
- Approved By: Production-head or his designee authorized by QA head or his designee.

➢ During approval process, if any major discrepancies observed in the batch record, update and reprint the batch record as applicable and cancel the checklist and use new checklist for approval purpose (if required). Purpose of cancellation must be specified in the checklist and same shall be filed along with master BMR.

➢ Master BMR will be effective after authorization by QA.

Preparation of Part-b Bmr

The following shall be considered while preparing the BMR (PART-B)

➢ Reconciliation of bulk solution a primary packing material shall be mentioned at appropriate stages in the BMR.

➢ In process checks regarding weight/ volume variation during filling of vials, clarity of reconstituted vials, sealing quality, temperature/ RH recordings etc., and its frequency are to be mentioned in BMR's.

➢ Line clearance, equipment identification numbers and related SOP names shall be specified in BMR.

➢ Identification of all unit operations and provision for recording names and signatures of all personnel involved in product handling activity at time of startup (e.g. via loading, collection etc.,) are to be included in batch manufacturing record.

➢ Provision and adequate space to be included in master batch records for recording any changes in job allocation during batch manufacturing activities.

➢ The header of the part-B BMR shall contain suite No, version No., and type of dosage form.

➢ The personnel responsible for preparing and checking the document shall ensure the accuracy and authenticity of the draft BMR against the process/ practices in the production area.

➢ Circulate the draft BMR to Cross functional teams for review and comments if any.

➢ A copy of relevant change controls, or supporting documents as applicable, shall be circulated (if required) along with the draft batch record for reference purpose during review and approval process.

➢ Based on review and comments, the BMR shall be corrected and printed in green A4 size sheets (indicating master copy).

➢ Master BMR shall be checked and approved by respective personnel on the columns as follows:

- Prepared By: QA Personnel
- Checked By: Production Personnel
- Checked By: QA Personnel
- Approved By: Production- Head or his designee

➢ Master BMR will be effective after authorization by QA. Enter BMR effective date manually after QA authorization.

Receipt of Master Packing Record

The master packing record consists of two parts

- Part one- Packing order
- Par two- Packaging instructions

➢ The MPR- Packing order consists of list of packing materials and the quantity each material as per the standard batch size.

➢ The MPR-Packaging instructions consists of detailed stepwise packing, details for Primary, Secondary, Intermediate, tertiary & palletization (if required). It also contains details on general instructions how to pack using the BOM given in packaging order, product specific requirements, customer specific requirements, DGFT notes etc.)

➢ The master packing order prepared, reviewed and approved by the personnel as specified. These master copies shall be under the control of packing development cell(PDC).

➢ Upon approval of MPR, the same shall be distributed to the site by uploading the scanned master copy into documentum.

➢ Prior to initiation of BPR preparation, production and QA personnel must ensure the availability of MPR in the documentum.

➢ Both production and QA personnel must verify the MPR for product details and approve the document by following the procedure as specified.

➢ After approval in docmentum, QA personnel shall print controlled document of approved MPR for initiation of BPR preparation.

➢ QA personnel shall prepare the BPR as per instructions mentioned in MPR and store it in QA documentation room. Store the master BPR in QA record room along with the controlled copy of MPR and attachments in line with product wise master file.

Preparation of Bpr

➢ The draft BPR shall be prepared by QA personnel based on production plan by using the approved and effective MPR in documentum.

➢ During revision of BPR, any change controls, CAPA's or incidents related to the preceding version shall be verified.

➢ BPR shall be prepared as two parts:

- **Part A -** Product specific record (shall be prepared for individual product In line with MPR).
- **Part B -** Process specific record (common format irrespective of product/ batch size).

Preparation of Part-A Bpr

The following shall be considered while preparing the Part-A BPR, (but not limited to)

➢ Material code, Material description, Brand name, Customer, Pack size, MPR number/ version.

➢ Shelf life of the product, overprinting details and packing profile.

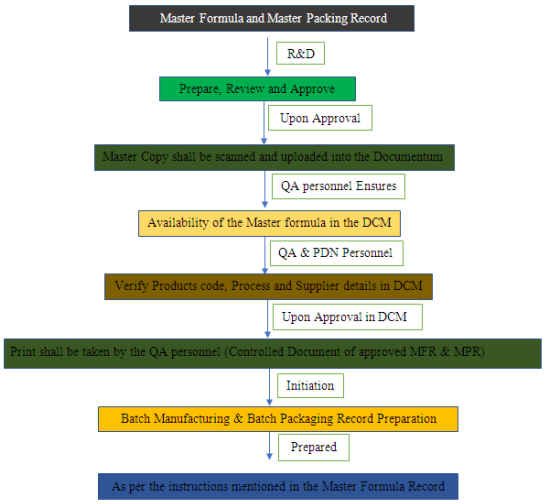
➢ The personnel involved in preparing and checking the document shall ensure the accuracy and authenticity of the draft BPR against the MPR and process/ practices in the production area.

➢ A checklist shall be generated along with draft BPR as a Table No:2.0, while preparation of BPR the person who prepares, reviews, checks and approves.
➢ Circulate the draft BPR to production department and QA department for comments.
➢ Based on review comments, the BPR shall be corrected and printed.
➢ During master BPR signing and approval the personnel shall cross verify all the columns marked during draft BMR review in Table No: 2.0 along with the reference document.
➢ Get the signatures of respective personnel on the columns as follows:
o Prepared By: QA
o Checked By: Production
o Checked By: QA
o Approved By: Production- head or his designee
o Authorized by QA head or his designee.
➢ During approval process, if any major discrepancies observed in the batch record, update and reprint the batch record as applicable and cancel the checklist and use checklist for approval purpose (if required). Purpose of cancellation must be specified in the checklist and same shall be filed along with master BPR.
➢ Master BPR will be effective after authorization by QA.

Preparation of Part-b Bpr

The following shall be considered while preparing the Part-B BPR, (but not limited to)
➢ Equipment name and equipment number, line clearance & operating procedures.
➢ Identification of all unit operations and provisions for recording names and signatures of all personnel involved in product handling activity to be included in batch packing records.
➢ Provision and adequate space to be included in master packing records for recording any changes in job allocation during batch packing activities.
➢ The header of Part-B BPR shall contain batch no. and revision number.
➢ The personnel involved in preparing and checking the document shall ensure the accuracy and authenticity of the draft BPR against the MPR and process/ practices in the production area.
➢ Circulate the draft BPR to production department followed by QA department for comments.
➢ Based on review comments, the BPR shall be corrected and printed.
➢ Get the signatures of respective personnel on the columns as follows:
o Prepared By: QA
o Checked By: Production
o Checked By: QA
o Approved By: Production- head or his designee
o Authorized by QA head or his designee
➢ Master BPR will be effective after authorization by QA.
- After authorization of master BMR/ BPR, availability of all pages (Appropriately) and signatories shall be verified by QA before uploading into documentum and archival of master copy and the same shall be recorded on check list (wherever applicable).
- After authorization, master BMR/ BPR must be immediately scanned and uploaded into documentum followed by its approval.
- Destroy the draft copy of BMR/ BPR by shredding/ tearing once the master BMR/ BPR is effective. Store master BMR/BPR in QA record room. Stamp earlier revision of master BMR /BPR as "SUPERSEDED" at the right-hand bottom of all the pages with signature on the first page and store securely in QA documentation room.

Process flow Chart of the Batch History Record[14]



Issuance of BMR/BPR

➢ Production shall request for both BMR and BPR by generating Process Orders from SAP. The same shall be printed, signed and submitted to QA.
➢ After receipt of process order, QA personnel must verify the process order against the BMR/BPR preparation checklist available in DCM for MFR-BOM / MFR-PI / MPR version number.

The batch records shall be issued only after meeting the below criteria's.

- The version numbers of MFR-BOM / MFR-PI / MPR are identical to process order.
- The version numbers of MFR-BOM / MFR-PI / MPR are not identical however the revision has no impact on batch record

(if specified in Table No: 1.0 / 2.0)

➢ If any changes (addition / deletion) are impacting the batch record the same shall be informed to Production head & QA head and necessary actions shall be initiated.
➢ Prior to issuance, the issuance personnel must *also* evaluate or assess all documents required for the given process order are available by considering the following but not limited to;

- Product name / Generic name.
- Product Strength
- Product code / FG code
- Market

- Product type (Ex. Vial-Inj, Vial-TS, Vial-Lyo, Infusion Bag-TS etc..) *and respective annexures if any.*
- Suite (in case of BMR).
- Batch size (in case of Part-A BMR)
- Product with specific process (in case of BMR) ex. Liquid products undergoing Lyophilization cycle

➢ Issuance of Process validation batches using Documentum shall be tracked manually by updating in BHR issuance log book Table No:3.0

➢ Following procedure shall be followed for issuance of Batch records manually during the Documentum server/network breakdown.

- Based on the receipt of SAP generated Process Order from production department, take photocopies of Master BMR/BPR and applicable annexures if any on yellow/Blue sheet (indicating controlled copy).
- Individual master BMR/BPR shall be Photocopied separately. Avoid taking photocopies of multiple masters BMR/BPR at a time.
- Stamp the batch number in black ink on every page of the BMR (Both part A & Part B) and applicable annexures if any at the top center of the page.

➢ During issuance enter the details like product name, product code, batch size, batch number, BPR/BMR reference number etc., manually in the first page of BMR/BPR (Part-A & Part-B) with sign and issued date in the appropriate column.

➢ In case BMR having multiple API source / Primary packing materials, before issuing the BMR for execution, requirement process validation shall be verified. If required BMR can be issued by striking off one API code /material code manually.

➢ In case of issuance of BPR (Part A- Product specific record) for same product/batch size executed in different suites, recommended batch yield shall be verified. If required, the same shall be updated manually.

➢ Stability requirements shall be verified before issuance of Batch Packaging Record / batch manufacturing record for execution.

- For Exhibit Batch and the commercial validation batches, the stability requirements / number of batches to be consider for stability shall be verified through the relevant change controls / Process validation protocol.
- For the annual batches stability requirement shall be verified through the SAP generated process order, this requirement should be considered on case to case basis.
- Upon confirmation, **"STABILITY BATCH"** shall be stamped on the first page of the Part-A and Part-B BPR.
- Prior to initiation of packing activity, the number of stability samples required for subject batch shall be verified and updated in the BPR by referring to an approved LIMS stability protocol.

➢ Issue the BMR's and BPR's to production personnel making relevant entries in BHR Issuance & Archival Register Table No: 3.0.

➢ QA shall verify the availability of all batch record pages (BMR's and BPR's) including annexures at time of issuance. Production shall verify availability of all pages during receipt of batch records from QA. Document the same in BMR Issuance & Archival Register Table No:3.0 with sign and date**.**

➢ Production department shall issue the applicable pages of batch record in bound/clip file to respective processing areas (to perform area specific activity and documentation). After completion of processing activities, production shall retrieve the issued BMR pages and shall be filed in the respective batch record.

➢ If any additional page / partial for BMR / BPR is required for additional entries during execution (or) whenever required, explaining the reason for the same and corrective action taken to avoid such cases in future if necessary. (E.g. when pages of issued BMR/BPR are soiled, torn, extended activity etc.,) production shall raise request through the Part –B BMR (In Additional page request column available in Part-B BMR/BPR) and approved by PDN & QA Head/Designee and shall be submitted to QA issuance personnel.

➢ After receipt of additional page request from PDN, QA personnel must verify the request for correctness of the details. QA must locate the exact document in documentum and manually update/edit the batch number and process order number in the "properties tab" of controlled document (requested BMR/BPR/Annexures).

Archival of Batch Records: Post release of batch, QA shall update the archival details of executed batch records in Table No: 3.0 once in a month.

Procedure to be followed during submission of batch data to Research and analytical department

➢ No original document shall be sent to RAD.

➢ As per request from RAD, the documents shall be photocopied in white sheets/ Scanned by QA personnel and same shall be submitted to RAD personnel.

➢ Archived documents shall be taken by authorized QA person by following the procedure. for retrieval of document.

➢ As per the submission requirement, document shall be photocopied in white sheets / Scanned by QA personnel and same shall be submitted to RAD personnel.

➢ After handover of the documents, original documents shall be verified for availability of all pages before re-archival at documentation cell.

Distribution of Master BMR/BPR to outside agencies:

➢ QA personnel shall take required number of photocopy from Master BMR/ BPR in concerned authorized pages (indicating uncontrolled copy).

➢ These Uncontrolled copies are issued for information purpose only and not for operational use.

Retention and Destruction of BHRs

BHRs shall be stored for 5 to 7 years from date of manufacturing depending the company's policy and regulatory requirements.

➢ All BHR's shall be destroyed after its retention period with due authorization by the DH – QA.

➢ All these documents shall be destroyed by shredding/burning by a QA representative who certifies

the destruction by signing in BHR record attached as Table No: 3.0

Cancellation of Issued bmr / bpr

- Issued BMR/BPR should be used for processing within specified time limits from the date of issuance. If the BMR/BPR issued is not executed for any reason, return the unexecuted BMR / BPR to QA with reason specified.
- If issued BMR/BPR is cancelled due to changes in MFR/MPR, same shall be retrieved and cancelled. New/revised BMR/BPR shall be issued bearing same batch No. and new BMR/BPR number.
- Mark "CANCELLED" for these entries in the BMR/BPR issuance register. Destroy the cancelled BMR/BPR by shredding and mention the same in BMR / BPR issuance register.
- If issued BMR/BPR is cancelled during process execution due to any reason, the same shall be handled through incident management. Mark "REJECTED" for these entries in the BMR/BPR issuance register and store the batch record in Central documentation cell.

Table No: 1.0: Example of Checklist for BMR Preparation, Review, Approval.

Company Logo	**Batch Manufacturing Record**	**Page No.: 1 of 50**
Product Name:	Product Code:	Effective Date:
Batch No:	Batch Size(kg):	Batch Size(units):
Manufacturing Date:	Expiry Date:	Shelf Life:
Prepared by:	Verified By:	Approved By:

Table No: 2.0 EXAMPLE CHECKLISTS for BPR Preparation, Review and Approval.

Company Logo	**Batch Packing Record**	**Page No.: 1 of 50**
Brand Name:	Customer:	Pack Size:
MPR Number / Version:	Material Description:	Material Code:
Packing Profile:	Overprinting Details:	Shelf Life of Product:
Prepared by:	Verified By:	Approved By:

Table No: 3.0 EXAMPLE of BHR Issuance and Archival Register.

ISSUANCE DETAILS		
Date		
Product Name		
SFG Code		
Lot No		
BMR No		
Batch Size		
Suite No		
No of pages issued		
Received by		
Remarks		
BPR No		
FG Code		

ARCHIVING DETAILS						
Mfg. Dt.	Exp. Dt.	BMR checked & archived by (including additional pages issued)		To be destroyed on	BMR Destroyed by	
		Sign	Date		Sign	Date

CONCLUSION[1-5]

It is used as a method for shaping the members and help them to be effective quality assurance professionals for gap assessment during audit periods. Above mentioned content regarding the documentation, tells how it is practiced in industry as a part of the daily activities. Which would give a strong evidence to face any kind of the regulatory audits. The batch records or documents becomes useful for authentication in case of complaints.

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REFERENCES

1. 21CFR111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Prepared by Food and Drug Administration (USFDA), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=111&showFR=1&subpartNode=21:2.0.1.1.11.9.
2. 21CFR211.100 written Procedure and Deviations, Prepared by Food and Drug Administration (FDA), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=211.100.
3. Patel kt, Chotai NP. Documentation and Records: Harmonized GMP Requirements. J Young Pharm, 2011 Apr-Jun; 3(2): 138–150.
4. Guide to Master Formulae, prepared by world health organization (WHO), https://www.who.int/immunization_standards/vaccine_quality/guide_to_master_formulae_final_2012.pdf
5. GDP for APIs: "How to do" Document, Prepared by Active Pharmaceutical Ingredients Committee (APIC), https://apic.cefic.org/pub/GDPHowtoDo_201405.pdf.
6. Suleman S. khoja. Review on Good Documentation Practice in Pharmaceutical Manufacturing Unit as per European Union GMP Chapter-4 on Documentation, https://www.pharmatutor.org/articles/review-on-good-documentation-practice-in-pharmaceutical-manufacturing-unit-as-per-european-union-gmp-chapter-4-on-documentation
7. Tim Sandle. Good Documentation Practices. Journal of Validation Technology, Dec 29, 2014.
8. Guide to Master Formulae, Prepared by World Health Organization, https://www.who.int/immunization_standards/vaccine_quality/guide_to_master_formulae_final_2012.pdf
9. Q7 Good Manufacturing Practice Guidance for Pharmaceutical Ingredients- Guidance for industry, Prepared by U.S. Department of Health and Human Services, https://www.fda.gov/downloads/Drugs/%E2%80%A6/Guidances/ucm073497.pdf.
10. Sec 30. Documentation and Records, inspection of Drug Manufacturing Facilities to improve compliance with GMP / GLP, Prepared by CDSCO, http://www.cdsco.nic.in/writereaddata/publicnoticechecklist28_5_2016.pdf.
11. Section 5. Documentation, Prepared by Therapeutic Goods Administration, https://www.tga.gov.au/sites/default/files/manuf-sunscreens-cgmp-9402.pdf.
12. Pharmaceuticals & Life Sciences, prepared by the indus novateur, http://indusnovateur.com/industries/pharmaceuticals-life-sciences/.
13. Introduction to Lab Information Management, Prepared by illumine, https://www.illumina.com/informatics/sample-experiment-management/lims.html.
14. Batch Manufacturing Record, prepared by Muneam Salim, https://www.scribd.com/document/384465166/Batch-Manufacturing-Record.
15. Bhat RS. Documentation in Pharmaceutical Industry pg.4 to 6, 2009.
16. Preparation of MFR for Pharmaceuticals, prepared by Pharmaceutical guidelines, https://www.pharmaguideline.com/2016/07/preparation-of-mfr-for-pharmaceuticals.html
17. 21CFR 226.102- Master-formula and Batch - production records, prepared by Cornell Law School, https://www.law.cornell.edu/cfr/text/21/226.102.
18. Master Formula Record, Prepared by Ashsish kumbhani, Slide No.1-14, http://www.authorstream.com/Presentation/aashishkumbhani-1763696-master-formula-record/.
19. Review of Batch Manufacturing Record, Prepared by Pharmaceutical Guidance, http://pharmaguidances.com/review-of-batch-manufacturing-record/.
20. Batch Production Record, Prepared by InstantGMP, https://www.instantgmp.com/feat/bpr
21. Manufacturing Formula and processing Instructions, 4.17-4.21, Prepared by Medicine & Healthcare Products Regulatory Agency (MHRA), http://www.ipa-india.org/static-files/pdf/event/ipf2018-presentation8.pdf.