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TITLE: PREPARATION, REVIEW, ISSUE AND ARCHIVAL OF BATCH PRODUCTION RECORD				

1.0 PURPOSE:

To lay down the procedure for Preparation, Review, Issue and Archival of Batch Production Record.

2.0 SCOPE:

This procedure is applicable for Preparation, Review, Issue and Archival of BPR(s) at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 BPR shall be Prepared and Reviewed by Production personnel. .
- 3.2 Head-Production/Designee is responsible for Review of BPR.
- 3.3 QA Personnel is responsible for Issue, Retrieval, Review and Archival of BPR(s).
- 3.4 Head-R&D /Designee is responsible for review of BPR.
- 3.5 Head-QA /Designee are responsible for review and approval of BPR.

4.0 DEFINITIONS:

Expected Yield: The quantity of material or the percentage of theoretical yield anticipated at any appropriate phase of production based on previous laboratory, pilot scale, or manufacturing data.

Theoretical Yield: The quantity that would be produced at any appropriate phase of production, based upon the quantity of material to be used, in the absence of any loss or error in actual production.


Critical Process Parameter: A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process.

5.0 PROCEDURE :

5.1 Preparation of BPR (Batch Production Record):

- 5.1.1 The BPR shall be prepared by production personnel as per the format QA007-F150 on the basis of Technology Transfer documents received from R&D/ Customer.

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- 5.1.2 Separate BPR shall be prepared for each batch size.
- 5.1.3 All contents of the BPR shall be in Times New Roman with font size 12. Unit of measurement shall be written for batch size in Kg/L, as applicable along with the quantity.
- 5.1.4 Header of first page contains Details of Document Number, Batch Number, Effective Date and Product Name.
- 5.1.5 Body of first page contains details Batch details, Contents and Approvals.
- 5.1.6 Header of all subsequent pages shall contain details of Document Number and Batch Number and Footer of all subsequent pages approved by with sign & date.
- 5.1.7 BPR document number shall be given as per below:

BPR/XXX/YYY-NN


Were,

BPR represent : Batch Production Record
XXX represent : Product Code along with stage
YYY represent : Serial Number of BPR
NN represent : Revision Number of BPR

Example: BPR/DAH-I/001-00 DAH Stage-I first Batch Production Record prepared.

- 5.1.8 In case of RP/RW/Crop recovery/Recovery/ Recovery solvent BPR necessary, follow the numbering system as BPR/XXX/AA/YYY-NN
- BPR represent : Batch Production Record
XXX represent : Product Code along with stage
AA represent : Category of BPR (i.e. RP represent: Re-process, RW represent: Re-Work, RE represent: Crop recovery/Recovery & RSMET represent: Recovery solvent Methanol)

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YYY represent : Serial Number of BPR

NN represent : Revision Number of BPR

Eg. BPR/DAH-I/RP/001-00, BPR/DAH-I/RW/001-00, BPR/DAH-I/RE/001-00 & BPR/DAH-I/RSMET/001-00.

5.1.9 For customer specific product numbering shall be follows:

BPR/XXX/UNYYY-NN

BPR represent : Batch Production Record

XXX represent : Product Code along with stage

UN represent : Unit code i.e. U indicates “Unit: and “N” indicates unit no. 1, 2, 3 etc...

YYY represent : Serial number of BPR

NN represent : Revision Number of BPR

Example: BPR/DAH-I/U1001-00 DAH Stage-I first Batch Production Record prepared for Mylan Unit-1.


5.1.10 Raw material input for the batch shall be described in the raw material input page of the BPR. The raw material input page shall have details of S.No, Raw Material Name, Units (Kg/L), Operation number, Standard Quantity, Charged Quantity, In-house Batch Number, Done by and Remarks.

5.1.11 Columns shall be provided to enter output details in “Yield Report Sheet” of the BPR.

5.1.12 “Yield Report Sheet” page contains columns for comments Product and Stage, Yield [Theoretical (Kg), Expected (Kg), Actual (Kg), percentage of Actual / expected yield calculation, done by and checked by.


5.1.13 Instructions for each activity should be split into simpler steps and each step shall be identified by operation number (Op. No.).

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- 5.1.14 Columns for entry of data shall be provided as Op. No, date, time (HH:MM) from (operation start time), to (operation end time) remarks, done by and checked by.
- 5.1.15 Instructions for carrying out the process shall be detailed stepwise and in simple language with inclusion of equipment numbers wherever appropriate.
- 5.1.16 The first operation of every BPR shall be ‘check the cleanliness of the equipment’. Specific instructions such as precautions to be taken in case of hazardous operations shall be given in operation column wherever appropriate.
- 5.1.17 Process steps like raw material charging and other critical and in-process control operations shall be in bold text and non critical steps shall be in normal text. Critical operations/steps are shall have the provision for ‘checked by’ sign and date, as appropriate.
- 5.1.18 Appropriate columns shall be provided for recording of temperature, vacuum, pressure and weights of wet and dry material. Annexure shall be provided for preparation of solutions / reagents (if required).
- 5.1.19 Wherever monitoring parameters (Like Temperature / Vacuum / Pressure) recording is required, recording table shall be provided. All recordings shall be done in tables.
- 5.1.20 Requirement of in-process tests, if any, shall be mentioned in respective operation steps.
- 5.1.21 A provision shall be made with predefined specification for recording results in analytical results record sheet.
- 5.1.22 Provision shall be made for recording deviations if any in operation/yield in the process in the “Deviation record” page.

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5.1.23 Training shall be given to concerned production personnel before the effective date of the BPR. The effective date of the BPR shall be pre printed / hand written by QA personnel.

5.1.24 For trial batches (experimental batches) of new products, or for any major changes in the existing process of the product (before validation), BPR shall be prepared and stamped as “TRIAL” on the top of all pages.

5.1.24.1 Deviations and changes / OOS shall not be logged for trial batches. It shall be recorded in the deviation record page provided in the BPR, if any investigations are conducted; the same shall be attached as annexure to the trial BPR. Changes from trial BPR to the validation / commercial BPR shall be documented with proper justification and annexed to the development report.

5.1.25 Validation BPR shall be prepared and stamped as “VALIDATION”.

5.1.26 For customer driven products, BPRs shall be prepared as per customer requirement.

5.1.27 All manufacturing processes shall be carried out using approved BPRs only.

5.2 Reprocess / Rework / Recovery BPR:


5.2.1 The format as detailed above shall be used for reprocess/rework/recovery BPR.

5.2.2 Sections for yield calculation and deviation in yield will be used in recovery BPR as applicable.

5.3 Powder Processing BPR:

5.3.1 The format for powder processing (dispatch related) BPR shall be prepare as per format QA007-F152. Header and footer details shall be same as given in step No. 5.1.3 to 5.1.9.

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5.3.2 If product wise BPR Document number shall be given as per following.

BPR/PPP/X/YYYY-NN

Were,

BPR represent : Batch Production Record

PPP represent : Product code along with stage code

X represent : Milling, Sieving, Blending etc., (M for Milling, S for sieving and B for Blending)

YYY represent : Sequential Serial Number

NN represent : Revision Number of BPR

Example: BPR/DAH-I/M/001-00 Milling Batch production record.

5.3.3 Common powder processing BPR Document number shall be given as per following.

BPR/X/YYYY-NN

Were,

BPR represent : Batch Production Record

X represent : Milling, Sieving, Blending etc., (M for Milling, S for sieving, and B for Blending)

YYY represent : Sequential Serial Number


NN represent : Revision Number of BPR

Example: BPR/M/001-00 Milling Batch production record.

5.3.4 The mesh size, if applicable shall be entered in the operation column for milling and sifting operations of BPR. Instructions to check the integrity of the mesh shall be incorporated at the start and completion of operation.

5.3.5 Critical operations in the BPR shall be in bold text and shall be signed by a second person in the 'Checked by' column.


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5.3.6 Details in the weighing record page shall be incorporated as per the requirement.

5.4 Preparation of ECR (Equipment Cleaning Record):

5.4.1 ECR all pages Header shall contains as follows:

 Discovery Labs	EQUIPMENT CLEANING RECORD		
Equipment Name			Page No.
Document Number		ECR Number	
Effective date		Equipment ID Number	

5.4.2 ECR first page footer shall contains as follows:

	Prepared By	Reviewed By	Approved By
Sign & Date			
Name			
Department	Production	Production	Quality Assurance


5.4.3 Remaining pages footer contains as follows:

Approved by	Sign & Date	Name	Department
			Quality Assurance

5.4.4 Body of the ECR first page contains ECR details, Contents of the ECR.

5.4.5 In the Second page of ECR contains cleaning reagent input details are described. Cleaning reagent input details page contains Op. No., Unit (Kg/L), Actual Quantity, In-House Batch No., Remarks, Done by columns.

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5.4.6 Instructions for the process shall be described in the operation sheet. Operation sheet contains OP. No, Operation, Date, Time (From & To), Remarks, Done by, Checked by columns.

5.4.7 Summary details shall be described in the ECR summary sheet.

5.4.8 For Equipment Cleaning Record numbering shall be as follows:

ECR/XX/YYY-NN

ECR represent : Equipment Cleaning Record

XX represent : Equipment Code

YYY represent : Serial Number of ECR

NN represent : Revision Number of ECR.

Example: ECR/RV/001-00

ECR/CF/001-00

ECR/NF/001-00

5.5 Recording of BPR:


5.5.1 All operations in the BPR should be entered online by the production personnel. Person who completes the activity shall sign in done by column.

5.5.2 Production Operator / Chemist / In-charge shall fill the BPR with blue / black indelible ink. Entries shall be legible and complete.

5.5.3 Production Operator/Chemist/In-charge shall check the batch number of the issued BPR and availability of material as requested in Material Requirement List- Production to Warehouse.


5.5.4 Production Operator/Chemist/In-charge shall enter the raw material batch number in the BPR according to the Raw Material Issue Form at the time of charging the batch.

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- 5.5.5 In case parameter record sheet is not sufficient for Trial / Validation Batches, the recordings shall be entered in the format QA007-FM151.
- 5.5.6 Time shall be entered in the 24 hour format and 00:00 hours shall be considered as new date for filling the BPR e.g. 10:00 am shall be written as 10:00 and 2:00 pm shall be written as 14:00.
- 5.5.7 If any correction is to be made to the entered data, strike off the error with a single line and input correct value with signature and date. The old entry should be legible.
- 5.5.8 If any pages in the BPR are damaged during manufacturing then production personnel shall raise the request to QA for additional pages. QA shall re issue the BPR pages and record the details in reconciliation register. Production personnel shall transcribe the details from executed BPR. After that QA personnel shall ensure the details and then damaged BPR pages shall be destroyed.
- 5.5.9 In case of any deviations during the processing of validation / commercial production batches, concerned Production supervisor shall raise the deviation report, investigate and record details.
- 5.5.10 Checked by signature of second person shall be at the following operations, but not limited to:
- 5.5.10.1 Weights and Subdividing operations
 - 5.5.10.2 Charging of Raw Materials
 - 5.5.10.3 Operations highlighted with bold letters in the BPR
 - 5.5.10.4 Equipment cleaning
 - 5.5.10.5 In-process control check points
 - 5.5.10.6 Yield calculations

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5.5.11 Requisition for in-process sample shall be sent along with the “Analytical data sheet”.

Attach the in-process analytical reports received from QC with BPR and enter results in the BPR.

5.5.12 After completion of the batch process, enter the output weights and yield ratio in the BPR and hand over to the shift in-charge.

5.5.13 Batch duration shall be counted from the starting time of first operation (i.e. Check the cleanliness of the equipment) to last operation (i.e. final weighing of the product).

5.5.14 The powder processing BPR should be closed on completion of all entries.

5.5.15 Label activity should be carried out as per labeling SOP and data shall be entered in label format.

5.6 Review of BPR:

5.6.1 Head-Production/Designee shall review the Executed BPR as per check list format QA007-FM008 and submit the same to QA within 48 hours or before release of batch which ever earlier. The receipt of the BPR shall be entered in “BPR issue and retrieval register” by QA.

5.6.2 Upon receipt of the completed BPR from Production, QA personnel shall check the same as per the check-list (QA007-FM008).


5.6.3 After completion of analysis, QC shall handover the completed analytical report to QA. The receipt of the completed analytical report shall be entered in the “BPR/Analytical issue and retrieval record” by QA.

5.7 Archival:

5.7.1 Keep the executed BPRs sequentially product, stage, and batch number wise separately in the document storage compactor.

5.7.2 Label the cover with details of year, product, stage and batch.

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5.8 Upon retention period completed of BPR and respective Analytical reports, a disposition on the batch shall be approval taken by Head -QA/ designee.

6.0 FORMATS / ANNEXURE(S):

- 6.1 Batch Production Record : QA007-FM150
- 6.2 Process observation sheet : QA007-FM111
- 6.3 Parameter record sheet : QA007-FM151
- 6.4 Powder processing Batch Production Record : QA007-FM152
- 6.5 BPR Review check list : QA007-FM008

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.06.2007	New SOP	---
01	01.07.2009	SOP format changed and reviewed for more clarity.	---
02	15.06.2014	Revised as per current SOP & more clear and clarity.	---
03	01.03.2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. Duration column removed. 3. BPR format included. 4. BPR review check list contents were modified. 5. Altogether procedure has been removed for better clarity.	QA-CRF-014/16
04	08.11.2017	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17028
05	20.12.2017	ECR Preparation and Numbering system has been introduced in the SOP.	CCF/GEN/17037

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