STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Disposition of Batch Returned Material	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for the disposition of batch returned material from production.

2.0 SCOPE:

This procedure is applicable to all materials issued to the production which are found abnormal in the quality before taking for processing / partially consumed/materials to be returned without opening the pack due to batch size change or change in the production plan.

3.0 RESPONSIBILITY:

Incharge -Production, Store, Quality Control & QA

Head - Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Procedure: A (For abnormal material)

5.1.1 Inform to shift in-charge/Plant in-charge whenever any abnormality observed in the raw material and packing material used in batch. Responsibility – Operator/Officer.

5.1.2 Disqualify (Put ‘X’) on the ‘Approved’ label. Responsibility – Officer

5.1.3 Fill the batch returned material disposition report (BRMDR) as per the format enclosed (Refer Annexure -II). Responsibility – Production.

5.1.4 Affix ‘TO BE SAMPLED’ label (with details) on the container separately. Responsibility – Production

5.1.5 Send a separate requisition slip along with the front page of BRMDR to raw material store for the issue of same quantity for process. Responsibility – Production

5.1.6 Issue new material from the same batch or next batch. Responsibility – Raw material store.

5.1.7 Send a note to production if any FIFO deviation observed in the raw material issue. Responsibility – Raw material store.

5.1.8 Fill a 'system deviation' for the FIFO deviation. Responsibility – Production.

5.1.9 Receive the new material from store and take for processing. Responsibility – Production

5.1.10 Send the BRMDR to Quality control department for sampling and testing. Responsibility – Production

5.1.11 Send a material return note, the copy of front page of the BRMDR and the raw material to raw material store after sampling by QC for storage. Responsibility – Production.

5.1.12 Draw sample for testing. Responsibility – Chemist /QC.

5.1.13 Keep the raw material in the 'Raw material storage area' of production plant.

5.1.14 Analyze the abnormality observed material and attach supporting data along with BRMDR. Give the comments about the quality in the BRMDR. Responsibility – QC.

5.1.15 Send the BRMDR to R&D for comments / suitability study irrespective of the quality. Responsibility – QC.

5.1.16 Conduct suitability study if required and give comments about the usage of material. Mention the suitability study reference number in the BRMDR. Responsibility – R&D. (QC personnel can assist for sampling)

5.1.17 Send the BRMDR along with suitability test report to QA. Responsibility- R&D.

5.1.18 Approve the BRMDR and give comments for the disposition of material. Responsibility : QA

5.1.19 Keep the approved BRMDR in QA. Send a copy of approved BRMDR to production, QC and raw material store. Responsibility - QA.

5.1.20 Affix label (Approved / Rejected) on the material based on QA decision. Responsibility - QC

5.1.21 Send the material to store along with material return slip to raw material store. Responsibility – Production.

5.1.22 Deduct the returned material quantity from the particular batch issue. Responsibility – Raw material store.

5.1.23 Issue to production as per the decision taken by QA if the material is 'accepted as is'. Responsibility – Raw material store

5.1.24 Deduct the entire stock of the particular consignment in the system if the material is

'Rejected'. Responsibility – Raw material store.

5.1.25 Disqualify (Put 'X') on the 'Approved' label on the entire consignment in the raw material store if the material is rejected. Responsibility – Raw material store.

5.1.26 Affix 'Quarantine' label (with details) on the container separately. Responsibility – Raw material store.

5.1.27 Keep the particular consignment in the raw material store till further decision will be taken by QA. Responsibility – Raw material store.

5.1.28 Draw samples from all the containers of the particular consignment and analyze. Responsibility – QC

5.1.29 Report the results of analysis to QA . Responsibility – QC

5.1.30 QA shall take decision about the disposition of the consignment (Either return to the supplier or to be sent for incineration) Responsibility – QA

5.1.31 Send a communication to QA about the rejected consignment if the material is to be returned to the supplier based on commercial department decision. Responsibility – Raw material store

5.1.32 Send the material for destruction as per SOP.

5.2 Procedure: B – For partially consumed material

5.2.1 Disqualify (Put 'X') on the 'Approved' label. Responsibility – Shift in charge.

5.2.2 Affix 'Quarantine' label (with details) on the container separately. Responsibility – Production

5.2.3 Fill the batch returned material disposition report (BRMDR) as per the format enclosed in Annexure I. Responsibility – Production.

5.2.4 Send the filled BRMDR to quality control department for sampling and testing. Responsibility – Production.

5.2.5 Draw sample for testing . Responsibility – QC Analyze the material only for identification by IR test in case of stable raw materials.

5.2.6 Analyze the material for critical test (s) for hygroscopic / sensitive material Responsibility – QC.

5.2.7 Enclose the supporting document along with the BRMDR and send to QA. Responsibility – QC.

5.2.8 Approve the BRMDR and give comments for the disposition of material. Responsibility : QA

5.2.9 Keep the approved BRMDR in QA. Send a copy of approved BRMDR to production, QC. Responsibility - QA.

5.2.10 Affix label (Approved / Rejected) on the material based on QA decision. Responsibility – QC

5.2.11 Send the, copy of approved BRMDR, balance material and raw material return slip to store. Responsibility – Production.

5.2.12 Receive and deduct the returned material quantity from the particular issue. Responsibility – Raw material store.

5.2.13 Dispose the material based on QA decision. Responsibility – Raw material store.

5.3 Procedure: C – Materials are return without opening the pack due to batch size change or change in the production plan

5.3.1 Send all the material to raw material store if any batch size change or change in the production plan along with raw material return note. (BRMDR is not required) Responsibility – Production.

5.3.2 Check all the raw material pack before accepting. Responsibility – Raw material store.

5.3.3 Receive the material if all the packs are in intact and deduct the quantity of all material for the particular batch issue and cancel the batch. Responsibility – Raw material store.

5.3.4 Raise a new requisition as per production plan and receive the material from store. Responsibility – Production.

5.3.5 Return the material to production if any pack found in opened condition. Responsibility – Raw material store

5.3.6 Follow batch return material disposition procedure. Responsibility – Production.

6.0 ABBREVIATION(S):

NIL

7.0 REFERENCE(S):

8.0 ANNEXURE (S):

ANNEXURE – I: Returned material information

ANNEXURE – II: Batch returned material disposition report

9.0 REVISION CARD:

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

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Annexure I

RETURNED MATERIAL INFORMATION (RMI)

From **RM Stores**	**To** **Commercial Department**
Name of the Product	
Batch No.:	
Inspection Lot No.:	
Purchase Order No.:	
Customer/Supplier Name & Address:	
Quantity:	
Reason for rejection:	

RMI	**Name**	**Signature**	**Date**
Prepared By **(In-charge) Dept.**			
Reviewed By **(Head – Dept.)**			

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Annexure II

BATCH RETURNED MATERIAL DISPOSITION REPORT (BRMDR)

Detail of Returned Material:	**Date:**
Name of the Material:	**Item Code:**
B. No.(s):	**QC. Ref. No.:**
Manufacturing Date:	**Quantity:**
Details of Container:	
No. of Containers received:	
No. of Containers in tact:	
No. of Containers in open:	
Physical condition of packing:	
Customer Details:	
Reason for Rejection:	

Proponent	Name	Signature	Date
Head–R/M Store			

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To be filled by QC

Material compliance with specification: ☐ **YES** ☐ **NO**

Comments:

(Enclose COA)

-	Name	Signature	Date
Head – QC			

To be filled by R&D

Comments:

-	Name	Signature	Date
Head – PD Lab			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Assessment by QA about Material Disposition

☐ **Accepted as is for Dispatch**
Comments:

Finished Goods Store shall dispatch the material on or before _____

☐ **Accepted for Reprocessing**
Comments:
Material shall be Reprocessed in _____

☐ **Rejected for Destruction**
Comments:

Corrective Action to be taken:

Communication to be sent to:

- ☐ **Finished Goods Store for Dispatch**
- ☐ **Production for Reprocessing**
- ☐ **Quality control for Information**
- ☐ **R&D for Information**

Approved By	Name	Signature	Date
Head - QA			