HANDLNG & DECONTAMINATION OF IN-PROCESS REJECTION

1.0 OBJECTIVE:

To lay down a procedure for Handling & Decontamination of In-Process Rejection.

2.0 SCOPE:

This SOP is applicable for Handling & Decontamination of In-Process Rejection during routine production.

3.0 RESPONSIBILITY:

Officer / Executive –Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 HANDLING AND DESTRUCTION OF REJECTED CONTAINER DURING FILLING / SEALING STAGE:

6.1.1 Rejected Container during initial adjustment of machine having less volume, Empty, neck cut, without dropper or leakage will be rejected online.

6.1.2 Such rejected containers shall be collected in designated bin in respective area and labeled as **"REJECTED CONTAINERS"**.

6.1.3 After completion of activity, rejected container bin open in respective area and rejection quantity shall be count in nos. and recording of rejection quantity in BMR and in log book as per **Annexure-I**.

6.1.4 Empty vials and ampoules shall be collected in separate container labeled as **"Empty Vials & Ampoules"** and send to scrap yard.

6.2 HANDLING & DESTRUCTION OF REJECTION DURING VISUAL INSPECTION STAGE:

6.2.1 After completion of visual inspection activity, rejection pigeon box shall be opened in presence of Production & IPQA personnel.

6.2.2 Different type of rejection shall be count and recorded in respective BPR and log book.

6.2.3 After recording of rejected quantity in BPR / log book, all type of rejection shall be transfer into Caret with proper status labeling as **"Rejected / Non Recoverable"**.

6.3 HANDLING & DESTRUCTION OF REJECTION DURING LABELING & PACKING STAGE:

6.3.1 During labeling & packing there are two typed of rejection shall be considered as per normal practices.

6.3.1.1 Non- Recoverable Rejection:

- Non recoverable rejection shall be considered if labeled container having damages / improper sealing or doubt on sealing integrity of container.
- Non recoverable container shall be kept in separate container labeled as **"Non Recoverable Rejection"**.
- After completion of labeling & packing activity, rejection shall be collected into plastic caret / container and transfer to destruction area for disposition.

6.3.1.2 Recoverable Rejection:

- Recoverable rejection shall be considered for those units having cross label, missing batch coding, smudge ink coding details or damage label during online labeling & packing activity.
- Recoverable rejection shall be collected in separate container having status label as **"Recoverable"** for further de-labeling & labeling.
- De-labeling shall be done in the presence of IPQA and production personnel and all de-labeled container shall undergo 100% visual inspection before labeling and packaging.
- De-labeling shall be performed by following method:
  - **a.** Remove the label by peel off followed by wet mopping of container label by clean cloth to remove the traces of label / gum.
  - **b.** Ensure that any sharp edge utensil i.e. knife, blade should not be used for de-labeling of vials/ampoules.
  - **c.** Ensure that vial/ampoules should not be scratched during de-labeling.
  - **d.** Count the entire vial /ampoules container and make entry in BPR.

Important Note: Don't use IPA or any other organic solvent to remove the de-labeling.

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7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
LDPE	Low density polyethylene
IPQA	In Process Quality Assurance
QA	Quality Assurance

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Handling & Decontamination of in-process Rejection	

9.0 DISTRIBUTION:

- Controlled Copy No.01 Production
- Controlled Copy No.02 Quality Assurance
- Master Copy Quality Assurance

10.0 REFERENCES:

Not Applicable

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		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

HANDLNG & DECONTAMINATION OF IN-PROCESS REJECTION

ANNEXURE – I

Department: **Line:**

S.No.	Product Details	Batch Number	Quantity of Rejected Material			Total Rejection	Checked By		Remark
			Filling & Sealing	Visual Inspection	Labeling & Packing		Prod. (Sign & Date)	QA (Sign & Date)	