



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Procedure for Handling & Destruction of In-Process Rejections

<b>SOP No.:</b>		<b>Department:</b>	Production	
		<b>Effective Date:</b>		
<b>Revision No.:</b>	00	<b>Revision Date:</b>		
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### 1.0 OBJECTIVE:

To lay down a procedure for Handling & Destruction of In-Process Rejections.

### 2.0 SCOPE:

This SOP is applicable for Handling & Destruction of In-Process Rejection during Filling & Sealing, Visual Inspection and Packing of products.

### 3.0 RESPONSIBILITY:

Officer/Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
DPI	Dry Powder Injection
HR	Human Resources
LI	Liquid Injection
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

Handling & Destruction of In-Process Rejection stage shall be done as per following procedure.

#### 6.1 FOR GENERAL BLOCK PRODUCTION AREA:

##### 6.1.1 Handling and Destruction of Rejected container during filling / sealing stage:

**6.1.1.1** Rejected Container during initial adjustment of machine having less volume, neck cut, defective tip or leakage will be rejected online.

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

**6.1.1.3** After completion of activity, rejected container bin transfer to unit preparation area and rejection quantity shall be count in nos. and recording of rejection quantity in BPCR and log book as per **Annexure-I**.

**6.1.1.4** After counting, rejected container (Filling & Sealing stage) shall be transferred in poly bag having status label "Rejected/Non-recoverable" and transfer to scrap area for further disposition.

**6.1.1.5** Before transfer to scrap area, flip off seal of filled and sealed vials shall be broken.



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**6.1.1.6** Rejected Ampoules / Glass vials shall be broken and solution shall be collected in separate container for further dilution in 1:5 ratio of treated water and further drain the solution in ETP for further treatment.

**6.1.1.7** Rejected empty ampoule / vials shall be crushed and collected in another container labeled as “**Glass scrap**” and send to scrap yard.

**6.1.1.8** Rejected LDPE container shall be opened by cutting the container and solution shall be collected in to another container for further dilution in 1:5 ratios of treated water and further drain the solution in ETP for further treatment.

**6.1.1.9** Empty / opened LDPE scrap shall be collected in separate container labeled as “**Plastic Scrap**” and send to scrap yard.

**6.1.1.10 Handling and Destruction of Rejected container during visual inspection activity:**

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

**6.1.1.12** Different type of rejection shall be count and recorded in respective BPCR and log book.

**6.1.1.13** After recording of rejected quantity in BPCR / log book, all type of rejection shall be transfer into Caret with proper status labeling as “Rejected / Non recoverable”.

**6.1.1.14** Collected rejection container shall be transferred to scrap yard for destruction.

**6.1.1.15** Before transfer to scrap area, flip off seal of filled and sealed vials shall be broken.

**6.1.1.16** Rejected Ampoules / Glass vials, flip off seal shall be broken and solution shall be collected in separate container for further dilution in 1:5 ratio of treated water and further drain the solution in ETP for further treatment.

**6.1.1.17** Rejected empty ampoule / vials shall be crushed and collected in another container labeled as “**Glass Scrap**” and send to scrap yard.

**6.1.1.18** Rejected LDPE container shall be opened by cutting the container and solution shall be collected in to another container for further dilution in 1:5 ratios of treated water and further drain the solution in ETP for further treatment.

**6.1.1.19** Empty / Opened LDPE scrap shall be collected in separate container labeled as “**Plastic Scrap**” and send to scrap yard.

**6.1.1.20** In case of partial inspected lot, rejection can be hold in lock & key at the end of same day activity.

**6.1.2 Handling & Destruction of Rejection during labeling & packing:**

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

**6.1.2.2 Non- recoverable rejection:**



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**6.1.2.2.1** Non recoverable rejection shall be considered if labeled container having hair crack, damages / improper sealing or doubt on sealing integrity of container.

**6.1.2.2.2** Non recoverable container shall be kept in separate container labeled as “**Non Recoverable Rejection**”.

**6.1.2.2.3** In case of vials, flip off seal shall be broken & deface the label with marker pen before putting the unit in container to avoid any mix-up during online activity.

**6.1.2.2.4** After completion of activity rejection shall be collected into plastic caret / container and transfer to destruction area for disposition as per section 5.1.2.5 to 5.1.2.9.

### **6.1.2.3 RECOVERABLE REJECTION:**

**6.1.2.3.1** 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.

**6.1.2.3.2** Recoverable rejection shall be collected in separate container having status label as “Recoverable” for further de-labeling & labeling.

**6.1.2.3.3** 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.

**6.1.2.3.4** De-labeling of Glass Ampoule / vials shall be performed by following method:

**6.1.2.3.4.1** Label shall be removed by peel off or dipping of container up to neck level in honey comb tray.

**6.1.2.3.4.2** Fill the water up to upper end of label in honey comb tray.

**6.1.2.3.4.3** Ensure that during de-labeling process vials do not dip completely in to the water inside the tray.

**6.1.2.3.4.4** Remove the label from Ampoule / Vials and clean it properly by using clean cloth.

**6.1.2.3.4.5** Count the de-labeled Ampoule / Vials and make entry in BMR / BPR.

**6.1.2.3.5** De-labeling of LDPE container shall be performed by following method:

**6.1.2.3.5.1** Remove the label by peel off followed by wet mopping of container label by clean cloth to remove the traces of label / gum.

**6.1.2.3.5.2** Ensure that any sharp edge utensil i.e. knife, blade should not be used for de-labeling of LDPE container.

**6.1.2.3.5.3** Ensure that LDPE container should not be scratched during de-labeling.



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**6.1.2.3.5.4** Count the entire de-labeled LDPE container and make entry in BPR.

**Important Note:** Don't use IPA or any other organic solvent to remove the label from all type of Container.

### 6.2 FOR DRY POWDER INJECTION BLOCK:

#### 6.2.1 Handling and Destruction of rejected container during filling / sealing stage:

**6.2.1.1** Rejected Container during initial adjustment of machine having less / high fill weight, without powder, without bungs & without flip off seal etc.

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

**6.2.1.3** After completion of activity, rejected container bin transfer to unit preparation area and rejection quantity shall be count in nos. and recording of rejection quantity in BPCR and log book as per **Annexure-I**.

**6.2.1.4** After counting, rejected container (Filling & Sealing stage) shall be transferred in poly bag having status label "Rejected / Non-recoverable" and transfer to scrap area for further disposition.

**6.2.1.5** Before transfer to scrap area, flip off seal of filled and sealed vials shall be broken.

**6.2.1.6** Rejected Glass vials shall be opened and powder shall be collected in separate container containing in 10% NaOH preparation solution add in 1:5 ratio for neutralization and further drain the solution in ETP for further treatment.

**6.2.1.7** Rejected empty vials, shall be collected in another container having 10% NaOH solution for neutralization of products traces.

**6.2.1.8** After neutralization crush the glass vials in container and transfer in poly bag labeled as "Glass Scrap" and transfer to scrap yard.

**6.2.1.9** Prepare the 10% NaOH solution by mixing 10 gm of NaOH pellets in 100 ml of water.

**6.2.1.10** Record the NaOH preparation & consumption record in **Annexure-III**, Titled "**Preparation & Consumption Record for Sodium Hydroxide Solution**".

#### 6.2.2 Handling and Destruction of rejected container during visual inspection activity:

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

**6.2.2.2** Different type of rejection shall be count and recorded in respective BPCR and log book.

**6.2.2.3** After recording of rejected quantity in BPCR / log book, all type of rejection shall be transfer into plastic container with proper status labeling as "Rejected / Non recoverable".



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**6.2.2.4** Collected rejection container shall be transferred to scrap yard for destruction as per section 6.2.1.5 to 6.2.1.8.

### **6.2.3 Handling & Destruction of rejection during labeling & packing:**

**6.2.3.1** During labeling & packing there are two typed of rejection shall be considered as per normal practices:

#### **6.2.3.2 Non- Recoverable Rejection:**

**6.2.3.2.1** Non recoverable rejection shall be considered if labeled container having hair crack, damages / improper sealing or doubt on sealing integrity of container.

**6.2.3.2.2** Non recoverable container shall be kept in separate container labeled as “**Non Recoverable Rejection**”.

**6.2.3.2.3** In case of vials, flip off seal shall be broken & deface the label with marker pen before putting the unit in container to avoid any mix-up during online activity.

**6.2.3.2.4** Flip off seal shall be broken before putting the unit in container to avoid any mix-up during online activity.

**6.2.3.2.5** After completion of activity rejection shall be collected into plastic caret / container and transfer to destruction area for disposition as per section 5.2.1.5 to 5.2.1.8.

#### **6.2.3.3 Recoverable Rejection:**

**6.2.3.3.1** 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.

**6.2.3.3.2** Recoverable rejection shall be collected in separate container having status label as “**Recoverable**” for further de-labeling & labeling.

**6.2.3.3.3** 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.

**6.2.3.3.4** De-labeling of Glass vials shall be performed by following method:

**6.2.3.3.4.1** Remove the label by peel off followed by wet mopping of container label by clean cloth.

**6.2.3.3.4.2** Clean the vial by wet mopping by clean cloth to remove the traces of label.

**6.2.3.3.4.3** Count the de-labeled Vials and make entry in BMR / BPR.



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### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	In-Process Rejection Log (Glass Ampoules / Vials)	
Annexure-II	In-Process Rejection Log (LDPE Container)	
Annexure-III	Preparation & Consumption Record of Sodium Hydroxide Solution	

**ENCLOSURES:** SOP Training Record

### 8.0 DISTRIBUTION:

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

### 9.0 REFERENCES:

Not Applicable.

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By







