



## STANDARD OPERATING PROCEDURE

**Title:** De-labeling of Filled and Sealed Vials

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 2

**1.0 OBJECTIVE:**

To lay down a Procedure for De-labeling of Filled and Sealed Vials.

**2.0 SCOPE:**

The SOP is applicable for De-labeling of Filled and Sealed Vials in Production area.

**3.0 RESPONSIBILITY:**

Officer / Executive Production

**4.0 ACCOUNTABILITY:**

Head Production

**5.0 ABBREVIATIONS:**

BMR            Batch Manufacturing Record  
BPR            Batch Packaging Record  
Ltd.            Limited  
No.            Number  
Pvt.            Private  
QA            Quality Assurance  
SOP            Standard Operating Procedure

**6.0 PROCEDURE:**

**6.1** During labeling, Vials are rejected due to improper Pasting, Peeling off the Label, Merging of Coding Details, Partial Printing, Cross Labeling etc.

**6.2** Arrange rejected Vials vertically in tray.

**6.3** Fill the water up to upper end of label and wait for half an hour.

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

**6.5** If vials submerge in water destroy that vials by removing the inner content.

**6.6** Remove the label from Vials and clean it properly.

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

**6.8** After QA release- re-label these Vials with fresh label followed by coding the overprinted matter same as per the details given in the particular BMR / BPR for that particular Batch.

**7.0 ANNEXURES:**

Not Applicable

**ENCLOSURES:** SOP Training Record



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### 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