



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Procedure for Re-Packing & Shrink Packing of Batch/ Product

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

1.0 OBJECTIVE:

To lay down a procedure for re-packing & shrink Packing of batch/ product.

2.0 SCOPE:

This SOP is applicable for the re-packing of the product or batch which are open for terminal inspection or any other reason of verification of packed batch in Production Packing Area of Parenteral Facility.

3.0 RESPONSIBILITY:

- Officer / Executive Production
- Officer /Executive QA

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Batch
BPR	Batch Packing Record
Ltd.	Limited
NA	Not Applicable
PD	Production
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
T.T.	Transfer Ticket

6.0 PROCEDURE:

- 6.1** Production shall give request for issuing additional pages to QA as per format “**Request cum Issuance form for Additional Pages**” in “**SOP**”.
- 6.2** After issuing additional pages, Production Officer / Executive shall perform the activity for re-packing of batch/ product.
- 6.3** Check the cleanliness of the Packing Area and ensure that it is free from the remains of the Previous Batch / Product.
- 6.4** Check the cleanliness below the turn table, Conveyor belt, Machine, Pallets for the absence of previous material processed in the area.
- 6.5** The line clearance of the Equipments/ Packing Area activities will be performed by Production Officer/ Executive and verified by QA Officer/ Executive as per check list given in respective BMR/BPR additional pages and shall affix the “**Line Clearance label**” as per SOP “**Status Labeling**”.



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- 6.6** Check the “Status Board” of the Packing Area for Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size, & MRP and ensure that the details are matching with the BPCR of present Batch to be processed.
- 6.7** Start re-packing of batch/ product & make entry of start time in log book & respective BPCR.
- 6.8** After completion re-packing of the batch/ product enter end time in log book & BPCR.
- 6.9** Attached the weight print of the re-packed of batch/ product in the BPR and record the details of the same.
- 6.10** If any additional packing material is used, should be reconciled after completion of packing.
- 6.11** If after re-packing, there is change in total packed quantity then the batch Transfer Ticket should be revised as per the revised quantity.
- 6.12** After completion of packing transfer the complete batch to Finish good store

7.0 ANNEXURES:

Not Applicable

ENCLOSURE: 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