PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Procedure for Packing Operation	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for Packing Operation.

2.0 SCOPE:

This SOP is applicable for to lay down general rules to be adopted in the packing section for maintaining, product identity and eliminating the potential mix-ups and smooth operation of the packing department.

3.0 RESPONSIBILITY:

Production: Operator/Officer /Executive/ Manager.

Head Production : To ensure execution and compliance

QA: To ensure the execution and compliance.

4.0 PROCEDURE:

4.1 Take line clearance of all the respective equipments involved in the operation as per SOP.

4.2 Check the product as per BPR and respective packing material with BPR requisitions sheet for conformance with identity and description before commencing operation as per SOP.

4.3 Transfer the primary packing material from PPM day store to the primary packing cubicle.

4.4 Transfer the bulk tablets/capsules from quarantine to the primary packing cubicle as per SOP.

4.5 Pack and store only one product at a time on any one packing line. Segregate the finished products and packing materials in the packing area by physical barrier or adequate special separation minimizing mix-ups.

4.6 Transfer the secondary packing material from packing material store to the respective packing line.

4.7 Technician of primary packing area shall be issued stereo for batch printing on printed Aluminium Foil as per BPR and SOP.

4.8 Technician shall give proof specimen of batch printing after his checking and signing on it to production officer/executive.

4.9 Production officer/Executive shall check the proof specimen with concerned BPR and give approval by signing on it followed by QA officer/Executive.

4.10 Similarly batch printing of secondary printed packing material (carton) shall be done and specimen proof shall be checked and signed by technician and then approved by production and QA officer/Executive.

4.11 For batch printing on final pack shipper, Handy coder shall be prepared as per BPR and specimen proof shall be made as per Annexure-I and signed by technician, then approved by production officer and QA officer/Executive.

4.12 Set parameter in Blister/Strip packing machine as per BPR and then start machine operation.

4.13 Carry out in-process checks during packing at regular interval in BPR as per SOP.

4.14 Ensure that checkers shall check blisters/strips, then allow to pack good blisters/strips and keep defective blisters/strips (Broken tablet, Empty pocket, misprint, black spot, cut pocket, improper sealing, deshaped blister) into rejection box under lock and key.

4.15 Empty out the rejection box when ever required/after completion of the batch under supervision of the Production supervisor.

4.16 De-foil the strips/blisters in the primary cubicle and collect the good tablets/capsules after inspection and do on-line packing.

4.17 Ensure no. of unit in carton packing as per BPR.

4.18 Ensure overprinting on carton as per BPR before it passes through Checkweigher.

4.19 Operate checkweigher as per its SOP.

4.20 Ensure no of unit pack carton in shippers packing as per BPR.

4.21 Perform Shipper sealing as per its SOP.

4.22 Stack the packed shipper on pallets batch wise with status label.

4.23 Weigh the packed shippers one by one and record the weight of packed shipper in BPR and recheck the shipper if found any discrepancy.

4.24 Report any discrepancies or irregularities during the packing operation to the department head and quality assurance department.

4.25 Fill the various logs to keep a detailed record of packing operation.

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Issue Date:	**Page No.:**

4.26 Return unused left over packing material to store as per SOP.

4.27 Destroy the left over printed packing material on completion of batch/product as per SOP and reconcile the same in BPR.

4.28 Collect and handle the non recoverable recovery as per respective SOP.

4.29 Check the BPR for correct completion of all documentation pertaining to the Packing, process before submitting it to QA.

4.30 Transfer the packed goods to BSR Finished Goods after completion of shipper weighing with QA approval.

5.0 ANNEXURE(S) :

Annexure –I: Shipper Coding Specimen.

6.0 REFERENCE(S):

SOP: Procedure for area line clearance.

SOP: Process for waste disposal.

SOP: Making entries in Inward/Outward Register in Production.

SOP: Procedure for indent, receipt, issue, use and destruction of rubber Stereo.

SOP: Reconciliation and destruction of left over coded packing material.

SOP: Return of unused left over packing materials to store.

SOP: In-process checks during Batch manufacturing and Packing.

7.0 ABBREVIATION (S) /DEFINITION (S):

BPR: Batch Packing Record.

ERP: Enterprise Resource Planning.

BSR: Bonded Store Room

QA : Quality Assurance

SOP: Standard Operating Procedure

IPQC: In Process Quality Control

PPM: Primary Packing materials.

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REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	--	--	NEW SOP	--