PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: IPQC during Packaging Operation	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1. **Purpose:** The purpose of this SOP is to define the procedure for in-process checks during packaging operation.

2. **Scope:** This SOP is applicable to in process checking during packaging operation at ……...

3. **References, Attachments & Annexures:**
   - 3.1 **References:**
     - 3.1.1 SOP No: Procurement, Handling and Destruction of Rubber Stereos
     - 3.1.2 SOP No: Cleaning and operation of Leak seal test
     - 3.1.3 SOP No: Cleaning and Operation of Check weigher
     - 3.1.4 SOP No: Challenge Test for Check weigher
     - 3.1.5 SOP No: Environmental Monitoring
   - 3.2 **Attachments:** NA
   - 3.3 **Annexures:**
     - 3.3.1 Annexure 1 - Action Plan taken during in-process checks failure in Packing
     - 3.3.2 Annexure 2 - Record for Physical Appearance of Tablet/Capsule and Morpholine test for PVDC foil.
     - 3.3.3 Annexure 3 – De-foiling verification record.
     - 3.3.4 Annexure 4 - Record for Roll Joints in Plain and Printed Foil.

4. **Responsibilities:**
   - 4.1 **Packing Department:**
     - 4.1.1 Packing person shall ensure timely documentation during on line packing.
     - 4.1.2 Packing person shall perform in process checks and record the same in BPR.
   - 4.2 **Quality Assurance Department:**
     - 4.2.1 QA person shall ensure timely documentation in BPR.
     - 4.2.2 QA person shall perform timely in process checks and record in BPR.
     - 4.2.3 To ensure the implementation of the SOP.
   - 4.3 **Quality Head, Regulatory Affair and Plant Head:**
     - 4.2.1 To review and approve the SOP.

5. **Distribution:**
   - 5.1 Quality Assurance
   - 5.2 Packing

6. **Abbreviations & Definitions of Terms:**
   - 6.1 **Abbreviations:**
     - 6.1.1 **SOP:** Standard Operating Procedure
     - 6.1.2 **BPR**: Batch Packing Record
     - 6.1.3 **NFD:** No Fill Detection

6.1.4 **BSR:** Bonded Storage Room
6.1.5 **BMR**: Batch Manufacturing Record
6.1.6 **QA:** Quality Assurance
6.1.7 **RH**: Relative Humidity
6.1.8 **PVDC:** Poly Vinyl Di-chloride
6.1.9 **MRP:** Maximum Retail Price
6.1.10 **Mfg. :** Manufacturing
6.1.11 **Exp. :** Expiry
6.1.12 **FIR :** Final Inspection Report

6.2 **Definitions of Terms:**

6.2.1 **Critical defect**: Defect those affect product Safety, Efficacy, Identity, and Purity (SISPQ) of product.
6.2.2 **Major defects:** Defect which affects the aesthetics of packing and become critical after period of time.
6.2.3 **Minor defects**: Defect that is not likely to become major or critical.
6.2.4 **Defects**: Any imperfection that would cause product damage.

7. Procedure:

Packing and QA person shall consider the following points while performing in-process checking during packing operation.

7.1 QA person shall check the stereo impression record as per SOP for Batch No., Mfg. Date, Exp. Date and MRP from METIS as per Work Order and approved Price List.
7.2 Check the BMR for Batch No., Mfg. Date and Exp. Date and on MRO it shall be stamping “REFER MFG. And EXP. Date from BMR and BPR only.”
7.3 Check the BPR for Batch No., Mfg. Date and Exp. Date and on MRO it shall be stamping “REFER MFG. And EXP. Date from BMR and BPR only.”
7.4 Check the temperature and RH of the cubicle as per SOP and record the same in the BPR at regular interval as specified in BPR.
7.5 QA person shall check the check weigher setting record at the start of packing activity as per SOP.
7.6 Packing person should ensure the performance of the leak seal test as per SOP at regular interval as specified in BPR and necessary entry to be made in the BPR.
7.7 Packing person should carryout Morpholine test for PVDC Foil used and QA person shall ensure the same and record in BPR or Annexure 2.
7.8 Packing person shall review the removal of strips which are likely to overheating due to machine stops. Also the operational efficiency of rejection mechanism that ensured and rejected due to heating, strips shall be separated immediately and shall be treated as non recovery.
7.9 Packing person shall check performance of Check weigher challenge test as per SOP and recorded in respective BPR and QA person shall be verified the same.
7.10 In case of any discrepancies observed by packing person then he shall intimate to HOD as well as QA.

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7.11 IPQA person shall de-foil the strip/blister and shall visually check the appearance of the tablets/ capsules at the initial, middle and final stage of packing and record in the annexure 2 or in respective BPR.

7.12 If rejected strips/blisters are to be de-foiled for packing, then de-foiling, sorting and packing activity is to be recorded as per Annexure -3 or in respective BPR.

7.13 Packing person and QA person shall check and verify respectively, the number of joints present in the printed foil and plain foil before operation and record in the Annexure – 4 or in respective BP.

7.14 During operation, operator shall attach all the joints in the BPR and record as per Annexure – 4 or in respective BPR.

7.15 After the completion of packing activity all the joints shall be physically checked by the packing person and it will be verified by the QA person as per Annexure – 4 respective BPR. After verification, all the joints shall be destroyed.

7.16 Packing and QA person should randomly select and inspect packed units for visual defects independently, from on line operation at intervals specified in BPR. In case of any defect is observed during in-process, follow the action plan as per Annexure -1 or in respective BPR.

Note: All sample of Morpholine test and Roll joints shall be destroyed after verification by QA and record shall be maintained.

7.17 In process checks during packing operation is segregated in two stages:

7.17.1 **Machine in process:** During machine in process, following points to be observed:

For Strip/Blister packing/Sachet/Bottle:

- Horizontal/Vertical Cutting
- Sealing temperature/Temperature of plate
- Forming Temperature
- No Fill Detection (NFD)/Camera
- Mfg/Expiry Date/Manufacturing License no.
- Unit Pack
- Ink Color

Note: IPQA shall ensure the machine in process check at the starting and every four hours up to batch completion.

7.17.2 **Line in process:** During line in process, following points to be considered:

Strip or Blister: The foil is inspected for the defects like

- ✓ Smudging
- ✓ Damage
- ✓ Empty pockets
- ✓ Cut pocket
- ✓ Defective printing
- ✓ Text missing
- ✓ Wrong/missing Manufacturing License no.
- ✓ Batch number.

- ✓ Proper Sealing (Peel Off problem)
- ✓ Manufacturing/Expiry Date
- ✓ Price and registration no, and
- ✓ Tablet appearance at the beginning, in the middle and at the end of the packing operation.

Show Box:

- ✓ The show box is inspected for the defects like dirty, torn, defective printing, text missing, wrong/missing Manufacturing License no., Batch No., Manufacturing/ Expiry Date, price and registration no., if any.
- ✓ **Package Insert/Outsert:**
  The package insert is inspected for the defects like Wrong/Missing Package Insert / Defective Printing/Text missing/Barcode Scanning.
- ✓ **Shipper:**
  The shipper is inspected for the defects like Dirty, Moist, Torn, Shipper label with wrong/missing Product name, batch no., Manufacturing/Expiry Date, Manufacturing License no., Quantity and Company address.
- ✓ Take random samples as per BPR for checking purpose and record the observation in BPR at specified interval.
- ✓ If any of the above defects are observed during the in process check of machine or line, then same should be rectified and brought to notice of Packing person and QA Head.

Note: IPQA shall ensure the secondary or Line in process check at the starting and every four hours up to batch completion.

7.18 **Visual defects:** All the above defects can be classified under Critical/Major/Minor as follows:

7.18.1 **Critical defects:**

- ✓ Product mix up
- ✓ Batch mix up
- ✓ Any visible contamination/cross contamination

7.18.2 **Major defects:**

- ✓ Defective printing and Defective Printed materials.
- ✓ Pocket punctured/torn and Pinholes
- ✓ Poor sealing (strips and blisters) and Improper Induction Sealing (Bottles)
- ✓ Broken tablet
- ✓ Knurling Defects/Cut pocket
- ✓ Leak seal test failure
- ✓ Coding missing/Coding not visible
- ✓ Wrong Bar Code, Stickers and Registration No. on Show boxes, Shippers, shipper labels, as applicable.
- ✓ Any change in the physical appearance of product

7.18.3 **Minor defects:**

- ✓ Dirty/Moist/Torn/Defective Shipper and Show Boxes
- ✓ Cross Labeling /coding
- ✓ Slightly Color variation in Packing Materials.
- ✓ Serial Numbering absent in Packed Inners and Outers.
- ✓ Shipper Label without Sign and date.
- ✓ Empty pocket.
- ✓ Less or more strip in a box

7.19 Make entry of the in process record of packaging operation in BPR.

7.20 If the shipper label is system generated (Metis), the shipper label shall be pasted on the shipper as space provided and duplicate copy is to be pasted inside the shipper or kept inside the shipper, as applicable.(In case of PS packing, no duplicate label is kept inside the shipper).

7.21 If the shipper label is of ITW signode shipper sealing machine, only one label shall be pasted on the shipper as space provided and no duplicate copy is to be pasted inside the shipper, but in case of loose shipper the shipper label shall be pasted on the shipper as space provided and duplicate copy is to be pasted inside the shipper or kept inside the shipper as applicable.

7.22 If any defect is found during in-process, then process is to be stopped immediately and problem to be rectified, all packed goods up to the last process to be checked.

7.23 After rectification of problem, the packing operation should be started and in-process checks to be performed.

7.24 The Packing person shall ensure that the filled shipper's pallets are transferred near the shipper weighing balance/overprinting machine, as applicable.

7.25 Packing person should check the legibility of over printing at regular interval.

7.26 Packing and QA person should ensure that the shippers are kept on the pallet for the verification of the BSR.

7.27 Packing & QA person shall ensure the quantity of packed goods in the loose shipper and sign in the shipper label before transferring it into the shipper's pallet.

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Annexure -1
Action Plan taken during in-process checks failure in Packing

Stage	In Process Test	Action if Limits of tests are not met
Packing	Leak Test	◆ Stop the machine ◆ Quarantine the strips/Blisters/Sachets/containers packed between previous Interval. ◆ Recheck the Strips/Blisters /Sachets/containers from the quarantine at random and repeat the Leak test. ◆ If found passing continue packing. ◆ If leak test falls perform random checks on previous shippers for leak test. ◆ All the shippers packed in that interval should be de-foiled. ◆ Falling packs should be destroyed. ◆ Strips/Blisters/Sachets/containers with defects like open pockets, poor sealing should be rejected, investigated and deviation should be recorded. ◆ In case, leakage is due to machine setting rectify the same and perform leak test and if found passing start the line. ◆ In case if leakage is due to packing material, reject the packing material, return to stores and perform the leak test on fresh materials, if found ok packing should be continued.
Packing	Camera/NFD	◆ Stop the machine ◆ Quarantine the strips/Blisters/Bottles packed between previous interval. ◆ Check all the quarantine strips/blisters/Bottles by performing 100% inspection. ◆ Rectify the NFD/Camera device. ◆ In case of Amber Al, Al opaque, Alu-Alu blister, de-foil all the packed blisters. ◆ Check proper functioning of NFD and alert the checkers. ◆ Start the line for packing.

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Stage	In Process Test	Action if Limits of tests are not met
Packing	Overprinting-details, Embossing	◆ Stop the overprinting or embossing. ◆ Destroy all the rejected overprinted/embossed materials. ◆ Check for damage of embossing stereo. ◆ Check for overprinting details, if found ok, start the line for packing. ◆ Start overprinting activity after checking proof from Quality Assurance. ◆ Check the quality of ink, ink roller, felt roller for proper overprinting.
Packing	Functioning of blisters sensor, leaflet sensor, carton sensor of cartonator	◆ Inform to department Head and Quality Assurance. ◆ Remove the filled cartons for rejection bin & check weigher. ◆ Rectify the problem immediately and check proper functioning before starting the line. ◆ Note: In this case shippers need not to quarantine because such packs are rejected by Check weigher.
Packing	Check weigher	◆ Stop the machine. ◆ Quarantine the packs weighed between the previous interval. ◆ Inform packing Head & QA for Investigation. ◆ Rectify the problem in Check weigher ◆ Calibrate the Check weigher. ◆ Pass all the quarantined packs packed in previous batch. ◆ Restart the complete packing activity.
Packing	Failure of bottle fill value	◆ Inform the department Head & QA. ◆ Quarantine the shippers packed between the previous interval. ◆ Remove that no filled bottles should be on line. ◆ The bottles in shippers should be unpacked in descending number of shipper & check no., of tablets by using count verification machine also check silica gel bag or cotton if applicable. ◆ Unpacking of bottles should be done until good pack is observed. ◆ Problem should be rectified and line officer should ensure containers fill value before starting the line.

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Annexure -2
Record for Physical appearance of Tablet/Capsule and Morpholine test for PVDC foil

PHYSICAL APPEARANCE			
Frequency: At the beginning/in the middle/at the end.			
De-foil the Strip or Blister and check for the appearance of the same. Note the observation below:			
Frequency	**Time**	**Date**	**Physical Appearance**
Initial			
Middle			
End			

RECORD FOR MORPHOLINE TEST FOR PVDC FOIL			
Frequency :For Every Roll Change			
Date	**Time**	**Test carried out by**	**Test checked By**

Note: All samples of Morpholine test shall be destroyed at the end of packing operation, (checks all sample & destroyed at the time of FIR preparation)

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Annexure-3
De-foiling verification record

Product	
Batch Number	
Mfg Date	
Expiry Date	

DEFOILING RECORD				
Date	**De-foiling Activity**		**De foiling done by**	**Checked by production**
	Start Time	**Stop Time**		

Note: Sorting to be done of the de-foiled tablets and then pack in last shipper

SORTING AND PACKING RECORD							
Date	**De-foiled tablets (kg)**	**Good tablets (kg)**	**Rejected tablets (kg)**	**Sorting done by**	**Packing done in shipper no.**	**Checked by production**	**Verified by (QA)**

REJECTED TABLET DESTRUCTION RECORD				
Date	**Total Quantity of rejected tablet in Kg or Nos.**	**Destruction done By**	**Checked By (Production)**	**Verified By (QA)**

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Annexure-4
Record for Roll Joints in Plain and Printed Foil

Product Name:		Batch Number:		Date:	
Total number of printed foil					
Total number of plain foil					

Roll Joints Records for Printed Foil					
S.No.	**Roll No.**	**Number of joints**	**Checked By (Packing officer)**	**Verified By (QA officer)**	**Roll changed by Operator Name/Date**

Remarks:……

……

……

Checked By (Packing officer)..... Verified By (QA Officer).....

Roll Joints Records for Plain Foil					
S.No.	**Roll No.**	**Number of joints**	**Checked By (Packing Officer)**	**Verified By (QA Officer)**	**Roll changed by Operator Name/Date**

Remarks:……

……

……

Checked By (Packing officer)..... Verified By (QA Officer).....

Note: All the roll joints shall be attached with BPR by the packing Officer/Operator and these joints shall be removed and destroyed after verifying by QA Officer.

8. History:

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