STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Packing procedure for Solid and Liquid Dosage form	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for packing of Solid and Liquid Dosage form.

2.0 SCOPE:

2.1 This procedure is applicable for packing of Solid and Liquid Dosage form.

3.0 RESPONSIBILITY:

3.1 Technical Associate/ worker - For Execution

3.2 Officer/ Executive Production Department- For verification and implementation of SOP

3.3 Head Production Department- Shall ensure compliance of the SOP.

4.0 DEFINITION (S):

4.1 **Dosage Form:** Dosage forms (unit doses) are pharmaceutical drug products in the form in which they are marketed for use, with a specific mixture of active ingredients and inactive components (excipients). Depending on the method/route of administration, dosage forms comes in solid, liquid, semisolid and Gaseous dosage forms:

4.1.1 **Solid Dosage Form:** Powders, Tablets, Granules, Capsules, Cachets, Pills, Lozenges, Suppositories, Poultices are solid dosage forms.

4.1.2 **Liquid dosage forms:** Collodions, Droughts, Elixirs, Emulsions, Suspensions, Enemas, Gargles, Gels, Linctuses, Lotions, Liniments, Mixtures, Mouth washes, Nasal drops, Paints, Solutions, Syrups.

4.1.3 **Semisolid dosage forms:** Ointments, Creams, Paste, Gels, Poultices.

4.1.4 **Gaseous dosage forms:** Aerosols, Inhalations, Sprays.

5.0 PROCEDURE

5.1 **Tablet & Capsule packing:**

5.1.1 Request the work order as per production plan to store for dispensing of Packing material.

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5.1.2 After dispensing transfer the Packing material from store to respective packing material staging area and secondary packing material to secondary packing quarantine with status label.

5.1.3 Dispensed carton, Label and leaflets to be stored under lock and key.

5.1.4 Start the packing process after taking the line clearance for primary packing (i.e strip, blister, Pouch, bulk packing etc.) and secondary packing.

5.1.5 Transfer the tablet or capsule from Quarantine area to primary packing cubicle after verification by production and Q.A, record the same in inward & outward register.

5.1.6 Production officer will Verify the packing Material before execution of packing activity as per status label for item, AR. no, quantity, Batch No., Product etc. Machine setting shall be carried out and all the bottles used in the settings destroyed at the end of packing process.

5.1.7 After striping or Blistering of tablet or capsule, manual packing shall be done as per following sequence -

Inspection → strip/blister Counting → carton (Printed/unprinted) packing along with leaflet / booklet (If applicable) → carton weighing on check-weigher → Carton printing → FMD label application on cartons (if required) → sealed carton packing in shipper / inner (Whichever is applicable) → Inner shipper printing or labeling (if applicable) → Inner/ carton packing in final shipper (Whichever is applicable) → Shipper taping → shipper strapping (If applicable) → shipper weighing (Printout to be attached if applicable) → packed finished material transfer to FG store.

5.1.8 After striping or Blistering of tablet or capsule, Cartonator packing shall be done as per following sequence -

carton packing along with leaflet / booklet (If applicable) on auto cartonator → carton weighing on check-weigher → Carton printing and FMD label application (if applicable)→ carton packing → carton packing in shipper / inner (Whichever is applicable) → Inner printing or labeling (Whichever is applicable) → Inner / carton packing in final shipper (Whichever is applicable) → Shipper taping → shipper strapping (If applicable) → shipper weighing (Printout shall be taken if applicable) → packed finished material transfer to FG store.

5.1.9 All the activity of point no. 5.1.7 and 5.1.8 which are performed, checked and recorded in BPR.

5.2 **Liquid orals packing i.e. bottle packing**

5.2.1 Request the work order as per production plan to store for dispensing of Packing material.

5.2.2 After dispensing transfer the Packing material from store to respective packing material staging area and secondary packing material to secondary packing hall with status label.

5.2.3 Dispensed carton, Label and leaflets to be stored under lock and key.

5.2.4 Start the packing process after taking the line clearance.

5.2.5 Production officer will verify the packing Material before execution of packing activity as per status label for item, AR. no, quantity, Batch No., Product etc.

5.2.6 The bottle shall pack as per following sequence :

Bottle washing → inspection of empty washed bottle → bottle filling & sealing → inspection of filled and sealed bottle → dosing cup insertion (If applicable) → Induction sealing (If applicable) → sticker labeling of filled and sealed bottle → inspection of labeled bottle → labeled bottle packing in carton / 3 ply inner / shipper (whichever applicable) → leaflet, Inserter, Dropper or any other required material insertion in carton (If applicable) → Carton / inner printing (If applicable) → carton / 3 ply inner packing in 5 ply/ 7 ply Shipper →Shipper taping → shipper Labeling (If applicable) → shipper strapping (If applicable) → shipper weighing → Shipper shrink wrapping (If applicable) → packed finished material transfer to FG store.

5.2.7 All the activity of point no. 5.2.6, which is performed, checked and recorded in BPR.

5.3 **Bulk packing**

5.3.1 Request the work order as per production plan to store for dispensing of Packing material.

5.3.2 After dispensing transfer the Packing material from store to respective packing material staging area and secondary packing material to secondary packing quarantine with status label.

5.3.3 Dispensed carton, Label and leaflets to be stored under lock and key.

5.3.4 Start the packing process after taking the line clearance.

5.3.5 Production officer will verify the packing Material before execution of packing activity as per status label for item, AR. no, quantity, Batch No., Product etc.

5.3.6 The Bulk packing as per following sequence :

Container cleaning with air jet cleaner →insertion of required filler such as silica gel pouch, Stablox etc. (Whichever is applicable) → Tablet / capsule counting with bulk counter → tablet/ capsule packing in container → closer placing on container → induction sealing for container → Sticker labeling of container with printing of batch details as per batch packing record → Placement of insert and its scanning (If applicable) →Scanning of helper code at 360 inspection and aggregation machine (if aggregation required) → Carton packing of container (If required) → Placing of inner shipper on bulk 2D inspection and aggregation machine for scanning (If required) → Leaflet or other required material insertion in carton (If required) → Carton printing → FMD label application on carton (if required) → labeled container / carton packing in 3 ply shipper / 5 ply shipper → insertion of Literature/ medication guide in inner / shipper (If required) → Shipper taping → shipper strapping → shipper weighing → packed finished material transfer to FG store.

5.3.8 All the activity of point no. 5.3.6, which is performed, checked and recorded in BPR.

5.4 **Pouch packing**

5.4.1 Request the work order as per production plan to store for dispensing of Packing material.

5.4.2 After dispensing transfer the Packing material from store to respective packing material staging area and secondary packing material to secondary packing quarantine with status label.

5.4.3 Dispensed carton, Label and leaflets to be stored under lock and key.

5.4.4 Start the packing process after taking the line clearance.

5.4.5 Production officer will Verify the packing Material before execution of packing activity as per status label for item, AR. no, quantity, Batch No., Product etc.

5.4.6 Start the packing process after taking the line clearance.

5.4.7 The Pouch shall pack as per following sequence :

Tablet counting with bulk counter or granules weighing (through manual weighing or through machine) → tablet/ granules packing in pouch → sealing of pouch with poly bag sealer or automatic machine Pakona → Labeling of pouch (If applicable) → Pouch weighing (If applicable) → inspection of labeled pouch (through foil or offline after packing) → labeled Pouch packing in carton / containers → Labeling of cartons (Manual process) / containers (with the help of labeling machine) → Weighing of carton / container → Packing of labeled cartons / containers in shipper → packed finished material transfer to FG store.

5.4.8 All the activity of point no. 5.4.7, which is performed, checked and recorded in BPR.

6.0 ABBREVIATION (S):

6.1 SOP : Standard Operation Procedure.

6.2 No. : Number.

6.3 BPR : Batch Packing Record.

6.4 PPM : Primary Packing Material.

7.0 REFERENCES (S):

7.1 NA

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Packers slip		

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department(02), Quality Assurance(01)

9.3 **Reference copy (s)** : Production department (03)

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10.0 REVISION HISTORY

S.No.	CHANGE CONTROL No.	REVISION No.	REASON (S) FOR REVISION	DETAILS OF REVISION	EFFECTIVE DATE
01	NA	00	New SOP	NA	

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ANNEXURE I
PACKERS SLIP

PACKERS SLIP

SHIPPER No.:

PACKED BY:

DATE:

Format No.:……..