PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Movement of Material from one Stage to Another	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for movement of material from one stage to another.

2.0 SCOPE:

2.1 This procedure is applicable to for movement of material from one stage to another stage during various processes in production department / stores department.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Operation

3.2 Officer and Executive : Supervision for cleaning and operation

3.3 Officer and Executive IPQA : Line clearance and SOP Compliance

3.4 Head Production : SOP Compliance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 Store to Dispensed Material Hold

5.1.1 Individual material shall be dispensed using clean individual SS scoops. Solvents shall be pumped from solvent store into stainless steel container.

5.1.2 During dispensing, raw material shall be transferred carefully from intact containers to double polybags using clean individual SS steel scoops.

5.1.3 The weight of the dispensed material shall be cheeked on pre-calibrated weighing balance.

5.1.4 Tie the mouth of inner polybag properly with fastener. Put the respective label in between two polybags. Then tie the mouth of outer polybag.

5.1.5 Transfer the dispensed material to the Dispensed Material Hold area.

5.1.6 In dispensed hold area all the materials to be kept on the pallets with shrink wrap/ cage trolley.

5.1.7 Make entry lot wise/batch wise in inward/outward register.

Note:

1. Place all the materials on pallets/ cage trolley only.
2. Before dispensing ensure that Q.C ‘APPROVED’ label is affixed on the container / bags.

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5.2 Dispensed material hold to Day's store

5.2.1 Collect and weight of dispensed materials as per respective BMR in Day's Store area before transfer to respective manufacturing area.

5.3 Day's Store to Granulation/Liquid Manufacturing

5.3.1 Transfer raw material from Day store lot wise to granulation area/ Liquid Manufacturing Area.

5.3.2 Transfer the dispensed material lot wise to sifting and paste preparation room followed by lubricants to sifting area.

5.3.3 Check the sieve number and integrity before setting it on vibratory sifter.

5.3.4 During sifting, material shall be transferred to sifter manually with stainless steel scoops.

5.3.5 Wear hand gloves/Personal protective equipment during sifting operation.

5.3.6 Collect the sifted material in pre-labeled SS IPC's used for sifting.

NOTE:-

1) Open the dispensed materials bag of the materials to be sifted one by one in sequence during sifting activity.
2) After sifting the Production officer ensure the sifted material and endorse with sign/date on back side of RM dispensing label.

5.4 Loading in to Paste Preparation Kettle

5.4.1 Transfer the binder in the sequence, mentioned in the respective BMR in to the paste preparation kettle/ SS container for preparation of binder.

5.4.2 Unload the binder in pre-labeled SS bin/container from the paste preparation kettle.

5.5 Loading in Rapid mixer granulator

5.5.1 Affix the IPC's of sifted material lot wise into Lifting and positioning device and lift the IPC above the top lid of RMG. Open the window of top lid. Load the Sifted material into RMG by opening the butterfly valve of the IPC's.

5.5.2 Transfer the binder solution in to the dry mixed material as per instruction and stage of operation mentioned in respective BMR.

5.5.3 If required, add measured quantity of additional purified water or solvent.

5.5.4 **Note:** Hold time of binder as mentioned in BMR.

5.6 Rapid Mixer Granulator to FBD Bowl for drying

5.6.1 Wet granules are to be unloaded directly into the FBD bowl by placing the FBD bowl below the discharge of RMG.

5.7 FBD to sifter and Multimill for sizing

5.7.1 Place the FBD bowl into tipper device and lift and tilt the bowl so that the mouth of the tipper sits perpendicular to the sifter to discharge the dried granules for sizing.

5.7.2 In case tipper is not present in the area load the dried granules from FBD bowl to sifter manually with the help of scoop.

5.7.3 Unload the sized granules in pre-labeled SS IPC's/container.

5.8 Sized Granules for lubrication

For Bin Blender:

5.8.1 Ensure discharge chute of the blender bin is closed.

5.8.2 Sized material and sifted lubricants are to be loaded directly into blender bin using Lifting and positioning device.

5.8.3 Before operation, ensure that air vent and top lid is firmly closed.

For Octagonal Blender 3000 Liters:

5.8.4 Bring the IPC's containing the sifted/milled material/granules to octagonal blender 3000 liters area.

5.8.5 Sized material and sifted lubricants are to be loaded directly into blender bin using Pneumatic Convening System.

Note:

1. Ensure that the discharge valves are close prior loading of granules in the blender.
2. Ensure that the safety guard is not locked during material loading.

5.9 Granulation area to granules quarantine

5.9.1 Bin blender containing lubricated granules shall be transferred to granules quarantine.

Note: Granules can be kept up to 30 days or as per product requirement mention in BMR in quarantine area before next step.

5.10 Granule quarantine to Compression or capsule filling/Compression or Capsule Feed Area

5.10.1 Check the specifications on status label of Bin blender as per respective BMR.

5.10.2 Transfer the Bin blender from granules quarantine into compression area.

5.10.3 Directly lift the Bin blender with the help of L & P device & position the butterfly valve of bin blender to hopper of compression machine.

5.10.4 In case of compression or capsule feed area directly fit the bin blender butterfly valve to hopper of feeding chute.

5.10.5 Collect the compressed tablets pass through metal detector and combo deduster in pre-labeled SS IPC's/HDPE containers lined with double poly bags.

5.10.6 SS IPC's/HDPE containers containing compressed tablets/capsule shall be transferred to tablet/capsule quarantine.

Note:1) Uncoated tablet can be kept up to 30 days or as mentioned in BMR of respective product in quarantine area before next step.

5.11 Compressed Tablet Quarantine

5.11.1 **Tablets/Capsules Stored in IPC's**

5.11.1.1 After completion of batch at compression stage, check the weight of IPC or all IPC's on the weighing balance or after completion of one by one container of batch and record in the respective BMR and kept in the quarantine on the floor and/or on the SS floor with the help of IPC's loader as per SOP "Cleaning and operation of IPC Loader".

5.11.1.2 Make entry container wise or batch wise in inward/outward log book.

5.11.1.3 Ensure that approved tablets are taken for coating.

5.11.1.4 Cross check the Weight of coating material with respect to respective BMR.

5.11.1.5 Transferred the cross checked coating material from coating material hold area to the coating solution preparation area.

5.11.1.6 Load the core tablets with SS scoop in the pan.

5.11.1.7 Transferred the coating solution into the coating solution hold tank.

5.11.1.8 Coated tablets shall be transferred to tablet storage area in pre-labeled SS container lined with double polybags.

Note: 1. Coated Tablet can be kept up to 30 days or as mentioned in BMR product wise in quarantine area before next step.

2. Hold time of coating solution as per mentioned in BMR.

5.11.2 **Tablets/Capsules/Pellets stored in HDPE Container's**

5.11.2.1 Pre tared container lined with double polybag shall be used for storage of tablets.

5.11.2.2 Enter the container tare weigh serially in BMR, serial no. shall be providing according to use.

5.11.2.3 Cleanliness of container shall be checked before use and record previous product and Batch no. serially according to use sequence. No need to preserve cleaned label incase of HDPE container is utilized for storage of intermediates.

5.11.2.4 Collect the compressed tablets/Capsules in the HDPE containers lined with double polybag, tie the inner polybag, folded the outer polybag, closed the lid, clean the outer surface of HDPE container with dry lint free cloth, transfer the respective quarantine containing 02 Nos of label product name, Stage, Batch number, Batch Size, tare weight and container No.

5.11.2.5 Take the gross weight without lid and record gross weight on label, calculate net weight, signed on label with date, keep one label outside of inner polybag and tied outer polybag. Another label with above information placed into label holder. Weight details recorded in respective BMR.

5.11.2.6 All containers of one batch staged on pellets. All the container/pellets of a single batch shall wrap for segregation.

Note: 1) Don't keep multiple batches on one pellet.

2) At the end of batch write the use before date and total number of container on outer label only

5.12 Coating to Inspection Area or quarantine to Inspection area

5.12.1 Transfer the coated /uncoated tablets /capsules to inspection area.

5.12.2 After Inspection, transfer the tablets / capsules in pre-labeled SS container lined with double polybags to Tablet/Capsule quarantine / Ready for packing quarantine.

5.13 Tablet/Capsule Quarantine to Blister /Strip Packing

5.13.1 Ready for packing tablets/capsules are kept in the quarantine. In case of place/move IPC's on SS floor with the help of IPC's stackers as per SOP "Cleaning and operation of IPC Loader".

5.13.2 Inspected approved tablet IPC's of a batch shall be transferred to blister/strip packing cubicle.

5.13.3 Blister packs and strip packs shall be transferred on conveyer belt to packing hall for packing into cartons and shippers.

5.14 Loading into Liquid manufacturing / Holding Tanks/ Filling line

5.14.1 Transfer the sugar into manufacturing tank through vacuum transfer device.

5.14.2 Transfer the API and other excipients into manufacturing tanks as per the instruction and sequence given in the manufacturing record.

5.14.3 Transfer the bulk through filtration unit to holding tank.

5.14.4 After release from QC start the filling and packaging as per the instructions given in the BPR.

5.14.5 **Note:** Hold time of liquid preparation as per mentioned in BMR**.**

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5.15 Movement of packing material (Tablet / Liquid)

5.15.1 Transfer the aluminum foil, PVC foil to the PPM staging area in primary area and shipper, cartons to the secondary packing area of tablet department.

5.15.2 Transfer the empty Bottles to the bottle decartoning area, ROPP caps to the filling area and Cartons, leaflets and shippers to the secondary packing area of liquid department.

5.16 Packing area to finished goods store

5.16.1 Packed goods shall be transferred to finished goods store after completion of batch or at the end of the day verified by quality assurance.

5.16.2 Packed goods shall be dispatched on requirement to respective location after release from Quality Assurance.

Note: Entries to be made in the Inward/Outward register as per SOP "Making entries in inward/outward register in In-process quarantine".

5.17 Movement of Process Waste/ Scrap.

5.17.1 Process waste (powder/tablets/used blister/empty bottles etc.) is to be collected from area waste bin at the end of the day or before change over of the respective area and treated as per SOP "Disposal in production department".

5.17.2 All collected process waste from IPQA, granulation, compression, coating and primary/secondary packing is to be sending to scrap room.

5.17.3 From scrap room send the collected waste i.e. blend/tablets/filled capsules to ETP and other waste material to scrap yard.

5.18 Movement of ready for packing/finished product.

5.18.1 Cross check the quantity of ready for packing/finished product in respective BMR.

5.18.2 Collect and move the ready for packing/finished product to PPM lift area.

5.18.3 Enter the details in Inward and Outward Log of the quarantine.

5.18.4 Bring the material to PPM store using PPM lift.

5.18.5 By following the Loading/Receiving Bay corridor to liquid corridor move the material from PPM store to FG-II area.

5.18.6 Move the material from FG-II area to RM store corridor.

5.18.7 By using material hatch move the material to GB expansion primary packing material corridor.

5.18.8 Now bring the material to ready for packing quarantine.

5.18.9 Enter the details in Inward and Outward Log of the quarantine.

PRECAUTIONS:

1. De-dust the outer surface of the containers and bins/IPC's with lint free duster.

2. Always maintain the inward and outward log of the quarantine.
3. Do not perform any haphazard activity during material movement.
4. Clean the out side of Bin/ IPC's using dry lint free cloth before transfer to another stage.

5.19 Flow chart for material movement:

1. Dispensed material movement from general block to general block expansion:

Dispensed material hold area in general block

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Store corridor in general block

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Liquid corridor in general block

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Receiving way air lock of general block expansion store

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General block expansion store corridor

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General block expansion material hold area air lock

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General block expansion material hold area

Note: Dispensed material movement from general block expansion to general block area is vice-versa as above flow chart 1.

2. Tablet/Capsule/Lubricated blend (Bin/IPC) movement from general block to general block expansion:

Quarantine area tablets/capsule/lubricated blend (Bin/IPC) in general block

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Corridor in general block

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RM/PM Lift in general block

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Store corridor in general block

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Liquid corridor in general block

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Receiving way air lock of general block expansion store

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General block expansion store corridor

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Material movement lift in general block expansion area

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General block expansion respective area corridor

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General block expansion quarantine

Note: Tablet/Capsule/Lubricated blend (Bin/IPC) movement from general block expansion to general block vice-versa as above flow chart 2.

3. Clean container/equipment movement from general block to general block expansion:

Clean container/equipment store in general block

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Corridor in general block

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RM/PM Lift in general block

↓

Store corridor in general block

↓

Liquid corridor in general block

↓

Receiving way air lock of general block expansion store

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↓

General block expansion store corridor

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Material movement lift in general block expansion area

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General block expansion respective area corridor

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General block expansion clean container/equipment area

Note: Clean container/equipment movement from general block expansion to general block vice-versa as above flow chart 3.

4. Primary packing material movement from general block to general block expansion:

Dispensed primary packing material hold area in general block

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Packing material lift in general block

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Store corridor in general block

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Liquid corridor in general block

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Receiving way air lock of general block expansion store

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General block expansion store corridor

↓

Material movement door in general block expansion area

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Primary packing corridor in General block expansion

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Primary packing material hold area in general block expansion

Note: Primary packing material movement from general block expansion to general block vice-versa as above flow chart 4.

5. Secondary packing material movement from general block to general block expansion:

Dispensed secondary packing material hold area in general block

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Finished good lift in general block

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Store corridor in general block

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Liquid corridor in general block

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Receiving way air lock of general block expansion store

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store corridor in General block expansion

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Secondary packing hall in General block expansion

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Secondary packing material hold area in general block expansion

Note: Secondary packing material movement from general block expansion to general block vice-versa as above flow chart 5.

6.0 ABBREVIATION (S):

6.1	FBD	:	Fluidized Bed Drier
6.2	SOP	:	Standard Operating Procedure
6.3	RMG	:	Rapid mixer Granulator
6.4	RM	:	Raw Material
6.5	SS	:	Stainless steel
6.6	IPC	:	In-process Product Container

6.7 HDPE : High Density Propyl Ethylene

7.0 RERERENCE (S):

7.1 SOP: Making entries in inward/outward register in Inprocess quarantine.

7.2 SOP: Cleaning and operation of IPC Loader.

7.3 SOP: Disposal in production department.

8.0 ANNEXURE (S):

8.1 Nil

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 (02), Store Department (01)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	NA