



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Movement of material from one stage to another	Effective Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for movement of material from one stage to another.

3.0 RESPONSIBILITY:

Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Store to Day store:

4.1.1 Dispensed material shall be transferred from stores to Day store area of manufacturing section in cage trolley/on pallet.

4.1.2 Dispensed solvent shall be transferred from store to day store area on pressure vessel.

4.2 Day Store To Granulation Area To sifting:

4.2.1 Cross check the weight of dispensed material in day store.

4.2.2 Dispensed material shall be transferred and kept on S.S Pallets/IPC Container and transfer from day store to granulation area.

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

4.2.4 Sifted material shall be collected in in-process containers/SS container.

Note:

- Dispensed raw materials can be kept up to 14 days in day store area before next step.
- If the raw materials kept for more than the specified period then each material has to be sending for test before next step.

4.3 Sifter to Rapid mixer granulator:



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4.3.1 Sifted raw material shall be transferred in RMG with the help of LPD. The IPC with sifted material shall be lifted and positioned over RMG charging window.

4.3.2 Material shall be loaded into RMG by opening the valve of in process container/poly-bag.

4.4 Rapid mixer granulator to FBD for drying:

4.4.1 Wet granules are to be unloaded directly into the FBD bowl.

4.5 FBD to Co mill for sizing:

4.5.1 Dried granules shall be passing through co-mill to get required size granules.

4.5.2 Sized granules are to be collected in IPC/ SS container.

4.6 Sized Granules for lubrication:

4.6.1 Sized material and Sifted lubricants collected in IPC/ SS container are to be loaded directly in Blender/ Bin Blender with the help of Vacuum Transfer System.

4.6.2 For Granulation area the bin of the pre-lubricated material shall be transferred to the Blending area. Sifted lubrication material shall be transferred to the blending area in ss container with the help of ss trolley.

4.6.3 Lubricated granules shall be transferred in IPC Bin with proper status label.

4.7 Granulation /Blending area to Granules storage area:

4.7.1 Lubricated granules shall be transferred to granules storage area in Bin/IPC containers.

Note:

- Granules can be kept up to 30 days in storage area before next step.
- If the granules kept for more than the specified period then granules have to be re tested before next step.

4.8 Granules Storage area to Compression/ Capsule filling :

4.8.1 Material for compression shall be transferred from granules storage area to granules feeding room.

4.8.2 Lubricated granules shall be feed to the compression machine from the granules feeding room with the help of SS Y- Chute / By manual scooping. (As applicable)

4.8.3 Material for capsule filling shall be transferred from granules storage area to capsule filling cubicle in ss container / IPC containers using ss trolley.

4.8.4 Lubricated blend shall be feed to the capsule filling machine by manual scooping in to hopper.



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4.9 Compression/ Capsule filling to Tablets and Capsule Storage area:

- 4.9.1 Collect the compressed tablets pass through Combo Metal detector cum Deduster in SS / HDPE container lined with double poly-bags.
- 4.9.2 Compressed tablet containers shall be transferred to tablet / capsule Storage area by using SS trolley.
- 4.9.3 Collect the filled capsules in SS / HDPE container lined with double poly-bags.
- 4.9.4 Filled capsules containers shall be transferred to tablet/ capsule Storage area by using SS trolley.

Note :

- Uncoated tablets/ capsules can be kept up to 30 days in tablet / capsule storage area before next step.
- If the Uncoated tablets/ capsules kept for more than the specified period then uncoated tablet/ capsules has to be re tested before Next step.

4.10 Tablets / Capsule Storage area to Coating Area:

- 4.10.1 Compressed tablet containers shall be transferred from tablet / capsule Storage area to coating by using SS trolley.
- 4.10.2 Coating solution shall be transferred from solution preparation room to coating area by using solution holding tank.
- 4.10.3 Dispensed solvent for coating / manufacturing to be transferred to areas in pressure vessel.

4.11 Day Store to Coating:

- 4.11.1 Weight of dispensed material shall be crosschecked.
- 4.11.2 Coating material shall be transferred from day store to solution preparation area.

4.12 Coating area to Tablets / Capsule Storage area:

- 4.12.1 Collect the coated tablets in SS /HDPE container lined with double poly-bags.



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4.12.2 Coated tablet containers shall be transferred to tablet / Capsule Storage area by using SS trolley.

Note:

- Coated Tablet can be kept up to 30 days in storage area before next step.
- If the Coated Tablet kept for more than the specified period then Coated Tablet have to be retested before next step.

4.13 Tablet / Capsule Storage area to Inspection area:

4.13.1 Transfer the Uncoated /coated/ Printed tablets/ Filled Capsules to inspection area by using ss trolley.

4.13.2 After Inspection, transfer the tablets/ Filled Capsules to tablet / capsule storage area.

4.14 Packing Material from PM store to Packing Area:

4.14.1 Transfer the dispensed packing material from PM store to Day Store area by closed SS cage trolley/on ss pallet.

4.14.2 Transfer the secondary Packing material to packing hall

4.14.3 Transfer the Primary packing material to the Primary packing material storage area in closed S.S. trolley/ on ss pallet.

4.15 Tablet / Capsule storage area to Blister / Strip Packing area:

4.15.1 For tablets/ Filled Capsules available in tablet / Capsule storage area transfer the required containers to primary packing room by using ss trolley.

4.15.2 Inspected tablet/ Filled capsules shall be transferred to Blister / Strip / Packing area by using SS trolley.

4.15.3 Blisters/Strips shall be transferred on conveyer belt/SS Table to packing area for packing into cartons or secondary packing materials.

4.16 Packing area to finished goods store:

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

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

4.17 From Finished Goods Store to packing area:



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4.17.1 Transfer the packed goods through the finished goods to the packing hall. Remove the shippers remove the Strip / blisters in ss container double lined poly-bag with lid and proper label. Pass the container to primary packing area.

De-foil the tablets from the primary pack and store in the respective primary area.

4.17.2 Collect the tablets in a S.S. container with double poly-bag duly labeled and transfer in tablet / capsule storage area on trolley.

4.17.3 Send the sample for Q.C. Analysis and inspect the de-packed tablets and transfer to storage area. (If required)

4.17.4 After release, transfer tablets to primary packing area.

Note:

1. Keep the batch on separate pallet or shrink wrap the total number of containers or segregate with help of rope chain (as applicable) for proper segregation in storage areas.

2. Use before Date for all stage should be count as follows;

- Operation end date is a zero day.
(eg. Operation date is 01/01/2020 use before date is 31/01/2020)
- For once retested Sample sampling date is a zero day.
(eg. Sampling date is 01/03/2020 use before date is 31/03/2020).

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Re-Dressing of Packed Finished Products.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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7.0 ABBREVIATION (S) /DEFINITION (S) :

- FBD : Fluidized Bed Drier.
- HDPE : High density polyethylene
- IPC : In process container
- LPD : Lifting and Positioning Device
- RMG : Rapid mixer Granulator

- SS : Stainless steel
- BPR : Batch Packing Record
- RM : Raw Material

REVISION CARD

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