



**PHARMA DEVILS**

**SOP FOR DISPENSING OF ACTIVE PHARMACEUTICAL  
INGREDIENTS AND EXCIPIENTS**

**SOP No.:**

**1.0 OBJECTIVE:**

To lay down the procedure for dispensing of active pharmaceutical ingredients and excipients.

**2.0 SCOPE:**

This SOP is applicable for Dispensing of active pharmaceutical ingredients and excipients.

**3.0 RESPONSIBILITY:**

Store Executive shall be responsible for implementing the SOP.

**4.0 PROCEDURE:**

**4.1 Planning**

4.1.1 Take weekly dispensing plan from Manufacturing Department. Get the Work order for the batches to be made in advance. Check the work order for products, batch nos., authorization and assay calculations (wherever applicable).

4.1.2 Check the availability of the released Active Pharmaceutical Ingredients and Excipients as per work orders. If there is any shortage in the released material report to Manager -Commercial. In case the material is available but under test from quality control department, no dispensing shall be done for such material.

**4.2 Preparatory work**

4.2.1 Arrange the cleaned SS Scoops/ Spoons / Spatula for materials to be dispensed.

4.2.2 Arrange cleaned SS pallets for keeping the dispensed materials.

4.2.3 Arrange cleaned S.S. tray for keeping potent API/Excipients.

4.2.4 Prepare the dispensing label by filling up necessary details on it for the material to be dispensed as per work order.

4.2.5 The differential pressure should be checked as per SOP. The reading should be filled in the format as annexure.

**4.3 Line clearance:**

4.3.1 Line clearance shall be given by Store Personnel and should be counter checked by Q.A. personnel.

4.3.2 Following are the key points to check line clearance:-

4.3.2.1 There is no material from previous product or batch including labels, documents in the dispensing area.

4.3.2.2 The floor is clean i.e. free from powder, oily matters, paper and lint.

4.3.2.3 The floor is dry.

4.3.2.4 The walls, view panels, doors and ceiling are free from powder deposits.

4.3.2.5 The grills are cleaned.



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4.3.2.6 The balance platform and table top are free from paper waste, lint, powder and dust.

4.3.2.7 The refuge bins are empty and clean from both inner and outer side, and should have clean poly bag inside.

4.3.2.8 The dust collector filter is cleaned.

4.3.2.9 The passages, inner and outer side glass, windows of pass box are clean.

**4.4 Equipment Cleanliness**

4.4.1 The Scoops, Spoons, Spatulas are cleaned and to be kept in SS box having 'CLEANED' status label.

4.4.2 The beaker or siphon pump to be used for dispensing of liquids is cleaned.

4.4.3 The containers to be used for dispensing of materials are cleaned from both inner and outer side.

4.4.4 Vacuum cleaner shall be cleaned after dispensing each product as per sop.

**4.5 Equipment setting:**

4.5.1 Check the calibration status of the balances.

**4.5.2** The zero error of balances is checked in the morning and recorded.

**4.6 Personnel hygiene:**

4.6.1 The personal cleanliness and hygiene shall be maintained as per SOP.

4.6.2 Clean gloves, snood and nose-masks if required are used during the dispensing operation.

**4.7 General precautions:**

4.7.1 The full sleeve gloves must be used only during actual scooping. Gloves must not be used while handling empty or filled container.

4.7.2 Clean snood, nose-masks or any suitable protective mask must be worn all the time during dispensing activity.

4.7.3 Any waste generated during operation must be removed immediately to the refuge bin. The bin must be closed properly so as to restrict the waste from coming out of it.

4.7.4 Material of one lot of a batch should be stored on one pallet.

4.7.5 Use clean intact hand gloves and clean scoop for dispensing of every ingredient.

4.7.6 Light sensitive materials should be dispensed under Sodium Vapour Light.

4.7.7 If there is any stoppage in the operation then no container should be left open.

4.7.8 Filter nose mask should be used wherever required.

4.7.9 During dispensing record the Temperature and Relative Humidity as per SOP at 09.30 a.m. and at 02.30 p.m (± 30 min)



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- 4.8 Used Gloves, polybags, fasteners generated from time to time must be stored in closed container specified for it and scrap them at the end of the entire batch.
- 4.8.1 The dispensing room must be kept clean and free from unnecessary material.
- 4.8.2 Dispense the material unto 150 gm on 220 gm capacity balance and similarly use suitable balance for dispensing of materials depending upon the quantities to be dispensed.
- 4.8.3 Stores Executive must carry out all dispensing operations in presence of production executive or quality assurance executive.
- 4.8.4 Entry and Exit procedure in Dispensing area should be followed as per SOP. Separate overcoats & booties should be used for dispensing of each Active Pharmaceutical Ingredients.
- 4.8.5 Always scoop out the entire quantity. Never pour the material by lifting polybag.
- 4.8.6 Check the manometer reading before commencing the dispensing operation as per SOP.
- 4.8.7 In case of power failure stop the dispensing operation. Wait to get restarted the 'AIR - HANDLING UNIT' and then 'BALANCES'. After resuming the power, wait for 15 minutes. Restart the 'Open fronted containment facility' and wait for 15-20 minutes before starting dispensing operation. **Note:** In case of a drum/ container of raw material and packs of printed packing material from which part material is dispensed for the batches, red tape (Approx 1" long) is to be affixed across on corner of the status label to indicate that the drum/ container/ pack has quantity which is less than the net quantity.
- 4.9 **Dispensing of excipients (other than Liquids):**
- 4.9.1 Dispense the excipients in sequence other than liquids as given in manufacturing work order.
- 4.9.2 Check the status of the required material physically for the following:
- 4.9.2.1 Q.C. release status.
- 4.9.2.2 Correct A.R. No.
- 4.9.2.3 Code No.
- 4.9.2.4 Pharmacopoeia & source status.
- 4.9.2.5 Retest date.
- 4.9.3 Take the container to the dispensing area through pass box.
- 4.9.4 Inspect the quality of the container before bringing the container inside the dispensing booth. If it is to be cleaned, take it outside the dispensing room and clean by wiping it with dry lint free cloth.
- 4.9.5 Take the material inside the Dispensing booth. Bring only one material in the dispensing booth at a time. Second material should be brought inside only when the first material is taken out from the booth.



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- 4.9.6 Check the name of the material to be dispensed on the labels of the original container as well as on Q.C. passed label against the work order and printed dispensing label.
- 4.9.7 Check the A.R.No., source code on Q.C. passed label and record the same on the dispensing label as well as on the work order.
- 4.9.8 Check the grade of the material on Q.C. passed label against work order & printed dispensing label.
- 4.9.9 Dispense the material in virgin polybag as below:
- 4.9.9.1 Take suitable cleaned container/ polybag for dispensing material. Check the Tare wt. of the container or virgin polybag in which the material is to be dispensed. Record the same on the dispensing labels and Work Order.
- 4.9.9.2 Calculate the gross weight required by adding tare weight and net weight of the material to be issued.
- 4.9.9.3 Open the container and observe for the quality of the material like extraneous particles, suspected fungal growth on container walls etc. If found, stop dispensing and bring it to the notice of department head immediately and further action should be taken in consultation with Q.A.
- 4.9.9.4 Transfer the material using clean scoop, from the original container to the dispensing container or polybag. Add the material till the gross weight is equal to the calculated gross weight. Record the Tare Weight, Net Weight and Gross Weight on dispensing label as well as on work order. Stores Executive shall sign the 'Weighed By' column and Production Executive shall sign the 'Checked By' column on dispensing label and work order.
- 4.9.9.5 Tie the polythene bag using cable tie / fastener after removal of entrapped air to the maximum extent possible from the bag. The upper end of the polythene bag should be twisted, folded and then tied firmly by cable tie / fastener so as to avoid spillage of material or to stop entry of air up to the maximum possible.
- 4.9.9.6 Put one label in between two polythene bags and another label on outer polythene bag using cable tie / fastener.
- 4.9.9.7 If material is dispensed in the bin, tie one label inside the bin & another label in the docket outside the bin.
- 4.9.9.8 For loose container, put the neutral label inside the container indicating all details, which are on the product label of that container. Close the container lid of that material properly and transfer it to the respective rack in approved area. Put the used scoops, hand gloves in polythene bag and transfer it in waste bin placed outside the booth for cleaning. "Used" utensils shall be moved to the washing area as per the SOP.
- 4.9.9.9 Transfer the container to the respective pallet and place it with the respective lot of the batch kept outside the dispensing room.
- 4.9.9.10 Even if the material is less than 100 gms then also it shall be dispensed in double polybag.
- 4.9.9.11 Use trolley for the movement of dispensed material to production area received through the pass box.
- Note:** After completion of weighing of one ingredient, clean the dispensing area, balance platform and table top with the help of vacuum cleaner/clean lint free cloth.
- 4.10 Clean the dispensing area after completion of dispensing activity.



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- 4.11 For dispensing of intact bag /container, transfer the container on weighing scale, check for Gross Wt., and record it on dispensing label and work order. Record the net weight as claimed by manufacturer on dispensing label and work order. Deduct the net weight from gross weight and record tare weight on dispensing label and work order. Cover the intact bags /container by virgin polybags.
- 4.12 **Dispensing of active ingredients:**
- 4.12.1 Follow the procedure as described in dispensing of excipients from point number 4.9.2 to 4.9.11.11.
- 4.12.2 Dispense all active materials under Open fronted containment facility & operate the OFCF. as per SOP.
- 4.12.3 Clean the Dispensing Area after dispensing of each API'S as per SOP.
- 4.12.4 Take the material inside the active dispensing area through pass box only as per SOP.
- 4.12.5 Use SS container / tray for the movement of material through pass box.
- 4.12.6 Check the source of active ingredients against the approved supplier list. Record the same on the work order.
- 4.12.7 Use black polybag and subdued light for light sensitive materials as per list provided by QA.
- 4.13 **Dispensing of liquids:**
- 4.13.1 Check the A.R. No. of raw material from A.R. No. list wise stock statement on FIFO basis to the extent practical.
- 4.13.2 Neat and clear dispensing pump shall be used for dispensing.
- 4.13.3 Check the status of the required material physically for the followings:
- 4.13.3.1 Q.C. release status.
- 4.13.3.2 Correct A.R. No.
- 4.13.3.3 Code No.
- 4.13.3.4 Pharmacopoeial status & Source code.
- 4.13.3.5 Retest date.
- 4.13 Loose container should be taken firstly for dispensing. (Wherever applicable).
- 4.14 Inspect the quality of the container. If necessary, clean it by wiping with dry lint free cloth. Use drum trolley for lifting and tilting the drums for dispensing if necessary.
- 4.15 Check the material name on the labels of the original container and passed label against the Work Order. Take the dispensing labels of this material for dispensing.
- 4.16 Check the A.R.No. on the container. Record the same on the dispensing labels and Work Order.
- 4.17 Dispense the material in S.S. canister as below:



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- 4.17.1 Check the Tare wt. of the canister in which the material is to be dispensed. Record the same on the dispensing labels and Work Order.
- 4.17.2 Calculate the gross weight requirement by adding tare weight and net weight of the material to be issued.
- 4.17.3 Add the material in S.S. canister till the gross weight is equal to the calculated gross weight. Record the same on the dispensing labels and Work Order. Record the net weight on the dispensing labels and Work Order. Stores Executive shall sign the 'Dispensed By' column and Production Officer shall sign the 'Checked By' column on dispensing label and work order.
- 4.17.4 Affix the dispensing label to the canister.
- 4.17.5 Close the container lid tightly.
- 4.17.6 Transfer the container to the pallet of respective lot of the batch kept outside the dispensing booth.
- 4.17.7 For dispensing of intact container, transfer the container on weighing scale, check for Gross Weight, and record it on dispensing label and work order. Record the net weight as claimed by manufacturer on dispensing label and work order. Deduct the net weight from gross weight and record tare weight on dispensing label and work order.
- 4.18 After completion of the weighing operation, check the Work Order for completion. Issue the batch to the manufacturing department along with the Work Order. Take signature for proper receipt of material. Hand over original copy of the work order to the production dept. and retain second copy in the Stores for accounting.

**5.0 SAFETY AND PRECAUTIONS:**

- 5.1 Before dispensing the hazardous raw material safety mask, goggles & gloves shall be worn.

**6.0 REVISION HISTORY:**

Revision No	Reason for revision	Superseded from and date
00	New SOP	

**7.0 REFERENCES:**

Not Applicable

**8.0 ABBREVIATIONS AND ANNEXURES:**

NO : Number



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Qty. : Quantity  
A.R. : Approved report  
QA : Quality assurance  
FIFO : First in first out  
FEFO : First expiry first out  
SOP : Standard operating procedure.

**9.0 ANNEXURE:**

Annexure-I : Dispensing Label  
Annexure-II : Loose Container label  
Annexure-II : Dispensing of Log Book  
Annexure-IV : Differential Pressure



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**Annexure-I  
Dispensing Label**

Item \_\_\_\_\_

Item Code \_\_\_\_\_ Gross Wt. \_\_\_\_\_

A.R. No \_\_\_\_\_ Tare Wt. \_\_\_\_\_

Net Wt \_\_\_\_\_

Product Name \_\_\_\_\_

Batch No \_\_\_\_\_

Dispensed By \_\_\_\_\_ Date \_\_\_\_\_

Checked By \_\_\_\_\_ Date \_\_\_\_\_





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**Annexure-II**

**Loose Container Label**

Item : \_\_\_\_\_

Item Code \_\_\_\_\_ Qty. \_\_\_\_\_

Count No \_\_\_\_\_ Of \_\_\_\_\_ Net Wt. \_\_\_\_\_

Date	Work order No	Qty. issued to Production Order (Kg)	Balance Qty. (Kg)	Issued By



