PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Dispensing of Raw Materials to Production Area	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Dispensing of Raw Materials to Production, Q-Block.

2.0 SCOPE:

This SOP is applicable to dispensing of Raw Materials to Production.

3.0 RESPONSIBILITY:

Operating Person – Warehouse

4.0 ACCOUNTABILITY:

Head – Warehouse

5.0 ABBREVIATIONS:

A.R.No.	Analytical Report Number
AHU	Air Handling Unit
API	Active Pharmaceutical ingredient
B.No.	Batch Number
BMR	Batch Manufacturing Record
BPCR	Batch Production and Control Record
FEFO	First expiry First Out
FIFO	First in First out
QA	Quality Assurance
RLAF	Reverse Laminar Air Flow
RM	Raw Material
SAP	System Application Products in Data Processing
SOP	Standard Operating Procedure
SS	Stainless Steel
WH	Warehouse

6.0 PROCEDURE:

6.1 Authorized Personnel's are allowed to enter the raw material dispensing area as per list displayed.

6.2 After receipt Planning Process Order/ Requisition from Production. Warehouse Officer/Executive shall debit or withdraw the material in SAP according to process order/Requisition. Warehouse Officer/Executive shall take the print of "Raw Material Issue Slip" and send to production for Cross verification of BOM.

6.3 After checking Officer/Executive Production shall send the signed copy to QA for verification and issuance of BMR.

6.4 After verification, Officer/Executive QA shall issue the BPCR to Officer/Executive Production.

6.5 After receipt of all documents Officer/Executive Production shall handover the BPCR to Officer/Executive Warehouse for dispensing of raw materials.

6.6 After receipt of BPCR, Officer/Executive Warehouse shall print the RM identification Slip.

6.7 After completion of above activities, Officer/Executive shall plan the dispensing of raw materials in the appropriate dispensing area and operate the RLAF as per SOP, **''Operation and Cleaning of Reverse Laminar Air Flow Unit''**.

6.8 Officer / Executive shall enter in the dispensing area following the gowning procedure as per SOP, **''Entry and Exit Procedure in Raw Material Dispensing Area Warehouse Q-Block''**.

6.9 For Line Clearance Refer **SOP** "**Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid".**

6.10 Officer/Executive shall check the area as per line clearance checklist as per BMR and fill the line clearance card for dispensing.

6.11 Officer/Executive Warehouse shall check the availability & validity of clean scoops, polythene bags, cable tie etc. required for dispensing of raw materials.

6.12 Officer/Executive Warehouse shall issue the raw materials product wise/batch wise following FEFO system.

6.13 Officer/Executive Warehouse shall collect the raw materials as per SAP Batch No. printed on RM identification Slip, on the pallets and transfer to material air lock of respective dispensing area.

6.14 Officer/Executive QA shall verify the following:

6.14.1 Issued BPCR is correct and properly arranged.

6.14.2 A.R.No. of raw materials as per RM identification Slip.

6.14.3 Do not use more than three A.R.No. API in any one batch or product.

6.14.4 Expiry date of finished product does not exceed than the expiry date of API.

6.14.5 Verify the seal of the raw material containers for dispensing of raw materials.

6.14.6 Availability of loose card/sampled label on the container.

6.14.7 Suitability of the temperature and relative humidity of the area with product.

6.14.8 Suitability of the Light with the product (Light sensitive).

6.14.9 Ensure that the AHU is ON.

6.14.10 Pressure differential of area as per its acceptance criteria.

6.14.11 Verification record of balance.

6.14.12 Ensure that the RLAF is ON.

6.14.13 Ensure that the Dynamic Pass Box is ON.

6.14.14 Pre-filter cleaning record of RLAF.

6.14.15 Calibration due date of hygrometer and magnehelic gauge.

6.15 Officer/Executive shall inform to Head Warehouse and Head QA in case of any deviation.

6.16 After verification, Officer/Executive Warehouse shall start the dispensing activity.

6.17 Clean the container by wiping with clean cloth before taking it to dispensing area.

6.18 Shift the raw materials containers one by one in the dispensing area through material static pass box.

6.19 Dispense the raw materials under RLAF in double polythene bag & tie it with cable tie & affix the RM identification tag and handover it to Officer/Executive Production in double poly bag.

6.20 Label each container by affixing one SAP Generated “Identification Slip" Affixes the label inside of the container between the two poly bags. Refer Annexure-XXXVII of SOP “Status Labelling” for format of Identification Slip.

6.21 Record the material details after Dispensed in **Annexure -I (Loose Container Bin) of SOP “Dispensing of Raw Materials to Production.**

6.22 Dispensing of Powder Raw Materials:

6.22.1 Dispense the loose quantities first in the double polythene bags.

6.22.2 Place the polythene bag on the balance platform and note the weight in BMR (Tare Weight).

6.22.3 Write the net weight to weighed in the BMR and calculate the gross weight and write in BMR.

6.22.4 Open the container, scoop/ladle out the material using previously cleaned scoop/ladle and this shall be put into the polythene bag which is already placed on top of the weighing platform and verify the gross weight as written in BMR.

6.22.5 During the dispensing, if any spillage observed follow the SOP (Spillage of Material).

6.22.6 Officer/Executive Warehouse shall sign the Issue Slip and affix it with material.

6.22.7 Shift the dispensed material to production day store through material hatch (Static Pass box) and the dispensed material shall be kept in SS cage trolley batch wise.

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6.23 Dispensing of Solvents/Liquid Raw Materials:

6.23.1 Dispense the solvents under RLAF in solvent dispensing area.

6.23.2 Dispense the solvents in SS container by weight.

6.23.3 Place the container on weighing platform and record the tare weight.

6.23.4 Calculate the weight of solvent/liquid to be dispensed using given below formula:

Weight in Kg.: Qty. issued in Ltrs. x wgt./ml
Where weight per ml of Isopropyl Alcohol is 0.78, Dichloromethane is 1.32,
Acetone is 0.79 and light liquid paraffin is 0.85

6.23.5 Transfer the required quantity by using barrel pump with the Stacking Filter Regulator.

6.23.6 Use cleaned/separate barrel pump for each solvent/liquid.

6.23.7 During the solvent dispensing, if excess quantity of solvent dispensed in the container, sampling cup shall be used for removing the excess quantity.

Note: In case for small Solvent/liquid containers below 50 Kg, dispensing shall be carried out directly by pouring the quantity available in the container into the S.S. Container. Dry mop the container before use with lint free cloth.

6.23.8 Weigh the solvent and wrote the details in BMR.

6.23.9 Officer/Executive Warehouse shall sign the Issue Slip and affix it with dispensed material container and hand over to production.

6.23.10 Shift the dispensed material to production day store through material hatch (Static Pass box) and the dispensed material shall be kept in SS cage trolley batch wise.

6.23.11 If Case of spillage of solvent/ liquid materials at dispensing period stores personnel shall **be handled as per SOP "Spillage Of Material"**

6.23.12 Issuance of Additional Quantity of Raw & Solvent/ Liquid Material

6.23.13 Material Requisition slip shall generate from SAP system.

6.23.14 Requisition slip shall be prepared by officer/ executive production and checked by HOD production and approved by QA.

6.23.15 The reason of additional quantity of material issuance will be mentioned on the additional material requisition slip. After filled requisition by SAP, Issue on SAP system.

6.23.16 After QA approval additional quantity of material shall be issued by warehouse personnel.

6.23.17 After receiving of the additional quantity of material manufacturing chemist will enclose original copy of requisition for additional quantity of material in the BPCR/BMR of respective batch of a particular Product.

6.24 After completion of dispensing activity, change the details on status board, clean the area and used scoops as per SOP, **''Area/Room Cleaning in Warehouse''** and, **''Handling and Cleaning of Dispensing Tools''**.

6.25 After completion of dispensing, enclose the line clearance card in the BMR at defined location.

6.26 Handover one signed copy of "Raw Material Issue Slip" along with BPCR to production along with dispensed raw materials and keep second copy in their record.

6.27 All the detail of dispensing activity will be recorded in **RLAF Utilization Record** as per **Annexure-II** of SOP**.**

6.28 Nitrogen Purging System:

6.28.1 Nitrogen purging system shall be used for the Sampling /Dispensing of the hygroscopic material as per requirement.

6.28.2 Ensure the nitrogen purging at the time of Sampling /Dispensing activity for Raw Material / liquid/solvent as per requirement.

6.28.3 Open the nitrogen line valve and ensure the air pressure of nitrogen gas between 0.5 to 2.0 kg and cm^2.

6.28.4 Flush (Drain) For 5 min. before use in Sampling /Dispensing activity.

6.28.5 Nitrogen Flushing shall be done in new sealed poly bags/ container in which the material going to be dispensed.

6.28.6 Fill the nitrogen gas inside the new sealed polybag. Container with the help of hand grip nitrogen flushing gun.

6.28.7 After completion of Sampling & dispensing activity close the valves of nitrogen gas.

6.28.8 Nitrogen purging detail shall be recorded in SOP, Annexure-III "Nitrogen Purging Log Book"

6.28.9 List of API/ Excipients, Liquid/ Solvent Available in sampling & dispensing booth which required Nitrogen purging AS per Annexure- VII of reference SOP.

6.29 Filter Integrity & Sterilization:

6.29.1 Filter should be placed inside the polybag and transferred to I-Block production area for filter integrity& sterilization.

6.29.2 Production person shall receive the filter and perform the filter integrity as per SOP

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6.29.3 After filter integrity and filter sterilization production person shall handover the filter integrity report and filter to warehouse person. Warehouse person shall store the filter integrity report.

6.29.4 Filter integrity shall be perform in **Quarterly ±7 Day or when over required.**

6.29.5 After Integrity of vent filter affix the status label as per Annexure-II '**Status label**" "SOP.

6.29.6 Record the filter Integrity details in Annexure –I" **Filter Integrity Testing Record of Vent Filters Title: Integrity Testing, Handling and Replacement of Vent Filters".**

6.29.7 Record the replacement details of vent filter in **Annexure No – III Vent Filter Replacement Record SOP.**

6.29.8 Record the vent filter destruction record in **Annexure No.- IV Vent Filter Destruction Record SOP.**

6.30 Cleaning of Dispensing Area during Material Dispensing Activity:

6.30.1 Dry Mopping: Dry mopping is done for the outer surface of RLAF, filter grills, floor, weighing balance platform by using lint free cloth. RLAF shall be in **"ON"** condition during the dry mopping.

6.30.2 Dry mopping shall be done from material to material (Excipients) changeover.

6.30.3 In RLAF utilization log book, dry mopping shall be written as "**D**".

6.30.4 If API of the different products are same, dry mopping shall be done.

6.30.5 Wet Mopping: Two types of wet mopping shall be done:

6.30.6 Wet mopping of dispensing booth shall be performed by mopping the surface by cleaning agent Lizol/Winpol/Dettol alternately and further sanitization by 70% IPA. RLAF shall be in **"ON"** condition during the wet mopping.

6.30.7 In RLAF utilization log book wet mopping shall be written as "**W**".

6.30.8 Wet mopping shall be performed in case of different API.

6.30.9 Wet mopping shall be performed after any maintenance work of product contact parts.

6.30.10 Wet mopping shall be performed for the changeover of the same product with descending potency.

6.30.11 Wet mopping shall be performed in case of Color/ Flavor/ Fragrances change (any strength).

6.30.12 Wet mopping of dispensing booth shall be performed by mopping the surface by cleaning agent Lizol/Winpol/Dettol alternately and further sanitization by 70% IPA. Filter shall be replaced in this cleaning. RLAF shall be in **"OFF"** condition during the wet mopping.

6.30.13 In RLAF utilization log book wet mopping shall be written as "**W1**"

6.30.14 Wet mopping shall be performed after 05 batches of the same product.

6.30.15 Wet mopping shall be done after the completion of batch.

6.31 Dispensing Shall be done as per below:

6.31.1 For single API for more than one batches:

(a) Individual Batch nos. entry will be shown in the Log book (RLAF Utilization Record) and the material shall be dispensed separately into the double poly bags for the respective batches at the same time and the operation details shall be updated accordingly to the respective batches.

For e.g. If the dispensing of Diclofenac sodium 20 kg, takes 5 minutes, the record will be updated as Batch No. 1, operation details 09.00 hrs. to 09.05 hrs. and the Batch No. 2, operation details 09.05 hrs to 09.10 hrs. With two respective entries, so on so forth.

6.31.2 For more than one API in a batch:

For the dispensing of the next API, the wet mopping shall be performed and API shall be dispensed separately into the double poly bags.

6.31.3 For Excipients/Colours:

Excipients shall be dispensed separately into the double poly bags and at the same time operation details shall be updated accordingly for the respective batches.

6.31.4 Dispensing process:

(a) Single material shall be transferred to dispensing area from material pass box.

(b) Dispensing shall be done in double polybag as per the required quantity.

(c) Dispensing shall be started for Raw Material (Powder): Excipients → API → Colour → Fragrance.

(d) Dispensing shall be started for Raw Material (Solvent/ Liquid): Excipients → API → Fragrance/ Perfume.

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7.0 ANNEXURES:

NA

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Warehouse
- Master Copy Quality Assurance

9.0 REFERENCES:

Schedule M of Drugs and Cosmetics Act 1940.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By