PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Dispensing of Non-Sterile Raw Material	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for the Dispensing of Non-Sterile Raw Materials.

2.0 SCOPE:

This SOP is applicable for Dispensing of Non-Sterile Raw Materials at Raw Material Store for injection facility.

3.0 RESPONSIBILITY:

Operating Person -Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

A.R No.	Analytical Report Number
BOM	Bill of Material
BPCR	Batch Production and Control Record
FEFO	First Expiry First Out
FIFO	First in First Out
IPQA	In process Quality Assurance
QA	Quality Assurance
Qty.	Quantity
RH	Relative Humidity
RLAF	Reverse Laminar Air flow
SOP	Standard Operating Procedure
WH	Warehouse

6.0 PROCEDURE:

6.1 General Instructions:

6.1.1 Ensure the Cleaning status of dispensing area.

6.1.2 Ensure the Room temperature, RH and pressure differential are in acceptable range.

6.1.3 Ensure the Balance for Calibration and its daily verification.

6.1.4 Ensure the Check the calibration due date magnehelic gauge, Hygrometer etc.

6.1.5 Ensure the RLAF is started before 15 minutes.

6.1.6 Only one material should be dispensing at a time.

6.1.7 First Dispense Excipients followed by Active and colors after solvent chemical shall be dispensed in the last (If any).

6.1.8 Material shall be dispensed under RLAF in a safe zone marked by red colour.

6.2 Procedure for Dispensing of Raw Materials:

6.2.1 After receipt Planning Process Order / Requisition from production, Warehouse Officer/Executive Shall debit or withdraw the materials in SAP according to process order /Requisition.

6.2.2 Warehouse Officer/Executive shall take the Print of "Raw Material Issue Slip" and send to production for cross verification of BOM.

6.2.3 After receipt of BPCR from production department, warehouse officer/executive shall plan the dispensing of raw materials.

6.2.4 Take the printout of identification slip after issuance the batch in SAP and affixes the inside of the container between the two poly bag.

6.2.5 Warehouse Officer / Executive shall check the Product Name, Batch No. , Batch Size and Control Stamp by QA.

6.2.6 Before start of Dispensing Store shall check for the availability of released approved raw material in stock both physically and in software.

6.2.7 If any shortage, Dispensing should not be start and shall inform to QA.

6.2.8 Warehouse officer / Executive shall transfer the approved material for Dispensing Area on Pallates as per the BOM of BPCR/BMR through trolley.

6.2.9 Warehouse shall ensure for the details of Approved Material for:

- Identity of the Material.
- Item Code Number
- Batch Number
- Manufacturing Date
- Expiry Date
- Retest Date

6.2.10 Start RLAF before 15 minutes of Dispensing Activity.

6.2.11 Take Line Clearance from QA before start of Dispensing Activity.

6.2.12 Warehouse officer / executive shall enter in dispensing Area from airlocks by proper gowning procedure as per SOP Entry and Exit 'Procedure in Non Sterile Raw Material Sampling/Dispensing Area in injection facility.'

6.2.13 De-dusted material Containers shall be entering inside through the Pass Box.

6.2.14 Record the A.R. No. and quantity of material dispensed in BPCR.

6.2.15 Dispensing activity shall be carried out under RLAF by taking one container at a time under RLAF and transfer the material in to a container carrying double poly bag.

6.2.16 Clean the balances and table top after dispensing at each material by clean lint free cloth dipped with 70% IPA.

6.2.17 In case of two or more API available in BOM, than below mention procedure shall be follow up.

6.2.18 After Dispensing of an API material, Inner surface and Outer surface of RLAF will be cleaned with lint free Cloth (Dry Cleaning

6.2.19 After dry cleaning of RLAF, mopping will be perform with 70% IPA (Wet Cleaning) then starts dispensing of next API as per BOM.

6.2.20 Before starting and after completion of Dispensing activity container outer surface shall be clean with 70% IPA.

6.2.21 Take the print of identification slip after issuance the batch in SAP and affix it inside of the container between the two poly bag.

6.2.22 Warehouse person shall ensure the material are dispensed following FEFO system strictly and shall check the material for its details.

6.2.23 Gross, Tare and Net Weight shall be recorded in identification slip.

6.2.24 IPQA person shall verify the dispensed material for name of material, Sap Batch No., weight and sign the identification label and BPCR/BMR.

6.2.25 All dispensed materials pass through by material out pass box.

6.2.26 Dispensed material shall be placed on trolley and handed over to the production along with the BPCR/BMR.

6.2.27 Used dispensing tools shall be kept in a container labeled with **"To be Cleaned"** and transferred to the equipment washing area for cleaning through pass box.

6.2.28 In addition to the above procedure special care should be taken while dispensing the light sensitive materials.

6.2.29 Switch off all light of dispensing during handling of light sensitive material.

6.2.30 Use two type poly bags, one white colour and another black colour.

6.2.31 White colour poly bag should put into black colour poly bag.

6.2.32 Use the sodium vapor lamp during dispensing.

6.2.33 Dispense the material in colour less bag.

6.2.34 Dispensed material black poly bag again put into the white poly bag for material verification with Raw Material identification slip in between poly bags.

6.2.35 Close the bags properly.

6.2.36 During Dispensing or after dispensing if material stock qty. not match with loose card then store person shall be verified the stock at present IPQA.

6.2.37 After verification store personal enter the all dispensed details in loose card, SOP Title **"Dispensing of raw material to production."**

6.2.38 After completion of physical verification of calculate the variance between book stock versus physical stock of RM if any discrepancy observed, **SOP "Reconciliation of Raw and Packing Materials''** shall be filled and forwarded to QA and plant head for approval of inventory adjustment Note.

6.2.39 Post Operation:

6.2.39.1 Completion of dispensing shall be followed by switch off of RLAF and cleaning of RLAF and **recording** of details in **"RLAF Utilization Record"** as per SOP Title **"Dispensing of raw materials to production''**

6.2.39.2 Dispensing area shall be cleaned and proper status shall be written on the status board.

6.3 Nitrogen Purging System:

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

6.3.2 Ensure the nitrogen purging at the time of Sampling/Dispensing activity for R.M as per requirement.

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

6.3.4 Flush (drain) for 5 min. before use in Sampling/Dispensing activity.

6.3.5 Nitrogen flushing shall be done in new sealed poly bags. / Container in which the material going to be dispensed.

6.3.6 Fill the nitrogen gas inside the new sealed polybag/container with the help of Hand grip nitrogen flushing gun.

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

6.3.8 Purging details shall be recorded in **Annexure- I "Nitrogen Purging Log book".**

6.3.9 List of API available in Sampling & Dispensing booth which requires Nitrogen purging as per reference SOP.

6.3.10 Filter Integrity & Sterilization:

6.3.11 Filter should be placed inside the polybag and transferred to production area for filter integrity & sterilization.

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

6.3.13 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.

6.3.14 Sterilized filter shall be transferred to warehouse Sampling/Dispensing area in surgical box.

6.3.15 Install the filter in nitrogen line of Sampling/Dispensing area.

6.3.16 Filter Integrity & sterilization shall be performed at a frequency of 15 ±2 Days.

6.3.17 Affix the filter stats label on all install filter show in **SOP.**

6.3.18 Record the details of install filter in **Annexure-II "Filter Install Record."**

6.4 Dispensing of Solvents:

6.4.1 Warehouse personnel are arrange the material to second floor non sterile dispensing area according.

6.4.2 BMR issued quantity provide by Lift from ground floor chemicals room & General block for large quantity.

6.4.3 All types of solvent/Chemical of small quantity which measure in unit Ltrs. shall be dispensed under RLAF by measuring cylinder.

6.4.4 All types of solvent/chemical of small quantity which measure in kgs. shall be dispensed under RLAF by weight on electronic Weighing Balance.

6.4.5 SS container / Glassware are kept on the platform of weighing balance for record tare wt.

6.4.6 After done dispensing warehouse personnel are sign the issue slip & identification slips and affix/ attached on the container and transferred to production by lift.

6.4.7 If case of spillage of solvent & chemicals materials at dispensing period stores personnel shall be handled as per SOP **"Spillage of Material".**

6.4.8 After completion of Dispensing activity store person shall be clean all dispensing area according SOP Title: Cleaning of Sterile and Non-Sterile Materials Sampling and Dispensing Area.

6.4.9 Cleaning & Sanitation Details of surrounding area will be recorded in **"Cleaning & Sanitation Record"** as per **SOP**

6.5 Issuance of Additional Quantity of Raw Material:

6.5.1 Material Requisition slip shall generate from SAP system.

6.5.2 Requisition slip shall be raised by production personnel approved by production.

6.5.3 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.

6.5.4 Additional material's requisition slip shall be further verified by IPQA personnel & Authorized by shift in-charge QA or Head QA personnel.

6.5.5 After QA approval additional quantity of material to issue by warehouse personnel.

6.5.6 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.

6.5.7 After dispensing all entries should be made in loose card, SOP Title **" Dispensing of raw material to production"**

6.5.8 Completion of dispensing shall be followed by switch off of RLAF and cleaning of RLAF and **recording** of details in **"RLAF Utilization Record"** as per SOP Title **"Dispensing of raw materials to production."**

6.6 Handling & Dispensing of Viscous, Expensive & Small Qty. Material:

6.6.1 Small qty. Material & viscous shall be handled and dispensed carefully.

6.6.2 During of receipt of material, Raw Material Receipt Check List shall be followed as per **SOP**.

6.6.3 Before start of Dispensing Store shall check for the availability of released approved raw material in stock both physically and in software.

6.6.4 If any shortage, Dispensing should not be start and shall inform to QA.

6.6.5 During dispensing of viscous material (In vial / pack) following steps shall be followed.

6.6.5.1 The gross weight, tare weight and net weight of vial shall be verified from receipt checklist.

6.6.5.2 Required material shall be dispensed and after dispensing the gross weight shall be verified.

6.6.5.3 Check the gross weight of vial after dispensing and this gross weight should be equal to the tare weight of vial (as per checklist) and remaining quantity as per quantity dispensed.

6.6.5.4 Above mentioned procedure shall be followed during next batches dispensing.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Nitrogen Purging Log book	
Annexure – II	Filter Installation And Destruction Record	

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:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

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ANNEXURE-I
NITROGEN PURGING LOG BOOK

Area: _____ **ID No:** _____

S. No.	Date	Product Name	Batch No	Purging Done by Sign & Date	Verified By QA Sign & Date	Remark

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ANNEXURE-II
FILTER INSTALATION AND DESTRUCTION RECORD

S.No.	Date	Location	Type of Filter	Filter Lot No.& Porosity	Filter Serial No.	Installation Dt.	Filter Integrity Dt.	Sterilization Dt.	Destruction On	Done By Sign. & Dt.	Verified By Sign. & Dt.	Remark