PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Dispensing of Packing Materials for Injection Section	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Dispensing of Packing Material for Injection Facility.

2.0 SCOPE:

This SOP is applicable for Dispensing of Packing Material in Packing Material Store for Injection Facility. .

3.0 RESPONSIBILITY:

Operating Person: Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

AR.No.	Analytical Report Number
BMR	Batch Manufacturing Record
BPCR	Batch Production and Control Record
BPR	Batch Packing Record
FIFO	First in First Out
LTD.	Limited
QA	Quality Assurance
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 After receipt of information from production Officer/Executive warehouse shall print "Packing Material Issue Slip" in duplicate and send to production for checking.

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

6.3 After verification Officer/Executive QA shall issue the BMR/ BPCR to Officer/Executive Production.

6.4 After receipt of all documents Officer/Executive Production shall handover the BMR/ BPR to Officer/Executive Warehouse for dispensing of packing materials.

6.5 After completion of above activities, Officer/Executive warehouse shall plan the dispensing of packing materials.

6.6 Officer/Executive Warehouse shall check the area as per line clearance checklist as per BMR/ BPR and fill the line clearance label for dispensing.

6.7 Officer/Executive QA shall verify the following:

6.7.1 Issued BMR/ BPR is correct and is properly arranged.

6.7.2 Verification record of balance.

6.7.3 Officer/Executive QA shall check the name of material, Material batch No. of material to be dispensed against the packing material issue slip.

6.7.4 Officer / Executive Warehouse shall inform to Head Warehouse and Head QA incase of any deviation.

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

6.9 Officer / Executive Warehouse shall issue the packing materials product wise / batch wise following FIFO system.

6.10 Dispensing of Primary Packaging Material:

6.10.1 Dispensed Packaging Materials to be used without coding & will be transfer to the respective section in Production Department (i.e. Three Piece Vial, Nozzle, Cap & Glass Vials /Ampoules to the Vials / Ampoules Decartoning Area, Rubber Stopper to the Bung Processing Area, Aluminum Seal to the Bung Processing Area and Granules to the production area.

6.10.2 Officer/Executive Warehouse shall issue the full Pack size of Three Pcs Vial, Nozzle, Cap, Glass Vial, Glass Ampoules, Rubber Stopper RFU & Rubber Stopper (General), Aluminum seal and Granules bag.

6.10.3 During Dispensing if required loose qty. in three pcs batches & RFU Rubber Stopper for dry powder batches then store person open the container/C-Box under LAF/RLAF and take the single full intact standard pack as provided by vendor & dispense required loose qty. and put in the double poly bag & close with cable tie with status label, Close the main C- box properly with tap.

6.10.4 After dispensing all entries should be made in loose card, **Annexure –I** SOP Title **" Dispensing of raw material to production."**

6.10.5 Loose Dispensing of Aluminum Seal or Rubber Stopper (General) Dispensed by weight under LAF/RLAF in Primary Packaging Sampling Cum Dispensing area and put in double poly bag close with cable tie with status label and transfer to the Production Area.

6.11 Operation of LAF/RLAF Unit:

6.11.1 Ensure that the area and LAF/RLAF unit is cleaned.

6.11.2 Switch ON the LAF/RLAF 15 minutes before activity of Sampling & Dispensing of packaging material.

6.11.3 Officer/Executive Warehouse shall be verify the reading of maganehelic gauge 5 to 15 mm of water and enter the details in **Annexure-III (Pressure Differential Record of LAF)**

6.11.4 Before any activity all box cleaned with lint free cloth & Transfer to under LAF/RLAF for dispensing.

6.11.5 After completion of the activity switch OFF the LAF and enter the details in **Annexure –IV (LAF Utilization Record)**

Remark: - If the Sampling/Dispensing activity of PPM completed under RLAF then follow the SOP "Title Operation and Cleaning of Reverse Laminar Air Flow Unit"

6.12 Cleaning of LAF/RLAF:

6.12.1 Switch "OFF" the mains.

6.12.2 Clean all surface with clean lint free cloth.

6.12.3 Filter shall be cleaned as per respective SOP.

6.12.4 LAF/RLAF Unit shall be mopped with 70% IPA once in a day before starting the activity and enter Details in **"Cleaning and Sanitization Record of LAF"** as per **Annexure – II.**

6.13 Dispensing of Secondary Packaging Material:

6.13.1 Officer/Executive Warehouse shall issue Cartons/Catch Covers by counting or if required by weight, in a polythene bag, tie it with cable tie & transfer to over printing area of I & Q-Block injection facility and enter the details in BPR.

6.13.2 Officer/Executive Warehouse shall issue the printed label rolls as per mention qty. inner side the core of label and count by label counter machine in a sealed container polythene bag, tie it with cable tie & transfer to over printing area of I & Q-Block injection facility and enter the details in BPR.

6.13.3 Officer/Executive Warehouse shall issue the printed Foil/PVC/PVDC/PG Paper by weight. Printed foil should transfer in sealed container polythene bag, tie it with cable tie & transfer to over printing area and enter the details in BPR.

6.13.4 Officer/Executive Warehouse shall issue leaflets/Polybag/Corrugated Box by counting or if required by weight & transfer to secondary packing area and enter the details in BPR.

6.13.5 Officer/Executive Warehouse shall issue as BOPP Tape / Cello Tape in role and transfer to secondary packing area and enter the details in BPR.

6.13.6 Affix line-clearance label in BPR at designated location after completion of dispensing.

6.13.7 After completion of dispensing, Officer/Executive Warehouse shall handover duly signed one copy of packing material issue slip to production along with BPR and keep the second copy in warehouse record.

6.13.8 All the details of dispensing activity will be recorded in **"Packing Material Dispensing Log Book"** as per **Annexure –I**.

Remark: Storage of Printed label and Foil available in I Block store only, Dispensing of these materials done from I block stores to Injection block with proper documents as per the requirements.

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6.14 Issuance of Additional Quantity of Packaging Material:

6.14.1 Material Requisition slip shall generate from SAP system.

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

6.14.3 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.

6.14.4 Additional material's requisition slip shall be further verified by IPQA personnel & Authorized by shift incharge QA or Head QA personnel.

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

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

6.14.7 All the details of dispensing activity will be recorded in **"Packing Material Dispensing Log Book"** as per **Annexure –I**.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Packing Material Dispensing Log Book	
Annexure-II	Cleaning and Sanitization Record of LAF	
Annexure-III	Pressure Differential Record of LAF	
Annexure-IV	LAF Utilization 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:

Schedule M of the Drugs & 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

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ANNEXURE – I
PACKING MATERIAL DISPENSING LOG BOOK

Block: **Month & Year:**

Date	Product Name	Batch No.	Material	Dispensed Qty.	Unit	Time		Dispensed By	Verified By	Remark
						From	To			

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ANNEXURE – II
CLEANING AND SANITIZATION RECORD OF LAF

AREA: **LAF ID No:**

Frequency: Daily **Cleaning & Sanitization Agent:** 70% IPA

Date	Cleaning and Sanitization		Done By	Checked By Officer/Executive Warehouse/QC	Verified Officer / Executive (QA)	Remarks
	From	To				

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ANNEXURE – III
PRESSURE DIFFERENTIAL RECORD OF LAF

AREA: **LAF ID No:**

Date	Time ↓	Pressure Differential	Monitored By Officer/Executive (warehouse/QC)	Verified By Officer / Executive (QA)	Remarks
	Limits →	HEPA Filter 5-15 mm of water			

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ANNEXURE-IV
LAF UTILIZATION RECORD

Date	Product Name & @Activity	Batch No.	Status of Activity	Operation Details						Cleaning Details				
				LAF "ON" Time	From	To	Done By	Checked By	Verified By	From	To	Done By	Checked By	Verified By

Remark: @Activity means Preventive Maintenance, Breakdown