PHARMA DEVILS

WAREHOUSE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a Procedure for Dispensing of Sterile Raw Material.

2.0 SCOPE:

This SOP is applicable for Dispensing of Sterile Raw Material in Raw Material Store in Injection Section.

3.0 RESPONSIBILITY:

Operating Person-Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
BPR	Batch Processing Record
FIFO	First in First Out
FEFO	First Expiry First Out
IPA	Iso propyl Alcohol
LTD.	Limited
Qty.	Quantity
QA	Quality Assurance
RM	Raw Material
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 “Raw Material Issue Slip” in SAP 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 BPCR.

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

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

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

6.6 After completion of above activities, Officer/Executive shall plan the dispensing of raw materials in the appropriate dispensing area.

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6.7 Enter the Store operator in dispensing area for dispensing as per **SOP "Entry & Exit in Sterile RM Sampling Cum Dispensing Area".**

6.8 Adequate No. of Sterile Garment (Boiler Suit, Head gears and Booties) should be available in Sterile Garment Storage Cabinet.

6.9 All the personnel to be involved in dispensing of raw material have worn proper Protective clothing e.g. inner Garments, Boiler Suit, Head gears and Booties.

6.10 Cleaned, Dry & Depyrogenated Tools required for dispensing are available.

6.11 The Dispensing Area shall be free from previously Dispensed Material and other unwanted material, the balances inside the Dispensing Area shall be Cleaned and daily verification and Calibrated.

6.12 Clean, Dry & Depyrogenated Tools will be transferred in to Dispensing room only through the designated Pass box.

6.13 After verified by QA all the dispensable Material will be brought from Approved area to the dispensing area one by one. The material of one Batch shall be dispensed at a time

6.14 Switch ON the RLAF for 30 minutes before starts Dispensing activity by store person.

6.15 Store Personnel will inform to QA department for line clearance and Production department to depute their personnel to monitor the dispensing activity of Raw material. QA person and production Person with warehouse officer will monitor the dispensing activity from the glass panel located in corridor.

6.16 Store Personnel will ensure that materials are dispensed following **FEFO** & **FIFO** system strictly.

6.17 **Dispensing of Sterile Material:** Dispensing of Sterile Materials will be done as per below mentioned procedure either in loose qty or as intact containers of sterile raw material.

6.17.1 **Dispensing of Loose Qty. of Sterile Material other than DPI:** Dispensing of Loose Qty. of Sterile Material will be done under RLAF in dedicated dispensing room.

6.17.2 Clean & Sterilized Dispensing tools will be brought inside the dispensing Room using Pass box designated for the same.

6.17.3 Dispensable Approved Raw Materials Containers outer Surface will be cleaned with 5% Salvicide/Virosil.

6.17.4 Switch 'ON' the RLAF 30 minutes before the start of dispensing activity and mention the record in RLAF Utilization Record as per SOP.

6.17.5 The Door of Pass box will be open from non sterile side and Materials container will be transfer or allowed to stay for 10 minutes inside under UV light.

6.17.6 Door of Pass box from Sterile Side will be Opened and all the containers from Pass box will be removed out and transfer inside the Sterile Materials sampling cum Dispensing Room in under RLAF.

6.17.7 Container will be opened under RLAF and required qty.of it will be dispensed in sterile container using the balance which shall again kept in sterilized SS container under RLAF.

6.17.8 After dispensing of material, sterile RM container having dispensed material as well as container having remaining material shall be closed properly.

6.17.9 Sterile RM container shall be closed after part API dispensing activity by placing the sterilized aluminum seal as per applicability of container size lid and crimp the aluminum seal with the help of sterilized sealer arms under grade A.

6.17.10 Sterile RM pouch having remaining material shall be closed with sterilized aluminum Tape which shall be followed by sealing of outer polybag with sealer machine and transferred to the approved sterile RM area.

6.17.11 **"Raw Material Dispensing Label"** will be filled and affixed on the entire individual poly bag by filling all the details required as per format provided for the same.

6.17.12 Dispensed Materials will be transferred for Production Department through Pass Box. From here it will be transferred in the lock & key cage trolley, and transfer to the Production Department through the Lift provided for the same.

6.17.13 Containers having remaining qty. of sterile material will be place at its specified place in the Store under Approved area.

6.18 Dispensing of Sterile Materials for DPI:

6.18.1 Dispensable approved materials container having "Approved Label will be brought from Approved Area.

6.18.2 On the basis of Tare weight given by the supplier net weight of the entire individual Dispensed Container will be calculated.

6.18.3 Raw Material Container keep on the weigh balance by warehouse person & verify the gross weight of container.

6.18.4 **Raw Material Dispensing Label"** will be filled and affixed on the entire individual container by filling all the details required as per format provided for the same.

6.18.5 Wrap the Raw material container & aluminum seal as per container size in Double polybag with Cable tie.

6.18.6 Load the Raw material container on lock & key cage trolley to transfer from sterile Approved Area to Production Area By operating lift ensuring cleaning of lift.

6.18.7 Unload the Raw material container from lift & Remove the Primary poly bag of Raw material Container than Transfer in RM Day Store through the Pass Box.

6.18.8 Production person Take the Raw material container from pass box in RM Day Store. Raw material container Transfer from RM Day Store to Material entry room by the help of trolley.

6.18.9 Production person will record in and out entry of sterile material in RM day store as per SOP, SOP Title ‘‘**Dispensed Material Inward and Outward Movement’’** titled ‘‘**Dispensed Materials Inward and Outward Movement”.**

6.18.10 Production personnel will be requested to take it and kept in RM Day Store, before starting filling operation, Raw Material Container transferred to Buffer Zone through the dynamic pass box for 10 min. under UV light. Before keeping in Dynamic Pass box, sanitize the outer surface of Raw Material Container with 5% Silviside and further by using Mobile LAF.

6.18.11 Production Personnel will kept the container in under Bench LAF of buffer room & open the seal of the container and dispense the required quantity of Raw Material in pre sterilized suitable Vessels / Utensils by pre Clean & Sterilized Scoops on suitable pan balance.

6.18.12 Sterile RM container shall be closed after part API dispensing activity by placing the sterilized aluminum seal as per applicability of container size lid and crimp the aluminum seal with the help of sterilized sealer arms under grade A.

6.18.13 Ensure the proper crimping of the API container, in case of crimping is not proper then re-crimp the seal of the container properly or use the new seal.

6.18.14 Incase intact container, it shall be transfer directly in filling area by mobile LAF from dynamic pass box (refer point no. 6.18.10) as such for further process aseptically.

6.18.15 Raw Material Stores personnel will receive the container, weigh it for its Gross weight and calculate the net returned quantity.

6.18.16 For the dispensing of any materials qty. in grams or in mg analytical weighing balance will be used for more accuracy.

Note:

- ***Intact sterile RM container (batch size) can be proceed as per customer requirement.***
- ***Loose quantity of above mentioned sterile RM shall be consumed within 75 days from the date of its opening.***
- ***Sterile RM container shall not be open more than 4 times.***
- ***If the Sterile RM was not consumed within 90 days (based on hold time study) then such RM shall be sampled during batch and tested for parameter- (Physical appearance, BET & Sterility).***

6.19 All the details of dispensing activity will be recorded in **RLAF Utilization Record** as per SOP.

6.20 All Loose Containers/Boxes/Bin shall be a **"Loose Container Bin Card"** Label with details of Name of Material, Material Batch No/Tare Wt., Net Wt./Quantity as per SOP**.**

6.21 All the details of dispensed raw materials details shown in given **Annexure-I**.

6.22 Nitrogen Purging System:

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

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

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

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

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

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

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

6.22.8 Purging details shall be recorded in **Annexure- I "Nitrogen Purging Log book"** of reference SOP.

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

6.22.10 Filter Integrity & Sterilization:

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

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

6.22.13 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.

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

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

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

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

6.22.18 Record the details of install filter in **"Filter Installation and Destruction Record" of reference SOP.**

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Raw Material Dispensing log book	

ENCLOSURE: 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 Change	Reason for Change	Effective Date	Updated By

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ANNEXURE I

RAW MATERIAL DISPENSING LOG BOOK

Department: **Block:** **Plant:**

Location: **Balance ID No.:**

Date	Product Name	Batch No.	Material name	A.R. No.	Time		Accessories no use for Dispensed	Dispensed Qty in lot	Total Dispensed Qty.	Dispensed Sign/date	Checked by Sign/date	Remark
					From	To						