



PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Warehouse

TITLE: Dispensing of Raw materials

SOP No.		Revision No.	
Effective Date		Supersedes No.	
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1.0 OBJECTIVE:

To lay down a procedure for dispensing of raw materials.

2.0 SCOPE:

This SOP is applicable for dispensing of raw materials.

3.0 RESPONSIBILITY:

Stores Officer ,Executive
Head Stores

4.0 PROCEDURE:

4.1 Receive authorized “Batch Manufacturing Record (BMR)” from production department for dispensing.

4.2 Before the start of dispensing operation ensures that there is sufficient approved stock of the raw materials to be used for dispensing.

4.3 Calculate the API potency. In case the potency is more than 100%, no calculation shall be done.

4.4 Before going for area clearance, check the followings & record it in respective records.

4.4.1 Air pressure differential at Material Entry & Personnel Entry of dispensing booth. (as per SOP)

4.4.2 Cleaning record of dispensing area as per SOP.

4.4.3 Temperature & Relative Humidity as per SOP.

4.4.4 Magnehelic gauge reading of RLAF as per SOP.

4.4.5 Weighing Balance verification & calibration as per SOP.

4.6 Record the details of dispensing in dispensing log as per Annexure- I.

Note: For light sensitive material use the sodium vapour lamp and dispense the same material in black polybags.

4.7 Before entering the dispensing booth & starting dispensing operations details like Product Name, B. No., Previous Product, Status, Sign and Date on status label to be filled outside the Dispensing booth.



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4.8 Enter into the Dispensing area through Personnel Air Lock after wearing secondary gown over primary gown, Nose mask & hand gloves while operation. Follow the entry and exit procedure as per SOP.

4.9 Ensure availability of cleaned utensils & poly bags for dispensing of raw materials.

4.10 Get Area clearance certified by QA on the BMR. After area clearance certification, start dispensing activity.

Note: Dispensing Activity Shall be Carried out in presence of Production officer & Stores officer.

4.11 Dispensing of Raw Materials:

4.11.1 Switch 'ON' the Reverse Laminar Air Flow unit & Weighing Balance for 15 minutes before starting the dispensing and ensure the required differentials air pressure on the magnehelic gauges.

4.11.2 Ensure calibration/weight verification of balance has been done & it should be within the acceptance limit and 'Zero display' should be check before the weighing of each and every item.

4.11.3 Take the excipients first for dispensing & actives at last. If colour is there, then dispense it after active raw material dispensing.

4.11.4 Take the raw materials FEFO wise on the basis of A. R. No. Follow Location Chart as per "SOP in attached Annexure- V" to locate the materials.

4.11.5 Bring the materials in to be dispensed in the material air lock.

4.11.6 Carry the materials from the material air lock into the R-LAF on a clean S.S. trolley dedicated for dispensing Area.

4.11.7 Take the "Loose" labeled pack first for dispensing.

4.11.8 Place the double polybag on balance.

4.11.9 Record the tare weight in BMR as well as on dispensing material label.

4.11.10 Record the other details in dispensing material label (Refer Annexure –IV) first.

Note: If ERP is not working, then use the Manual Dispensing Label (Refer Annexure –III)



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- 4.11.11 Scoop out/transfer the material in double poly bag as per the quantity mentioned in BMR against that particular item. After that take gross weight & record the same in the BMR requisition & Dispensed material Label.
- 4.11.12 Take the clean scoop for Active & In active material dispensing from the “Scoop cabinet”.
- 4.11.13 Put the used scoops after dispensing in “Used Scoop” container lined with polybags labeled as “To be cleaned”.
- 4.11.14 Store person shall sign at the place “Issued by” while production person shall sign at the place of “Checked by” on both BMR requisition & Dispensed material label.
- Note:** Ensure that fresh cleaned scoop for dispensing of each excipients as well as active is used.
- 4.11.15 Tightly close the double poly bag with the nylon thread/cable tie by keeping the dispensed material label in between two polybags showing the required details.
- 4.11.16 Close the loose container properly & affix Loose label (Refer Annexure-II) on it beside the approved label and update the quantities in loose label after each dispensing and transfer it to Approved stores area.
- 4.11.17 Dispense the materials one by one & keep it on the pellet/SS Container/SS Cage labeled with “Dispensed Material” label (Refer Annexure –IV) for that particular’s Batch No.
- 4.11.18 In case of different lots for a particular Batch No., separate pellets / SS Container / SS Cage shall be used for separate lots.
- 4.11.19 After dispensing of the material, clean the loose pack by using duster then take the same in the material air lock and shift the material in storage area & update the location chart.
- 4.11.20 Before completion of dispensing ensure that all the items of the BMR requisition are being dispensed & properly documented.
- 4.12 After Dispensing Of Materials:**
- 4.12.1 Handover the dispensed materials to production officer along with BMR & acknowledge the same.
- 4.12.2 Enter the details of dispensing activity in “Dispensing Log” , as per Annexure-I
- 4.12.3 Switch off the RLAF.
- 4.12.4 Discard the Hand gloves in the Waste bin.



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4.12.5 Exit from the dispensing area through Personnel air lock.

4.13 Precaution:

4.13.1 In case of multiple active raw materials to be dispensed for one Product after weighing of every active raw material, clean the R-LAF area (visually clean with the help of Vacuum Cleaner or lint free duster).

4.13.2 FEFO can be deviated with suitable justification & authorized by QA.

4.13.3 Discard the empty containers of the materials to the scrap yard after defacing the labels affixed on the container.

4.13.4 Always open & dispense the container of the material within safe zone of the R-LAF & as nearer as possible to the R-LAF grills.

4.13.5 For active material & excipients, scoop is numerically marked.

4.13.6 Multiple batches (Maximum three batches) of same product can be dispensed item wise in a single session.

5.0 ANNEXURE (S):

ANNEXURE – I : Dispensing Log.

ANNEXURE – II : Loose Label.

ANNEXURE – III : Manual Dispensing Label.

ANNEXURE – IV : ERP Specimen for Dispensing Label.

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S) :

A. R. No. : Analytical Report Number.

BMR : Batch Manufacturing Record

FEFO : First Expiry First Out.



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HDPE : High Density Poly Ethylene.

IPC : In- process Container.

QA. : Quality Assurance.

R-LAF : Reverse Laminar Air Flow.

S.S : Stainless Steel.

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	--	--	NEW SOP	--



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ANNEXURE 1 Dispensing Log

S.No.	Date	Cleaning done	Cleaning Time		Cleaned By	Checked By	Product	Batch No	Batch size	Item	Dispensing Time		Issued By	Checked By
			From	To							From	To		
										Inactive				
										Active				
										Color				
										Inactive				
										Active				
										Color				
										Inactive				
										Active				
										Color				
										Inactive				
										Active				
										Color				

Note:--put "NA" remark, if not applicable.



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ANNEXURE 3 Manual Dispensing Label

DISPENSING LABEL (RM)

Stage/Lot No :

Material :

Item code :

Pack No. :

A. R. No. :

B. No. :

Product :

Gross Wt. :

Tare Wt. :

Net Wt./Nos. :

Dispensed By :

Checked By :

Verified By :

Date :

Date :

Date :



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ANNEXURE 4

ERP SPECIMEN FOR DISPENSING LABEL

DISPENSING LABEL (RM)

Stage/Lot No :

Material :

Item code :

Pack No. :

A. R. No. :

B. No. :

Product :

Gross Wt. :

Tare Wt. :

Net Wt./Nos. :

Dispensed By :

Checked By :

Verified By :

Date :

Date :

Date :