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Discovery Labs

STANDARD OPERATING PROCEDURE			
SOP No.:	SOP-PD-014-05	Effective Date:	01.01.2018
Supersedes:	SOP-PD-014-04	Next Review Date:	31.12.2020
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1.0 **PURPOSE:**

To lay down the procedure of handling, storage and packing of materials.

2.0 **SCOPE**:

This procedure applicable for handle the raw materials, intermediates, finished materials at manufacturing area.

3.0 **RESPONSIBILITY:**

It is the responsibility of Production personnel to follow the procedure.

4.0 **DEFINITIONS:** Nil

5.0 **PROCEDURE:**

5.1. Handling of Raw materials in shop floor:

- 5.1.1. Receive the Raw materials from ware house.
- 5.1.2. Wear personal protective equipment before handling the raw materials.
- 5.1.3. Cross check the label like material name /material code, Batch number, approved status, quantity, re-test / expiry date...etc.
- 5.1.4. If any discrepancy observed, send back the raw materials to ware house.
- 5.1.5. Check the storage conditions of Raw materials; store the materials as per labeling.
- 5.1.6. Place the Raw materials on cleaned pellet by segregating material as batch wise.
- 5.1.7. Before charging the Raw materials, ensure the batch number, quality and quantity.

5.2. Return of unused Raw Materials to ware house:

- 5.2.1. Whenever production planning is cancelled, the unused raw materials shall be returned to ware house.
- 5.2.2. Production person shall identify the balance raw materials/ Unused raw materials with their quantities and batch numbers.

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- 5.2.3. Production shall capture the details of raw materials into Material transfer note.
- 5.2.4. The production personnel shall send the raw materials to where house.

5.3. Handling of Inprocess materials:

- 5.3.1. Inprocess materials like organic layer, crude material, wet material and dried material etc.. where the material shall be processed further to complete the manufacturing process.
- 5.3.2. Wear safety apparel.
- 5.3.3. Unload / pack the material in respective container.
- 5.3.4. Label the packs / containers with identification labels in which product name, batch number and status shall be mentioned and shall affix to bag or container.
- 5.3.5. Transfer the material container to respective area for further process.
- 5.3.6. Once the material is loaded / charged into next equipment previous labels shall be removed or defaced immediately.
- 5.3.7. Inprocess solvents also shall be labeled with identification label.

5.4. Handling of Intermediates:

- 5.4.1. The intermediate material, which is isolated / after completion of process, the material shall be unloaded into dedicated containers / bags.
- 5.4.2. Production personnel shall paste the Quarantine label on each container and transfer the material to Quarantine area / identify with yellow rope.
- 5.4.3. Send the communication to Quality control to collect the sample.
- 5.4.4. Quality control shall come with sampling tools along with sampled labels to collect the sample.
- 5.4.5. Sample shall be collected from all the containers as per procedure and shall affix the sampled label on the containers

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- 5.4.6. After completion of analysis, the quality control personnel shall paste the Approved / Rejected label on yellow portion of the quarantine label.
- 5.4.7. Once the batch is approved, the material shall be transferred to approved area / identify with green rope, the material can be used for further consumption.
- 5.4.8. The approved material shall be dispensed as per further process requirement and record the details in product reconciliation record.
- 5.4.9. If any loose quantity is available, loose quantity label (Identification label) shall be pasted.
- 5.4.10. If the batch is rejected, transfer the material to Rejected area / identify with red rope and put under controlled area.
- 5.4.11. If the material is planned for dispatch, handover the material to the packing section for further packing as per customer requirement.

5.5. Packing Procedure

- 5.5.1. Once the material is approved the material shall be packed as per packing requirement.
- 5.5.2. Packing activity shall be carried out in the packing area itself.
- 5.5.3. Indent and get the packing material from warehouse. (Append the packing conditions of each product to this SOP)
- 5.5.4. Ensure the cleanliness of the packing material, if required clean the packing containers with lint free cloth.
- 5.5.5. Ensure the packing room is cleaned and all accessories and materials of previous product is removed from the packing room and ensure line clearance is completed after cleaning.
- 5.5.6. Ensure the balance is calibrated and accessories for dispensing is cleaned before start the activity.

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- 5.5.7. Take the tare weight of the each container along with poly bags, lid and note the tare weight in the packing record.
- 5.5.8. Dispense the material as per required quantity into the container as per packing condition. Packing condition for each product shall be prepared as annexure to this SOP.
- 5.5.9. After dispensing tie the inner poly bags with fastener and close the lids
- 5.5.10. Record the gross weight and net weight in the packing record.
- 5.5.11. Seal the containers and record the seal numbers in the packing record.
- 5.5.12. Record the dispensing details in the respective product reconciliation record.
- 5.5.13. Prepare the product labels as per requirement and affix the product labels on the container.
- 5.5.14. Submit the packing record to QA for further release of the batch.
- 5.5.15. Prepare the product label as per packing record.
- 5.5.16. Paste the product label on containers as per packing record.
- 5.5.17. Transfer the material to warehouse along with transfer note.
- 5.5.18. Store the material as per storage condition requirement.

5.6. Packing room cleaning procedure

- 5.6.1. Packing room shall be cleaned after dispensing the product.
- 5.6.2. If the same product of different batches are packed in the same room, the cleaning is not required.
- 5.6.3. Line clearance shall be carried before start the packing of the product.
- 5.6.4. To avoid the cross contamination, the packing room shall be cleaned to remove previous product contaminants.
- 5.6.5. All previous product containers, material, documents, labels, accessories shall be removed.

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- 5.6.6. Mop the room, doors, weighing machine, walls, windows etc.. with dry lint free cloth
- 5.6.7. Mop the entire area with wet cloth.
- 5.6.8. Check the cleanliness visually.
- 5.6.9. Record the cleaning details in the respective Packing area usage log.

6.0 **FORMATS** / ANNEXURE(S)

S. No	Details	Format No. (Current version)
1.	Material Transfer Note	PD014-FM002
2.	Identification Label	PD014-FM003
3.	Packing List	PD014-FM004
4.	Product Reconciliation Record	PD014-FM014
5.	Dispatched material Reconciliation Record	PD014-FM017
6.	Quarantine Label	PD014-FM029
7.	Packing area usage log	PD014- FM043
8.	Packing area line clearance checklist	PD014-FM042

7.0 **CHANGE HISTORY:**

Revision No.	Effective date	Details of Revision	Ref. CCF No.
00	01.01.2009	New SOP is introduced	
01	01.01.2011	Format introducing	
02	01.01.2013	Material transfer note, Intermediate reconciliation record, Finished product reconciliation record &Dispatch product reconciliation record are introduced.	
03	01.06.2014	Formats are the part of SOP. So prepared Separately.	
04	01.01.2017	Procedure elaborated and SOPs PD-016, PD-022 and PD-026 are merged in this SOP.	PD-CRF- 024/16
05	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/ GEN/17035

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