

STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Reconciliation of Raw and Packing Materials	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for Reconciliation of Raw and Packing Materials.

2.0 SCOPE:

This SOP is applicable for reconciliation of Raw and packing Materials stock in stores.

3.0 RESPONSIBILITY:

Officer / Executive – Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

- Ltd. Limited
- T.S & C Technical Support & Compliance
- QA Quality Assurance
- QC Quality Control
- SOP Standard Operating Procedure
- SOS Save On Sole
- WH Warehouse

6.0 PROCEDURE:

6.1 RECONCILIATION OF RAW AND PACKING MATERIALS:

- **6.1.1** Store person shall carry the reconciliation of material after exhaust of particular Mat. Batch. No./SAP Batch No.
- **6.1.2** Warehouse personnel shall generate the stock statement from SAP and export the data into Excel sheet.
- **6.1.3** Warehouse personnel shall verify the material as per the location code mentioned in downloaded SAP stock and check the details like item code, material description, qty., manufacturing date, expiry date, retest date mentioned on the mother label/approved label affixed on the containers.
- **6.1.4** Physical verification of RM: Count the intact drums/pack/containers and calculate the net weight of all intact material, take the weight of the loose material and then sum up entire quantity of material against respective batch number.
- **6.1.5** For primary packing material follow the procedure as per 6.1.12 & 6.1.22.

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- **6.1.6** For all secondary and tertiary packing materials intact shall be checked as per mother label/approved label and loose shall be counted or weighed manually.
- **6.1.7** Weight verification of loose container shall be performed in pre staging area (material shall not be exposed) in case of RM.
- **6.1.8** All the counted containers/pack shall be multiplied with their net weight mentioned on the mother label for calculation of exact quantity.
- **6.1.9** If the net weight is not mentioned on the mother label then net weight shall be calculated by subtracting the tare weight from the gross weight.
- **6.1.10** If the tare weight is not mentioned on the mother label then take the loose container/bag in dispensing booth under RLAF and take out the material from container or bag. Put the poly bag on weighing balance and note down the weight and add it to the weight of polybag in which material is available. Now subtract the total weight of polybags from the gross weight which will be tare weight. Now calculate net weight by subtracting the tare weight from the gross weight.
- **6.1.11** After completion of physical verification, calculate the variance between book stock versus physical stock of RM/PM if any discrepancy observed, Inventory Adjustment Note shall be filled by warehouse forwarded to Operation head & QA for approval and SAP adjustment by T.S& Compliance /Inventory dept.
- 6.1.12 Calculation of discrepancy criteria for RM & PM =A-B/C*100

Where,

- A: Quantity available in SAP system
- B: Physical stock quantity
- C: Quantity received as per the consignment

The limits shall be considered for all the raw & packing materials shall be as below:

- Active Raw Materials $\pm 0.5\%$
- Excipient Raw Materials ± 1%
- All liquid Raw Material ±3%
- All Packing materials : ±1%

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- **6.1.13** If the discrepancies found within the limits store personnel shall prepare Inventory adjustment Note as per **Annexure I.**
- **6.1.14** Stock adjustment for Psychotropic/Narcotics materials shall be done in presence of QA Head based on competent authority approval.
- **6.1.15** Numbering system for stock adjustment note no shall be written as below:

For Stock Adjustment Note (G Block) GRM/YY/XXX

- **6.1.16** After approval of Stock Adjustment note from authorized persons (Warehouse/QA/Plant Head) **Annexure I** shall be forwarded to Inventory Team/ Technical support & compliance for adjustment in SAP system.
- **6.1.17** Original controlled copy shall be retained with warehouse.
- **6.1.18** During physical verification in some cases stock found excess due to any reason in containers, excess within limit material shall be integrated in SAP system and same shall be approved by plant head /QA head.
- 6.1.19 Stock verification of excipient shall be carried out once in a year or SOS basis.
- **6.1.20** Stock verification of all the API's shall be carried out every six month or SOS basis.
- **6.1.21** Stock verification of all the packing material shall be carried out once in a year or SOS basis.
- **6.1.22** Warehouse personnel shall follow point of stock adjustment note and get approved by plant head/QA to remove/add the stock from SAP.
 - Active Raw Materials ± 0.5%
 - Excipient Raw Materials ±1%
 - All liquid Raw Material ±3%
 - All Packing materials : ±1%
 - If any abnormal loss is observed by store person like spillage, it shall be immediately brought into concern to HOD- stores, HOD-QA, PPIC Head, and Operation Head though mail or verbal communication. And inventory adjustment note shall be initiated on priority to adjust the physical and SAP stock.
- **6.2** If certain materials are consistently outside the acceptable limits, same shall be intimated to purchase department for further discussion/resolution from supplier.

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- **6.3** If a material has been consistently within the acceptable limits and an instance falls outside the limits, an investigation must be conducted to determine the cause. This investigation must be fully documented.
- **6.4** In case during dispensing if there is any shortage in API or excipient, activity shall be Hold for that particular product/batch.
- 6.5 Issue slip shall be reversed for that particular batches/product and inform to QA personnel.
- **6.6** After reversal of issue slip QA shall re-calculate/reserve as per available physical quantity of next material batch number.
- 6.7 Re-calculation shall be performed where applicable.
- **6.8** Store person shall re-issue the slip in SAP and further activity of dispensing shall be continued with concern of IPQA/Store personnel.
- **6.9** In case of shortages/ excess as mentioned in loose card, inventory adjustment note shall be prepared and details **Annexure-I** shall be recorded.

7.0 ANNEXURES:

TITLE OF ANNEXURE	FORMAT No.
Inventory Adjustment Note	

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 INVENTORY ADJUSTMENT NOTE

Inventory Adjustment Note No. Initiated by stores Department

Date	Item	Item	GRN	SAP	Quantity	Physical	SAP	Difference	Within a
	Description	Code	No.	Batch No.	received	stock	Stock		limit Yes/No

	Verified by Warehouse Head	Authorized by Head Operation	Approved by QA Head	Adjustment done by (T.S & Comp/ Inventory Dept.)
Sign				
Date				
Name				