PHARMA DEVILS

WAREHOUSE DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Warehouse | **SOP No.:** |
| **Title:** Receipt of Raw Materials in Warehouse | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

**1.0 OBJECTIVE:**

To lay down a Procedure for the Receipt of Raw Materials in Warehouse

**2.0 SCOPE:**

This SOP is applicable for the receipt of Raw Materials in Warehouse.

**3.0 RESPONSIBILITY:**

Operating Person – Warehouse.

**4.0 ACCOUNTABILITY:**

Head – Warehouse

**5.0 ABBREVIATIONS:**

| | |
|---|---|
| API | Active Pharmaceutical Ingredient |
| COA | Certificate of analysis |
| FTL | Full Truck Load |
| GRN | Goods Receipt Note |
| Ltd. | Limited |
| PPIC | Production Planning and Inventory Control |
| Pvt. | Private |
| QC | Quality Control |
| QA | Quality Assurance |
| SAP | System Application and Products in Data Processing |
| SOP | Standard Operating Procedure |
| WH | Warehouse |
| TH | Thousand |

**6.0 PROCEDURE:**

**6.1 For Receiving:**

**6.1.1** Upon arrival of the vehicle with material, the security personnel checks the documents and ensures that consignment is meant for ……..

**6.1.2** After confirmation of the address, the documents related to the consignment shall be sent to warehouse receiving bay office for verification in SAP with PO (purchase order) before making entries into “Security Register for incoming consignment.

**6.1.3** After ensuring the adequacy of the received documents; the warehouse personnel shall send back the documents to security personnel to make entries in the “Security Register.

**6.1.4** Security personnel shall make entries in the “Security Register for Incoming materials accordingly.

**6.1.5** After entering the required details, the security personnel shall put stamp on the Invoice / Delivery Challan with serial number, receiving date along with signature and send the vehicle to receiving bay.

**6.1.6** All incoming consignments shall be recorded /unloaded through Central receiving on a First-In / First-Out basis unless the nature of the material dictates special handling like 2ºC to 8ºC materials.

**6.1.7** Priority to 2 ºC to 8 ºC materials unloading and transferring to Cold Storage details shall be recorded in **Annexure-V**. **"2ºC to 8ºC materials Receipt /Transfer to Cold Storage Log Book"** and also storage bin shall be updated in SAP accordingly.

**6.1.8** Materials of other blocks shall be distributed/ handed over to the concern person on their arrival at receiving bay. Bulk consignments (like FTL) shall be unloaded at designated blocks.

**6.1.9** Material of different blocks shall be segregated with green color rope only. This shall differentiate G block material from others. Material of different blocks shall be kept on different pallets tied with rope.

**6.1.10** Before unloading of consignment, warehouse person shall make following checks…

GST Invoice/Chillan
E-way bill of the consignment.
Appropriateness of company address on the delivery documents.
Approved Manufacturer / Supplier address with AVL (Approved Vendor List).
Availability of Vendor Certificate of Analysis copy
Reference of Purchase Order number on the documents.
Description of the material (Material name, grade/ pharmacopeia status, quantity) in purchase order tallies with consignment delivery document. Etc.

**6.1.11** In case of any discrepancies observed shall be informed to HOD–Warehouse and HOD-Purchase for further corrective action. This communication shall be via phone or mail for rectification.

**6.2 Pre-Unloading Activities:**

**6.2.1** Upon arrival of the vehicle of material at unloading bay following activities shall be performed.

**6.2.2** Ensure that the vehicle is covered properly to protect the material.

**6.2.3** Instruct the vehicle driver to stop the engine to avoid carbon spillage from silencer/Spark Arrestor for Vehicle carrying of Solvent, till completion of unloading and transfer of material onto receiving bay. Ensure cleanliness of vehicle floor.

**6.2.4** Warehouse personnel shall check the consignment to ensure absence of material other than mentioned in the delivery documents, in order to avoid mix-ups.

**6.2.5** Ensure the cleaned pallets are available at the receiving platform and conveyor belt is in working condition.

**6.2.6** Before starting the De-dusting operation ensure de-dusting tunnel door are closed.

**6.2.7** Ensure the weighing balances are calibrated.

**6.3 Unloading Activities:**

**6.3.1** The material shall be unloaded from the vehicle in presence of warehouse & security personnel.

**6.3.2** Warehouse shall check the vehicle physically for cleanliness and absence of any foreign residue / hazardous materials with transported materials and enter the details in **Annexure-I (Raw Material Receipt Check List).**

**6.3.3** Ensure to unload the material safely from the vehicle onto the cleaned pallets at receiving platform.

**6.3.4** Warehouse shall check the consignment against invoice / challan and unload the materials on pallets batch wise/lot wise.

**6.3.5** Warehouse shall prepare checklist as per the physically received consignment. Accordingly observed details shall be recorded in **Annexure-I (Raw Material Receipt Check List)** and weight shall be mentioned on the each bag/container/drum along with the current date. Put cross [✕] on manufacturer approved label with black marker.

**6.3.6** All containers shall be checked for integrity of package and seal.

**6.3.7** If any material does not fall in following standard that shall be brought into consideration of PPIC and purchase HO through mail. GRN shall be kept HOLD in quarantine area with "MATERIAL AWAITING FOR GRN". Acceptance shall be as per HO.

| | | |
|---|---|---|
| | Local Manufacturer | API- Older than 6 months |
| | | Excipient- Older than 12 months |
| | Imported Manufacturer | API- Older than 9 months |
| | | Excipients- Older than 12 months |

**6.3.8 Standard for Weighing of Containers:**

**6.3.8.1 For API:** 100% Weighing of all container/bag/drum & shall be recorded in Annexure-I "Raw Material receive check List"

**6.3.8.2 For Excipients**: 100 % weighing up to 3 container/bags/drum & $\sqrt{n}+1$ in case of more than 3 container/bags/drum container (where 'n' is the total number of containers).

**6.3.8.3** Weighing shall be required as given below.

| Total number of containers received | No. of containers to be weighed |
|---|---|
| 01 to 03. | For all container/bags/drum |
| √n+1 above 03. | √n+1, where 'n' is number of container/bag e.g. if a batch of excipient is receive having 121 Container/Bags, the total number container 12 are to be weight as per √n+1= √121+1=√11x11+1= 11+1=12. |

**6.3.8.4** Observed weight shall be recorded on each container bag, same shall be recorded in Annexure-I, Raw Material Receipt Check List.

**6.3.8.5** If receipt materials is found less in quantity with reference to mother label and invoice quantity store shall prepare the checklist accordingly and shared to PPIC Head/Purchase Head and Store head through mail for further action.

**6.3.8.6** On receipt of reply from Head office purchase, GRN shall be initiated & prepared as per actual receipt Quantity.

**6.3.8.7** ***Note: (1) Actual gross weight of API container shall be accepted within ± 0.5% of the gross weigh mentioned on the manufacturer label.***

**6.3.8.8** ***Note: (2) Actual gross weight of Excipient container shall be accepted within ± 1.0% of the gross weight mentioned on the manufacturer label.***

**6.3.8.9** A material short voucher shall be auto generated in SAP. One copy of this is shared with HO purchase and other is kept with store.

**6.3.8.10** Weighing of small quantity material which is in MG shall be weighed in analytical balances. Material shall be accepted as per vendor's claim and any physical shortage shall be shared when stock exhaust of that Material SAP Batch number.

**6.3.8.11** Empty vial shall be weighed along with the cap and aluminum round seal. Vial shall be kept till the stock of that material /SAP batch number is not exhaust.

**6.3.8.12** All incoming GST invoice shall accompany E-way If E-way Bill is not received along with consignment for invoice value 50 thousand and above , store shall inform to Store head , PPIC, LL Concern person ,Purchase dept.to arrange the same from customer or Transporter for further process of receiving.

**6.3.8.13** If the containers of received consignment found damaged, inform to IPQA and follow the directions mentioned by QA on Checklist.

**6.3.8.14** Warehouse personnel shall store the damage or exposed containers / bags separately having status "**Materials Awaiting for GRN"** in Quarantine area for further approval of QA head / Purchase head.

**6.3.8.15** After getting remarks of Q.A Head /Purchase head, In case of exposed or damaged container which are not acceptable, Stores shall prepare separate GRN in SAP for damaged/exposed container and send requisition for analysis intimation to QC to Reject in SAP.

**6.3.8.16** Accordingly QC shall affix label on each bag/container/drum and store shall arrange the material in rejected room for further process of return to vendor.

**6.3.8.17** All rejected material shall be returned to vendor within 90 working days. If due to any cause material is not returned within the stipulated time period store shall put a status with specific reason of delay.

**6.3.8.18** Consignment shall be received along with Certificate of analysis from the manufacturer. In case Certificate of Analysis is not available at the time of receipt, information shall be given to purchase to provide the COA **within six working days**. GRN shall be prepared on receipt of COA from purchase dept. after getting from vendor.

**6.3.8.19** All received materials shall be stored in quarantine area before preparation of GRN having status of **Awaiting for GRN** with blue rope.

**6.3.8.20** Sometime in single invoice vendor deliver material from more than single vendor batch, store shall prepare checklist accordingly quantity wise and batch wise.

**6.3.9** In case if any material is received in polybag packing etc. this material shall be kept in a cleaned container to avoid any spillage / contamination and safety of material.

**6.3.10** This new container shall be labeled appropriately with complete details of the material & manufacturer, using a computerized label.

**6.3.11** Operating Person warehouse shall enter the details in **Annexure-II (Raw Material Inward Register)** after verification of raw materials.

**6.3.12** Unloading of solvent from vehicle shall be handled through stacker only and movement with hand stacker.

**6.4 Cleaning of Receipt Bag/Container/Drum :**

**6.4.1** After Receipt of raw materials container / bags warehouse shall mop the received raw materials to remove the dust by using dry clean cotton cloth and shall place the cleaned drum /bag/ container on cleaned pallets at receiving bay.

**6.4.2** Once cleaning activity is over, cleaned drum/containers /bag shall be transferred to quarantine area through De- dusting conveyor tunnel.

**6.4.3** Warehouse shall operate the De-dusting conveyor tunnel as per SOP "Operation and Cleaning of De-dusting Tunnel" and receive the cleaned & de-dusted raw materials and record shall enter in **Annexure-I of SOP "Operation and Cleaning of De dusting Conveyor Tunnel".**

**6.4.4** For 2ºC to 8ºC degree material cleaning activity shall be done on priority and addressed immediately through de-dusting conveyor tunnel.

**6.4.5** Once GRN is prepared and sampled by QC material shall be transferred to designated area.

**6.4.6** In case of Solvent materials store person shall transfer the drums to solvent yard. Yard is under lock and key and shall be opened only for sampling, dispensing cleaning and physical verification of stock purpose.

**6.4.7** If there is any damage/leakage & spillage of materials store person shall inform to HOD stores /purchase/QA & Safety.

**6.4.8** Leakage & Damaged containers/drums shall be returned to supplier/Manufacturer in co-ordination with Purchase department.

**6.5 Preparation of GRN of Raw Materials:**

**6.5.1** GRN (Goods Receipt note) shall be initiated in SAP (**Systems Applications and Products** in Data Processing.) once physical verification and checklist preparation is completed.

**6.5.2** AVL shall be checked before GRN preparation in SAP.

**6.5.3** If vendor is not in AVL, warehouse person shall inform QA through mail to update the same. GRN shall be kept pending and material shall be stored in quarantine area in BLUE STRIP tied with blue rope labeled "Materials **Awaiting for GRN**". GRN shall be prepared on receipt of mail response from QA for updation of AVL.

**6.5.4** In case of API & Excipients where expiry date is not given, check Schedule "P" for shelf life, if not provided in schedule "P" Expiry 5 years shall be considered from date of manufacturing.

**6.5.5** In case of flavors, "Best before" on mother label /COA shall be considered as "Expiry Date" from date of manufacturing. "Retest /Best before" date shall be considered as expiry date, unless the extension is provide by the manufacturer.

**6.5.6** Except flavors, "Re-test" date is given shall be checked in Schedule "P" for shelf life' if not provided in Schedule "P", Expiry of the raw material shall be considered 5 years from date of manufacturing.

**6.5.7** In case of raw materials, where manufacturing & Expiry time is given in different months on the mother label, Store person shall consider First day of the particular month of manufacturing as Manufacturing date and last day of the particular month of expiry as expiry date at the time of preparation of GRN in SAP .

**6.5.8** In case of raw materials, where manufacturing & expiry is given of same month on the mother label/COA, Manufacturing month's Last day shall be considered as manufacturing date, And Second Last day of the month as expiry shall be considered as expiry date or as per COA GRN shall be Generated in SAP.

**6.5.9** After preparation of GRN (Goods receipt note) in SAP warehouse shall take print the "Requisition for Analysis of Raw material" and send one copy of this duly signed to Quality control department for sampling.

**6.5.10** In case of receipt of LL (Loan License) materials warehouse shall affix a computerized labeling of name of the company on each bag/container/drum.

**6.5.11** Print of Quarantine label shall be taken from SAP after preparation of GRN duly signed and shall be affixed on each bag/container/drum.

**6.5.12** Received Raw Materials shall be kept in Quarantine area for maximum **six working days** with status "**Materials Awaiting for GRN"** racks & in blue color rope in Quarantine.

## 7.0 ANNEXURES:

| ANNEXURES No. | TITLE OF ANNEXURE | FORMAT No. |
|---|---|---|
| Annexure-I | Raw Material Receipt Check List | |
| Annexure- II | Raw & Packing Material Inward Register | |
| Annexure- III | 2ºC to 8ºC materials Receipt/Transfer to Cold Storage Log Book | |

## 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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| **Issue Date:** | **Page No.:** |

## ANNEXURE – I
## RAW MATERIAL RECEIPT CHECK LIST

| | | | |
|---|---|---|---|
| Material Name | | Receiving Date | |
| Manufactured By | | | |
| Supplied By | | | |
| Del. Challan /GST invoice No. | | Date | |
| Unit of measurement | | Storage Condition | |
| Transporter's Name | | | |

| S.No. | To Check | | Yes | No | Remarks |
|---|---|---|---|---|---|
| **1.** | Whether the material is received from Approved Vendor with address? | | | | |
| **2.** | Whether the Purchase Order is available? | | | | |
| **3.** | Whether the transporter's vehicle is clean? | | | | |
| **4.** | Whether the consignment is Physically damaged in transporter's vehicle? | | | | |
| **5.** | Whether the Intactness /Integrity of seal of all the containers maintained | | | | |
| **6.** | Whether the containers are labeled properly? | | | | |
| **7.** | Packing slip of material received or not. ? | | | | |
| **8.** | e-way Bill receipt along with GST Invoice/Challan? | | | | |
| **9.** | Whether the consignment received along with the GST Invoice? | | | | |
| **10.** | Whether at the time of receipt, our consignment is accompanied with any Harmful material? | | | | |
| **11.** | Whether the consignment is accompanied with Certificate of analysis from the manufacturer? | | | | |
| **12.** | Whether the container is cleaned by De-dusting tunnel/Clean cloth | | | | |
| **13.** | Whether the material received through cold chain / deep freezer transportation? | | | | |
| **14.** | Whether the material received along with data logger if yes attached printout? | | | | |
| **15.** | Local Manufacturer | API- Older than 6 months | | | |
| | | Excipient- Older than 12 months | | | |
| **16.** | Imported Manufacturer | API- Older than 9 months | | | |
| | | Excipients- Older than 12 months | | | |
| **17.** | Satellite sample received with new consignments from the manufacturer/ supplier | | | | |

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| | |
|---|---|
| Quantity – As per Party's Challan | G/Kg/Ltrs./TH |
| Quantity – Received | G/Kg/Ltrs./TH |
| Quantity - Accepted | G/Kg/Ltrs./TH |

| S. No. | Cont. No. | Seal No. | Mfg. Batch No. | Gross Wt. Mentioned | *Gross Wt. Actual (Limit API ±0.5% Excipient±1.0%) | Tare Wt. Mentioned | Net wt. | Mfg. Date | Expiry Date/ Retest Date/Best before |
|---|---|---|---|---|---|---|---|---|---|
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**TOTAL** -_____ g/Kg/Ltrs./TH

Condition of the Packing (Packs): _____.

Material Packed in: Drum/Container (Fiber / Plastic / MS / Tin / Aluminum/SS) and Bags (Paper/ Nylon/ Other).

**For API:** 100% Weighing of all container/bag/drum

**For Excipients**: 100 % weighing up to 3 container/bags/drum & √n+1 in case of more than 3 container/bags/drum container (where 'n' is the total number of containers).

***Note**: ***(1) Actual gross weight of API container shall be accepted within ± 0.5% of the gross weight mentioned on the manufacturer label.***

***(2) Actual gross weight of Excipient container shall be accepted within ± 1.0% of the gross weight mentioned on the manufacturer label.***

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| **Issue Date:** | **Page No.:** |

**Received By (Warehouse)**
**Sign & Date (Operating Person)**

**Checked By (Warehouse)**
**Sign & Date (Operating Person)**

**Comments of Quality Assurance (If discrepancy observed):**

**(Quality Assurance)**
**Date:**

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## ANNEXURE-II
## RAW & PACKING MATERIAL INWARD REGISTER

| S.No. | Date of receipt | Transporter Name | Docket No. | Material Description | Supplier / Manufacture Name | Vendor Batch No. | Challan/ Invoice & Date | Challan/ Invoice Qty. | No. of Containers | Recd. By Sign /Date | Remark |
|---|---|---|---|---|---|---|---|---|---|---|---|
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## ANNEXURE-III

## 2ºC to 8ºC MATERIALS RECEIPT/TRANSFER TO COLD STORAGE LOG BOOK

**Room ID.: ……..**

| S.No. | Date of receipt | Name of Material | Vendor Batch No. | Receipt Qty. | No. of Container | Time of unloading at receiving bay | Time for Transfer in Cold storage | Sign. & Date | Remark |
|---|---|---|---|---|---|---|---|---|---|
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