



PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Warehouse

SOP No.:

Title: Handling of Vitamins

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down a Procedure to Handling of Vitamins.

2.0 SCOPE:

This SOP is applicable to Handling of Vitamins.

3.0 RESPONSIBILITY:

Officer/Executive Ware house
Executive Production
Executive QC
Executive QA

4.0 ACCOUNTABILITY:

Head-Ware House

5.0 ABBREVIATIONS:

MSDS Material Safety Data Sheet
Temp. Temperature
%RH Relative Humidity
Mfg. Manufacturing
QC Quality Control
QA Quality Assurance
DHA Docosahexaenoic Acid

6.0 PROCEDURE:

6.1 RECEIPT OF VITAMINS:

6.1.1 After receipt of consignment, Officer/Executive warehouse shall check the Challan / Invoice of raw materials (Vitamins).

6.1.2 Warehouse officer shall check for the transportation condition.

6.1.3 Officer/ Executive warehouse shall check the vehicle physically for cleanliness and absence of foreign residue/ hazardous materials with transported materials and enter the details in (Raw material receipt check list as per SOP).

6.1.4 Officer/ Executive warehouse shall ensure that the objectionable materials have not been transported along with the received consignment which may impact the quality of raw materials (Vitamins).

6.1.5 Officer/ Executive warehouse shall check the consignment against invoice/ challan and unload the materials on pallets batch wise / lot wise.

6.1.6 Officer/ Executive warehouse shall check the received consignment as per SOP (Raw material receipt check list).



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6.2 STORAGE OF VITAMINS:

- 6.2.1 Light sensitive material shall be packed in black polybag to protect from light.
- 6.2.2 Consignments of vitamins should not be older than 6 months of manufacturing during receiving at site.
- 6.2.3 Vitamins shall be N₂ purge during packing to avoid oxidation.
- 6.2.4 N₂ gas shall be free of oxygen and N₂ should be filtered through 0.2 µm.
- 6.2.5 N₂ flushing should be controlled, ensure presence of pressure gauge on N₂ cylinder.
- 6.2.6 Officer/ Executive shall prepare list of raw materials (Vitamins) with storage condition.
- 6.2.7 For the raw materials, which are not included in the list, fill the details as per SOP with storage condition.
- 6.2.8 Storage condition shall be updated on list as per SOP and control copy issued to warehouse.
- 6.2.9 List of vitamins shall be prepared as per **Annexure-I**.
- 6.2.10 Nitrogen purging shall be performed during open & closure of container.
- 6.2.11 Materials requiring cold storage conditions i.e. 2 °C to 8°C shall be stored in the “**COLD STORE**” maintained at 2°C to 8°C with status label on the container as “**QUARANTINE**”, “**UNDER TEST**”, “**APPROVED**” and **MATERIAL AWAITING GRN.**”
- 6.2.12 Executive / Officer Warehouse shall dispense the raw material as per SOP “Dispensing of Raw Materials”.
- 6.2.13 Executive / Officer QC shall performed the sampling activity as per SOP sampling of RM.

6.3 SAMPLING/DISPENSING OF VITAMINS:

- 6.3.1 Handled the vitamin as per instruction given in specification.
- 6.3.2 Following Requirements shall be ensure during activity,
 - Low intensity (Sod. lamp)
 - Presence of subdued light
 - Availability of black color sampling polybag
 - Availability of N₂ purging in the area



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- Availability of seal

6.3.3 Minimum exposure of the vitamin during sampling/dispensing ensures that containers are properly sealed before and after sampling.

6.3.4 N₂ purging after sampling/dispensing.

6.3.5 Storage condition of sample for analysis & control sample should meet the condition.

6.3.6 Retest should be done within 6 months of release.

6.3.7 Warehouse officer/ Executive shall capture or debit the material in SAP according to process order / requisition received from production.

6.3.8 Warehouse officer/ executive shall take the print of “Raw material issue slip” and send to production for checking.

6.3.9 Warehouse officer/ executive shall check dedicated nitrogen purging system before starting the dispensing / sampling activity and follow the system of nitrogen purging to reduce moisture.

6.3.10 Officer / Executive shall be check pressure in gas cylinder through megnehaulic gauge.

6.3.11 After completion of dispensing activity warehouse personnel shall purge in leftover materials ON the nob of nitrogen system and before purging check the pressure gauge between limit 0.5 to 1.5 kg.

6.3.12 After checking of pressure, dispensing personnel shall purge nitrogen gas in dispensed materials by air gun after that immediately tied & close by cable tie.

6.3.13 Drums / container shall affix label properly, then materials shall be shifted to appropriate space in day store area.

6.3.14 Switch off the RLAF booth of dispensing / sampling & start the cleaning activity as per cleaning procedure.

6.4 PRECAUTIONS DURING MANUFACTURING:

6.4.1 Mfg. process shall be performed under subdued light.

6.4.2 N₂ purging facility shall be available in manufacturing.

6.4.3 Stirrer shall be off during vitamin addition for liquid orals.

6.4.4 Ensure addition of small quantity of vitamins like D₃, Biotin etc.

6.4.5 Temperature of bulk shall be maintained.



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6.4.6 Bulk shall be protected from air tight container.

6.5 PRECAUTIONS DURING Filling / Packing:

6.5.1.1 Subdued light shall be available.

6.5.1.2 Avoid exposure

6.5.1.3 N₂ purging / 316 SS pipelines.

6.6 PRECAUTIONS DURING PURCHASE:

Precaution shall be taken during transportation w.r.t, breakage/damage & packing to avoid light transmission.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Vitamins	
Annexure-I	Does and Don't Do's	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Ware House
- Master Copy Quality Assurance

9.0 REFERENCES:

WHO TRS
PIC/S

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 II Does and Don't Do's

S.No.	Does	Don't Do's
1.	Vitamin kept in black polybag.	Do not use transparent polybag for storage /dispensing of vitamin.
2.	N ₂ purging in dispensing.	Don't dispense without N ₂ purging under RLAF
3.	Store at temperature specified by manufacturer/supplier.	Temperature must not exceed than specified.
4.	Use Sodium lamp.	Don't dispense without sodium light.
5.	Presence of subdued light.	Don't expose/dispense in fluorescent light.
6.	Used tightly closed container	Avoid using loose containers. Loose containers must be tightly closed.