PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Handling and Storage of Raw Materials in Dry Powder Injection Section	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Handling & Storage of Raw Materials in Dry Powder Injection Section.

2.0 SCOPE:

This SOP is applicable for Handling & Storage of Raw Material in Raw Material Warehouse of Dry Powder Injection Section.

3.0 RESPONSIBILITY:

Officer / Executive – Warehouse

4.0 ACCOUNTABILITY:

Head – Warehouse

5.0 ABBREVIATIONS:

GRN	Goods Receipt Note
PPIC	Production Planning Inventory Control
QC	Quality Control
QA	Quality Assurance
SOP	Standard Operating Procedure
WH	Warehouse

6.0 PROCEDURE:

6.1 After receipt of raw materials, Officer/Executive warehouse shall prepare GRN and affix printed duly singed "Quarantine" label on each container following SOP "Receipt of Raw Materials in Warehouse".

6.2 Officer/ Executive QC shall take the sample for analysis from the containers as per SOP "Sampling Procedure of Raw Materials" and affix duly signed "Sampled" label.

6.3 After sampling, Officer/ Executive QC shall affix printed duly signed "Under Test" label on each container following SOP "Sampling Procedure of Raw Materials" and shift the containers to under test area.

6.4 AFTER ANALYSIS OF RAW MATERIALS:

6.4.1 On rejected raw materials, Officer/ Executive QC shall affix printed duly signed "Rejected" label on the rejected containers following SOP "Sampling Procedure of Raw Materials" and shift the containers to rejected area.

6.4.2 Officer/Executive warehouse shall inform to PPIC about Rejected Raw Materials with "Certificate of Analysis".

6.4.3 With consent of PPIC, Head warehouse shall return the rejected raw materials with proper gate pass and maintain the record.

6.4.4 On approval of raw material, Officer/Executive QC shall affix "Approved" label while following SOP "Sampling Procedure of Raw Materials".

6.4.5 Officer/ Executive warehouse shall check the list of raw materials with storage conditions and shift the approved raw materials to appropriate approved raw materials store.

6.4.6 List of Raw Material with Storage Condition:

6.4.6.1 Officer / Executive QA shall prepare list of raw materials with storage condition on **Annexure-I.**

6.4.6.2 For the raw materials, which are not included in the list, fill the details on **Annexure-II** and send to QA to provide the storage condition.

6.4.6.3 QA shall write the storage condition on the **Annexure-II** and return to warehouse, keeping one copy with the QA department.

6.4.6.4 QA shall update the list at-least once in six month or whenever required.

6.4.7 Raw materials having specific storage conditions shall be stored at manufacturer recommended storage condition.

6.4.8 Always keep the materials away from the walls and other raw materials for easy cleaning purpose.

6.5 Executive / Officer Warehouse shall dispense the raw material as per SOP "Dispensing of Raw Materials.

6.6 Temporary arrangement may be done in case of space constraint, to store materials in either Quarantine Area, Under Test Area or in Approved Area with appropriate identification labels so as to indicate the status of the materials.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Raw Materials with Storage Condition	
Annexure-II	Storage Condition of Raw Materials	

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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:

- 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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ANNEXURE – I
LIST OF RAW MATERIALS WITH STORAGE CONDITION

Effective From: …… **Block:** ……..

S.No.	MATERIAL NAME	CATEGORY	Pharmacopoeia Reference (IP/ BP/ USP/ IH)	STORAGE CONDITION	
				Storage Condition (2°C to 8°C / 8°C to 25°C / Below 30°C)	LABEL (if any)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					

Prepared By
Officer/Executive Warehouse
Sign & Date

Checked By
Head Warehouse
Sign &Date

Approved By
Head-QA
Sign &Date

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ANNEXURE – II
STORAGE CONDITION OF RAW MATERIALS

Date: ……

To:
Quality Assurance

From
Warehouse

Kindly provide the storage condition of given below Materials

S.No.	MATERIAL NAME	CATEGORY	STORAGE CONDITION	SIGN & DATE (OFFICER / EXECUTIVE QA)	SIGN & DATE (HEAD QA)
1.					
2.					

WAREHOUSE COPY

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QA COPY

STORAGE CONDITION OF RAW MATERIALS

S.No.	MATERIAL NAME	CATEGORY	STORAGE CONDITION	SIGN & DATE (OFFICER / EXECUTIVE QA)	SIGN & DATE (HEAD QA)
1.					
2.					