STANDARD OPERATING PROCEDURE	
Department: Warehouse	**SOP No.:**
Title: Procedure for Maintaining Manufacturer Seal Album & Resealing of API	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for maintaining the manufacturer Seal album & Resealing of API after Sampling and Dispensing.

2.0 SCOPE:

This SOP is applicable for maintaining the manufacturer Seal album & Resealing of API after sampling and dispensing in Warehouse.

3.0 RESPONSIBILITY:

Officer / Executive – Warehouse/QA/QC

4.0 ACCOUNTABILITY:

Head – Warehouse/QA/QC

5.0 ABBREVIATIONS:

API	Active Pharmaceutical Ingredient
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless steel

6.0 PROCEDURE:

6.1 MAINTAINING MANUFACTURER SEAL ALBUM:

6.1.1 During sampling of the respective API's seal of manufacturer shall be removed & handover to the Warehouse Incharge for making of the seal album for every first source as per **Annexure-I**.

6.1.2 At least one seal shall be handover to Warehouse Incharge**.**

6.1.3 Records for the first source of API seal shall be maintained and keep in the receipt area.

6.1.4 Manufacturer seal album shall be used for the cross checking of the next consignment of the same source of the same API seal with the seal album.

6.1.5 Warehouse department shall be responsible for updating & control of Manufacturer seal album.

6.1.6 This SOP is applicable for maintaining the manufacturer Seal album & resealing of API's Raw materials for applicable of Customer only. Or in future if required by other Customers.

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6.2 RESEALING OF THE API CONTAINERS:

6.2.1 During sampling of the respective API's, manufacturer seal shall be removed one by one.

6.2.2 After completion of the sampling API seals affixed to each container issued from QA department.

6.2.3 For API received in poly bag / gunny bags should be tie with the plastic cable tie also tie separately the inner and outer poly bags firmly with plastic fastener.

6.2.4 API received in the Aluminum container / SS containers shall be sealed with the sterile tape if applicable.

6.2.5 For inject able / Sterile API, sterile tape shall be affixed on containers of sterile API's.

6.2.6 API received in the Corrugated Boxes shall be sealed with BOPP tape & wrapped with the poly bag & securely tie using the fastener.

6.2.7 Maintain the resealing of API containers record as per **Annexure-II** and controlled by QA department.

6.2.8 At the time of dispensing of API's, follow point 6.2.1 to 6.2.8.

6.2.9 After completion of the dispensing of API (Check for the old seals and replace the same with the new seals after dispensing for loose container) QA department maintain and control the resealing of API.

6.2.10 All the above activities shall be done by QC during sampling and by Warehouse during dispensing the 'Checker' during dispensing (QC / Production / QA).

6.2.11 The above activities shall be done under the observation of QA.

6.2.12 The storage of the seals shall be done under lock and key and the same is to be issued as per the requirement by QA.

6.2.13 Storage & reconciliation record of seals shall be maintain by QA as per Annexure-II.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Manufacturer Seal Album	
Annexure-II	Reconciliation of Material Seal	

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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled copy No.01 Quality Assurance
- Controlled copy No.02 Warehouse
- Controlled copy No.03 Quality Control
- Master copy Quality Assurance

9.0 REFERENCES:

- Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE – I
MANUFACTURING SEAL ALBUM

Date of Receipt	Item Code	Name of API	Manufacturer Name and Address	Seal Sample	Checked By

PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE – II
RECONCILIATION OF MATERIAL SEAL

Date	Opening Stock (A)	Receipt of seal (B)	Product/Material Name	B. No./Lot No.	No. of containers	Purpose Sampling/ Dispensing	Issued Qty. (in Nos.) (C)	Closing Stock (in nos.) (A+B)-C	Recorded By (QC/Store)	Issued By (QA)	Rejected Qty. Return to QA (in nos.)	Rejected Qty. Destroyed By (QA)	Remarks