



# PHARMA DEVILS

WAREHOUSE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Warehouse	<b>SOP No.:</b>
<b>Title:</b> Handling and Cleaning of Sampling & Dispensing Tools for Ointment Section	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Handling and Cleaning of Sampling and Dispensing Tools.

### 2.0 SCOPE:

This SOP is applicable for Numbering, Usage, Cleaning & Drying of Sampling and Dispensing Tools used in Raw Material/In process/Semi-finished.

### 3.0 RESPONSIBILITY:

Officer / Executive Warehouse

### 4.0 ACCOUNTABILITY:

Head-Warehouse

### 5.0 ABBREVIATIONS:

IPA            Isopropyl Alcohol  
Ltd.            Limited  
SOP            Standard Operating Procedure  
WH            Warehouse

### 6.0 PROCEDURE:

#### 6.1 RECEIPT OF NEW SAMPLING AND DISPENSING TOOLS:

**6.1.1** All Sampling and dispensing tools shall be of SS 316.

**6.1.2** New Sampling and dispensing tool shall be entered in **Annexure-I (List of Sampling / dispensing tools)**.

**6.1.3** If any discrepancy is found in accessories like rusting, cracking, damage, unfit for use, it shall be removed from area immediately and look for new or any other alternate for the same.

**6.1.4** Accessories like Scoops, Ladle, Spatula, Spoon, Measuring Cylinder, Sampling rod or other items shall be reviewed against the master list every six months by concerned department and QA to verify their fitness for intended purpose as per **Annexure-IV**.

#### 6.2 NUMBERING SYSTEM FOR SAMPLING AND DISPENSING TOOLS:

**6.2.1** Each Sampling and dispensing tool shall have a unique identification number.

**6.2.2** The Sampling and dispensing tool numbering system shall be **PD/XX/YYY-NNN**

Where,

PD     :     Indicates Pharmadevils



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XX : Indicates Department code & Q - block code  
: Indicates Separator

YYY : Indicates Equipment code.

NNN : Equipment serial no.

**For e.g.** - Numbering system for first Sampling and dispensing Scoop of ointment section shall be as: PD/XX/YYY- NNN Equipment code shall be assign as per **Annexure-III**.

### 6.3 USAGE OF SAMPLING AND DISPENSING TOOLS:

**6.3.1** All Sampling and dispensing tools shall be preserved according to the Sampling/dispensing area wise.

**6.3.2** Use the Separate sampling / Dispensing tools for each material.

**6.3.3** Officer / Executive Warehouse/QC shall check the tools visually for cleanliness before Sampling and dispensing.

**6.3.4** Officer / Executive Warehouse/QC shall use the Ladle / spoon for Sampling and dispensing of small quantity of raw material.

**6.3.5** Officer / Executive Warehouse/QC shall use the Scoop for Sampling and dispensing of large quantity of raw material.

### 6.4 CLEANING OF SAMPLING AND DISPENSING TOOLS:

**6.4.1** Officer / Executive Warehouse shall collect the to be cleaned dispensing tools in a double polythene bag in HDPE/ SS Container and labeled to be cleaned and take to Ointment Manufacturing Washing Area through Static Pass Box & Hatch Pass Box.

**6.4.2** Officer / Executive Quality Control shall collect the to be cleaned Sampling tools in a double polythene bag in HDPE/ SS Container and labeled to be cleaned and take to Ointment Manufacturing Washing Area through → Dynamic Pass Box → Under Test Raw Material Lift → Approved Raw Material Store → Solvent/Liquid Day Store Solvent/Liquid Dispensing → Hatch Pass Box → Ointment Manufacturing Washing Area.

**6.4.3** Rinse the Sampling and dispensing tools with hot purified water.



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**6.4.4** Start cleaning the parts with hot purified water and Extran MA- 02 solution 2%v/v after then rinse with hot purified water.

**6.4.5** All cleaning shall be done in Ointment Manufacturing Washing Area.

**6.4.6** Enter the cleaning details in **Annexure – II (Cleaning Record of Sampling/Dispensing Tools)**.

### **6.5 DRYING OF SAMPLING AND DISPENSING TOOLS:**

**6.5.1** Dry the Sampling and dispensing tools by Hot Air Oven/ Hot Air Gun or filtered compressed air.

**6.6** Mop the Sampling and dispensing tools with 70% v/v IPA solution. Wipe the Sampling and dispensing tools with dry lint free cloth and check the Sampling and dispensing tools visually clean for any adhesive particles and kept in clean double polythene bag with cleaned status label.

**6.7** All the details of cleaned & to be cleaned Status Label for Dispensing & Sampling Tool will be recorded in Status & Labeling of SOP.

**6.8** Then transfer the clean Dispensing & Sampling Tool into the respective area in clean HDPE/ SS container.

**6.9** Officer/ Executive Warehouse shall collect the cleaned dispensing tools in a double polythene bag in clean HDPE/ SS Container and labeled as cleaned and take through Static Pass Box & Hatch Pass Box into raw material dispensing area and solvent/ liquid dispensing area.

**6.10** Officer / Executive Quality Control shall collect the cleaned Sampling tools in a clean double polythene bag in HDPE/ SS Container and labeled as cleaned and take into respective area through:  
Ointment Manufacturing Clean Equipment Area → Hatch Pass Box → Solvent/Liquid → Dispensing → Solvent/Liquid Day Store → Approved Raw Material Store → Approved Raw Material Lift → Under Test Raw Material Lift → Dynamic Pass Box → Sampling Room.

### **6.11 FREQUENCY OF CLEANING:**

**6.11.1** After single material use.

### **6.12 VALIDITY:**

**6.12.1** Dirty Sampling and dispensing tools shall be valid upto NMT 24 Hrs.



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**6.12.2** Clean Sampling and dispensing tools shall be valid upto NMT 168 Hrs. (Weekly)

**6.12.3** If clean validity shall be beyond due valid the time period than reclean the Sampling/dispensing tools and used for Sampling and dispensing.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Sampling and Dispensing Tools	
Annexure-II	Cleaning Record of Sampling and Dispensing Tools	
Annexure-III	List of Sampling and Dispensing tools Equipment code	
Annexure-IV	Check list for Verification of Sampling/ Dispensing Tools	

**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 Drugs and 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 – III LIST OF SAMPLING AND DISPENSING TOOLS EQUIPMENT CODE

S.No.	Name of Sampling/Dispensing Tools (Scoop / Spoon / Ladle)	Equipment code
1.	Scoop	SCO
2.	Ladle	LDL
3.	spoon	SPO
4.	Spatula	SPT
5.	Sampling rod	SAR
6.	Liquid Sampling rod	SAR
7.	Solid/semisolid sampler	SS SPL
8.	Barrel Pump	BRL
9.	Measuring Cylinder	MCL



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### ANNEXURE – IV CHECK LIST FOR VERIFICATION OF SASMPLING/ DISPENSING TOOLS

<b>Frequency: Six Month</b>		<b>Block :</b>		
<b>S.No.</b>	<b>Name of Sampling /Dispensing Tools</b>	<b>Verify Status OK/ NOT OK</b>	<b>Checked By (User Department)</b>	<b>Verified By (QA)</b>
1.	Scoop			
2	Spoon Small/Big			
3.	Spatula			
4.	Sampling Rod			
5.	Measuring Cylinder			
6.	Barrel Pump			