

STANDARD OPERATING PROCEDURE		
Department: Warehouse	SOP No.:	
Title: Handling and Cleaning of Dispensing Tools	Effective Date:	
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Numbering, Usage, Cleaning & Drying of Dispensing Tools used in Raw Material Warehouse.

3.0 RESPONSIBILITY:

Officer / Executive Warehouse

4.0 ACCOUNTABILITY:

Head Warehouse

5.0 ABBREVIATIONS:

%	Percentage
IPA	Isopropyl Alcohol
LTD.	Limited
SOP	Standard Operating Procedure
SS	Stainless Steel
v/v	Volume by volume
WH	Warehouse

6.0 **PROCEDURE:**

6.1 **RECEIPT OF NEW DISPENSING TOOLS:**

- **6.1.1** As per requirement, concerned department shall raise the requirement for procurement of Stainless accessories.
- 6.1.2 All dispensing tools shall be of SS 316.
- 6.1.3 New dispensing tool shall be entered in Annexure-I (List of dispensing utensils).
- **6.1.4** All Existing usage utensils like as scoops, spatula, spoons, barrel pump, and ladle etc. shall review & verified by warehouse & QA every six month or when required.
- 6.1.5 If found damage like as mentioned ID Not visible for read or found any types of damages need to be replaced new or need to procure additional utensils & details shall be recorded in **Annexure-IV** (Check List of storage tools).

6.2 NUMBERING SYSTEM FOR DISPENSING TOOLS:

- **6.2.1** Each dispensing tool shall have a unique identification number.
- 6.2.2 The dispensing tool numbering system shall be PD/GB/XX/NN.



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Where,

- PD : Pharma Devils (plant name)
- GB : G Block
- XX : Dispensing tool code (SC for Scoop, SP for Spoon & SL for Spatula, BL for Barrel pump, MC for Measuring Cylinder, BP for barrel pump.
- NN : Dispensing utensil serial number which starting from 01, 02, 03.....etc.
 - : Indicates Separator

For e.g. Numbering system for first dispensing Scoop of OSD section shall be as: PD/GB/SC/01

6.3 USAGE OF DISPENSING UTENSILS:

- 6.3.1 All dispensing tools shall be dedicated booth wise for API & Excipients.
- **6.3.2** Warehouse shall check the Utensils visually for cleanliness before dispensing.
- **6.3.3** Warehouse shall use the spatula / spoon for dispensing of small quantity of raw materials.
- **6.3.4** Warehouse shall use the utensils/Scoop for dispensing of large quantity of raw material and utensils ID shall recorded in Annexure-II "RLAF Utilization log book" of SOP.
- 6.3.5 Used of dispensing utensils shall be kept inside SS container in operation booth
- **6.3.6** Warehouse shall use the SS barrel pump for dispensing of Solvent raw materials like IPA, MDC, and Acetone etc.

6.4 CLEANING & DRYING OF DISPENSING TOOLS:

- **6.4.1** After completion of dispensing activity collect the used utensils in a polythene bag and take to the designated washing area.
- 6.4.2 Wash the utensils with potable water first.
- 6.4.3 Clean the utensils with 2.0% v/v Extran MA-02 solution using nylon brush or scrubber.
- **6.4.4** Again wash the utensils with potable water thoroughly.
- 6.4.5 Finally rinse utensils with in purified water.
- 6.4.6 Wipe the dispensing tools with dry lint free cloth and check visually the utensils are clean.
- 6.4.7 Allow the cleaned devices to get dry completely in Hot Air Oven in specified temperature.
- **6.4.8** After completed drying of Utensils, Utensils shall be collected and kept inside poly bags of designated place in washing area.
- 6.4.9 Sanitize the utensils by mopping with a dry lint free cloth damped with 70% IPA solution
- **6.4.10** After sanitize keep the utensils in a polyethylene bag and tied with cable tie and an affix status label for "CLEANED" on utensils indicating the date of cleaning and sign it.



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- **6.4.11** Keep the cleaned utensils in a separate close SS Trolley or in close HDPE containers.
- 6.4.12 Enter the cleaning details in Annexure II (Cleaning Record of Dispensing Tools).
- 6.4.13 All dispensing utensils shall be dried in Hot Air Oven (HAO) as per SOP.
- 6.4.14 Drying time details shall be recoding in Annexure-II (Cleaning Record of Dispensing Tools).

6.5 ISSUANCE, PREPARATION AND USAGE OF IPA SOLUTION:

- **6.5.1** Requisition shall be generated in SAP system. Requisition/request No. shall be approved by Head warehouse before issuance in SAP.
- **6.5.2** Based on the requisition Store Officer/Executive shall issue IPA in SAP and issued.
- 6.5.3 Measure the required quantity of IPA in a clean measuring cylinder.
- **6.5.4** Prepare IPA solution in a proportion of 70:30, (IPA: water).
- 6.5.5 To prepare IPA Solutions as per follow the instruction in table below table.

S.	Name of Solution	Preparation of	Use Before	Usage/ Purpose
No.		IPA 70% Solution.		
1.	Isopropyl Alcohol	Take $100\% = 5$ litter IPA of	24 hours.	For sanitize and SS
	Solution	30% IPA =1.5 litter add of		equipment &
	(70% v/v)	Purified water and		Container.
		Mix and found volume 6.5		
		litter. or as per required		
		Qty. of IPA 70% solution.		

6.5.6 IPA 70% issuance record shall be mentioned in Annexure-V (IPA 70% Preparation, Usage and Destruction Record).

- 6.5.7 Date of preparation and Use before date shall be recorded in Annexure VI.
- **6.5.8** Leftover quantity of 70% shall be discarded in washing area.

6.6 CLEANING PROCUDURE OF BARREL PUMP:

- **6.6.1** After completion of dispensing take the barrel pump to the washing area in a polyethylene bag and affix "To be Cleaned " label on it
- **6.6.2** Take water in a bucket/ drum to dip the barrel pump and pipe in it. Dip the inlet and drain through the outlet.
- **6.6.3** Wash the outer surface with plenty of potable water.
- **6.6.4** Extrand 2% solution shall be used for viscous materials followed by purified water for final rinsing. Compressed air to be used for the removal of water droplets for the drying.



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- **6.6.5** Solvent like IPA, MDC, and Acetone etc. shall be cleaned with compressed air to remove the solvent droplets. Only outer surface shall be cleaned with purified water and inner surface shall be clean with compressed air.
- **6.6.6** Take potable water and dip the inlet and drain through the outlet. Repeat the process again.
- **6.6.7** Finally rinse the barrel pump with purified water.
- 6.6.8 Dry the pump with compressed air. And then with hot air gun.
- **6.6.9** Clean the outer surface by mopping.
- **6.6.10** Wipe the barrel pump with dry lint free cloth.
- **6.6.11** Cover the barrel pump with polyethylene bag and put status label on it.

6.6.12 DRYING PROCEDURE OF BARREL PUMP BY USING HOT AIR GUN:

- **6.6.13** Hot Air gun shall be use for drying only Barrel Pump of which is using in solvent dispensing for Solvent Liquid item.
- 6.6.14 Ensure that the Hot Air Gun is clean.
- 6.6.15 Connect the power supply and Switch 'ON' the Hot Air Gun.
- **6.6.16** Set the Air Pressure & Heat Controller as per requirement by using red button of Lower for low & upper high temperature of Hot Air Gun.
- **6.6.17** Barrel Pump Drying start time & End time shall be recorded in Annexure-II of SOP.
- 6.6.18 After drying of barrel pump switch "OFF" the Hot Air Gun and disconnect the power supply.
- **6.6.19** For cleaning of Hot Air Gun that first ensure that the Hot Air Gun is cool before cleaning then clean by using dry clean cloth.
- 6.6.20 After cleaning Hot Air Gun, pack in a poly bag and affix "Cleaned" label.

6.7 FREQUENCY OF CLEANING:

- 6.7.1 After every Product Changeover or Material to material.
- **6.7.2** Uncleaned dispensing tools is kept not more than 48 hours.
- **6.7.3** If cleaned dispensing tools is kept idle for more than 72 hours.
- **6.7.4** If the cleaned barrel pump remains unused for 72 hours, clean externally by mopping with dry lint free cloth.



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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Dispensing Tools	
Annexure-II	Cleaning Record of Dispensing Tools	
Annexure-III	Status Label	
Annexure-IV	Check List of storage tools	
Annexure-V	IPA 70% Preparation and Usage record	
Annexure-VI	IPA 70% Solution Label	

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ENCLOSURES: SOP Training Record

8.0 **DISTRIBUTION:**

- Controlled Copy No. 01
 Quality
- Controlled Copy No. 02
- Master Copy

- Quality Assurance Warehouse
- Quality Assurance

9.0 **REFERENCES**:

Not Applicable.

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 DISPENSING UTENSILS

REVISI	ON No.: EF	FECTIVE DATE:	BLOCK :
S. No.	Name of Dispensing Utens	ils Dispensing Are	ea ID No.
	Prepared By Operating Executive	Checked By Operating Manager	Approved By Head

	Operating Executive	Operating Manager	Head Quality Assurance
Sign			
Date			
Name			



PHARMA DEVILS

WAREHOUSE DEPARTMENT

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ANNEXURE – II **CLEANING RECORD OF DISPENSING TOOLS**

Date		Name of	ID. No.	Cleaning				•	•	Verified ByRema	
		Dispensi ng Tools		Start Time	End Time	Start Time/ Temperature	Temperature	-	Warehouse Sign & Date	QA Sign & Date	rks
-											



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ANNEXURE-III

STATUS LABEL				
Dispensing Tool				
ID No.				
Date of Cleaning				
Use Before Date				
Cleaned By: (Sign & Date)		Checked By: (Sign & Date)		



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ANNEXURE – IV CHECK LIST OF STORAGE TOOLS

Frequ	Jency: Six Month	BLOCK	:
S.No.	Name of Sampling/Dispensing Tools	Verify Status OK/ NOT OK	Verified By QA
1.	Scoop		
2	Spoon Small/Big		
3.	Spatula		
4.	Ladle		
5.	Measuring Cylinder		
6.	Barrel Pump		





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ANNEXURE – V IPA 70% PREPARATION USAGE AND DESTRUCTION RECORD

AREA:					NAME OF SO	LUTION:				
Preparation				Usage and Destruction						
Date	Quantity of IPA (Ltr.)	Quantity of purified water in (Ltr.)	Total volume of solution.	Prepared by Sign & Date	Using area/section	Quantity for used (Ltr.)	Balance qty. of solution(Ltr.)	Un used solution for Discarded	Issue/discarded By (Sign &Date)	Remarks



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ANNEXURE – VI **IPA 70% SOLUTION LABEL**

	IPA 70% SOLUTION					
Name of Solution .	Name of Solution					
Date of Preparation	Date of Preparation:					
Use Before (Date)	:					
Prepared By (Sign & Date)	:					