



STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Handling, Cleaning and drying of Sampling and Dispensing Tools	Effective Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable to Injection Section.

3.0 RESPONSIBILITY:

Operating Person – Warehouse

4.0 ACCOUNTABILITY

Head-Warehouse

5.0 ABBREVIATIONS:

°C	Degree Celsius
HNO ₃	Nitric Acid
hrs.	Hours
IPA	Isopropyl Alcohol
Ltd.	Limited
min	Minute
No.	Number
SLS	Sodium Lauryl Sulphate
SOP	Standard Operating Procedure
SS	Stainless Steel
WFI	Water for Injection
WH	Warehouse

6.0 PROCEDURE:

6.1 Receipt of New Dispensing Tools:

6.2 As per requirement, concerned department shall raise the requirement for procurement of Stainless accessories.

6.2.1 All dispensing tools shall be of SS 316.

6.2.2 New dispensing tool shall be entered in **Annexure-II (List of Dispensing tools)**.

6.3 Numbering System for Dispensing Tools:



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6.3.1 Each dispensing tool shall have a unique identification number.

6.3.2 The dispensing tool numbering system shall be **PD/IB/XXX-001**.

Where,

PD : Indicates plant code.

IB : Indicates injection section.

/ : Indicates Separator

XXX : Indicates code for dispensing tool (SCO for Scoop, SPO for Spoon & SPL for Spatula & MCL for Measuring Cylinder).

- : Indicates Separator

NNN : Indicates dispensing tool serial number which starting from 001, 002, 003..... etc. for particular tool.

For e.g.

Numbering system for first dispensing Scoop of injection section shall be as: PD/IB/SCO-001

6.4 Precautions:

6.4.1 Use only soft brush for Dispensing tools cleaning, hard Nylon brush may cause scratches on tools.

6.5 Cleaning & Drying of Sampling / Dispensing Tools:

6.5.1 Warehouse Staff shall wear the hand gloves and transfer the SS Container containing used for sampling & Dispensing tools labeled as **“TO BE CLEANED”** as per the SOP Titled **“Status Labeling”** to Equipment Washing Area in ware house through dynamic pass box.

6.5.2 Wash the Sampling / Dispensing Tools with Purified Water & ensure that no foreign matter should be visible on tools and clean by Scrubbing with soft brush under Purified water.

6.5.3 Used SLS 0.1% with soft brush for cleaning tools.

6.5.4 Take the SLS under RLAF as per requirement and enter the details in RLAF Utilization record as per **Annexure- II**.

6.5.5 After dispensed the material and enter the details in loose container bin card paste on the container.

6.5.6 Method of preparation of SLS 0.1% Solution as per given below.

S.No.	Name of Solution	Solution Code	Concentration	Used Within	Method of Preparation
1.	Sodium Lauryl Sulphate (SLS)	Not Applicable	0.1% w/v	24 Hours	Take 1.0 gm. SLS in a small SS container and make up volume up to



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					1.0Ltr by measure cylinder with water for injection
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6.5.7 Finally rinse the tools with Purified Water.

6.5.8 Wipe the washed Sampling / Dispensing Tools with Lint Free Cloth or compressed air and transfer tools to hot air oven blower for drying.

Remark: Used the Compressed Air for Measuring Cylinder, Sampling Rod, Barrel Pump, Scoops or other any equipment for wipe inner side.

6.6 Filter Integrity & Sterilization of compressed air install filter

6.6.1 Filter should be placed inside the polybag and transferred to production area for filter integrity & sterilization.

6.6.2 Production person shall receive the filter and perform the filter integrity as per SOP.

6.6.3 After filter integrity and filter sterilization production person shall handover the filter integrity report and filter to warehouse person. Warehouse person shall store the filter integrity report.

6.6.4 Sterilized filter shall be transferred to warehouse equipment washing area in surgical box.

6.6.5 Install the filter in compressed air line of equipment washing area.

6.6.6 Filter Integrity & sterilization shall be perform as per frequency of 15 ±2 Days.

6.6.7 Affix the filter stats label on all install filter of SOP.

6.6.8 Record the details of install filter in Annexure “Filter Installation and Destruction Record” SOP, Title: “Dispensing of Non-Sterile Raw Material”.

6.6.9 Handling of cleaned tools used for Non-sterile Raw Material Sampling and Dispensing:

6.6.9.1 Cleaned tools used for Non Sterile Raw Material Sampling / dispensing shall be kept in an Oven at temperature 110°C for 60 min.

6.6.9.2 Section wise wrap the cleaned and dried tools with aluminum foil and shall be kept in closed SS container and affix the ‘CLEANED’ status labels as per the SOP Titled “Status Labeling”.

Remark: All Dispensing tools shall be kept of section wise in separate container.

6.6.9.3 Used sampling and dispensing tools shall be cleaned with in 12 hrs.

6.6.9.4 Unused sampling and dispensing tools shall be cleaned within 48 hrs.



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6.7 Operation of Hot Air Oven:

- 6.7.1 Before using the Hot air oven ensure that it is clean from inside and outside & is free from any dust particle.
- 6.7.2 Concerned person shall be check of Preventive Maintenance tag as per plan.
- 6.7.3 Connect the plug to the power source and switch “ON” the power and switch “ON” the mains of oven.
- 6.7.4 Warehouse person shall be set the temperature of oven at 110°C. & close the door of oven for maintain the temperature.
- 6.7.5 Warehouse person shall be switch off the oven after complete the temperature of oven and shall be transfer all cleaned & dry tools in oven at temperature 110°C for 60 min.
- 6.7.6 Warehouse person shall be note the operation time from wall clock hanging on civil wall in equipment washing area.
- 6.7.7 Warehouse person shall be check the oven temperature status and after ensure shall be stop the oven & note the complete timing in operation log book.
- 6.7.8 Warehouse staff shall record the cleaning & Drying details in “**Sampling / Dispensing Tools Cleaning and Drying Record**” as **Annexure-I**.

6.8 Cleaning of Hot Air Oven:

- 6.8.1 Hot air oven shall be Switch “off” before start the cleaning.
- 6.8.2 Disconnect the plug of HOA.
- 6.8.3 Clean the outer surface of oven with dry lint free cloth.
- 6.8.4 Clean the oven from inner side and outer side with 70% IPA solution.
- 6.8.5 Record the Hot air oven cleaning details in **Annexure –IV’ Cleaning record of Hot air oven.**”
- 6.8.6 **Frequency of cleaning:**
- 6.8.7 **Daily cleaning:** Clean the Hot Air Oven using dry lint free cloth.
- 6.8.8 **Weekly Cleaning:** Clean the Hot Air Oven using lint free cloth & mop with 70% IPA solution for sanitization.

6.9 Cleaning & Drying of New Tools:

- 6.9.1 Any new accessories which are supposed to be used in dispensing area of warehouse shall be implemented through change control procedure.
- 6.9.2 While preparing acid solution, always add acid to water and not a vice versa.
- 6.9.3 Treat all the new Dispensing tools same as mentioned in below given table.



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S.No.	Dispensing Tools Description	Cleaning Agent to be used	Method of Preparation of Cleaning Agent	Treatment to be given
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Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By
1.	New Dispensing tools	5 % HNO ₃ Solution	Dilute 50 ml of Conc. HNO ₃ to 1000 ml with WFI		Soak Dispensing Tools for 30 min.

- 6.9.4** Rinse the treated dispensing tools with Purified Water. Fill the dispensing tools fully with Purified Water, shake them and drain the water. Repeat this three times till the cleaning agent washed off.
- 6.9.5** Finally wash it thrice with Purified Water.
- 6.9.6** Ensure the cleaning of tools and its cleaning agent by thoroughly washing three times with Purified Water.
- 6.9.7** Wrap all the aforesaid Cleaned New Tools and Dry it following all the procedure mentioned above for the same.
- 6.9.8** All Dispensing Equipment ID No. are displaying in warehouse washing area.
- 6.9.9** If any of accessories is found any discrepancy like, rusted, cracking, Damage, unfit for use, it shall be removed from List & area immediately and look for new or any other alternate for the same.
- 6.9.10** In case of any glass & SS accessories breakage store person can update the previous ID. No. Mention on the new glass & SS accessories.
- 6.9.11** Accessories like Scoops, Spoon, and 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.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sampling / Dispensing Tools Cleaning and Drying Record	
Annexure-II	List of Sampling/Dispensing Tools	
Annexure-III	Check List of storage tools	
Annexure-IV	Cleaning record of Hot air oven	

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:



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Not Applicable

10.0 REVISION HISTORY:



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ANNEXURE-I SAMPLING / DISPENSING TOOLS CLEANING AND DRYING RECORD

Block:

Month/Year:

Area:

Date	Tool Used For (Product Name) & @Activity	Batch No.	No. of Tools	Operation /Cleaning Details		Done By Sign/Dt.	Checked By Sign./Dt.	Drying Details		Done By Sign/Dt.	Checked By Sign./Dt.
				From	To			From	To		

@Activity- Unused Tools cleaning as per defined frequency.



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ANNEXURE – III
CHECK LIST OF STORAGE TOOLS

Frequency: Six Month

BLOCK :

S.No.	Name of Sampling /Dispensing Tools	Checked Of Tools Qty.	Checked by Warehouse/ QC Sig. /Dt.	Verified Status OK/ NOT OK	Verified By QA Sign/Dt.	Remark
1.	Scoop					
2.	Spoon Small/Big					
3.	Spatula					
4.	Sampling Road					
5.	Measuring Cylinder					
6.	Barrel Pump					

Remark (if any):.....

