


|  Discovery Labs | STANDARD OPERATING PROCEDURE | | | |
|---|------------------------------|----------------------------|-------------------|------------|
| | SOP No.: | SOP-QA-037-00 | Effective Date: | 01.01.2018 |
| | Supersedes: | SOP-PD-012-03 QC-006-02 | Next Review Date: | 31.12.2020 |
| | Department: | Quality Assurance | Page: | 1 of 4 |
| TITLE: CLEANING OF UTENSILS AND SAMPLING TOOLS | | | | |

1.0 PURPOSE:

To provide a procedure for cleaning utensils and sampling tools.

2.0 SCOPE:

This procedure is applicable for cleaning of utensils and sampling tools used in Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 Ware House, Production and QC person is responsible to follow this SOP.

3.2 Head/Designee of Ware House, Production and QC is responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

4.0 DEFINITIONS:

Nil

5.0 PROCEDURE :

5.1 CONTAINERS

5.1.1 All the product containers should be identified clearly with Product name Material.

5.1.2 Wash the container with water thoroughly.

5.1.3 Check the containers for any material adhering to the sides.

5.1.4 Rinse the container with suitable solvent used for the particular stage, if the material is adhering to the inner sides.


5.1.5 Allow the container to dry.

5.1.6 Check the container for visually for cleanliness

5.1.7 Check the containers for any damage if any damage found replace with new Container in place of the damage container.

5.1.8 Before using of container check it for cleanliness if it is not clean, clean as per the above procedure.

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5.2 DRUMS:

- 5.2.1 All the product drums should be identified clearly.
- 5.2.2 Wash the drums with water thoroughly.
- 5.2.3 Allow the water to drain.
- 5.2.4 Rinse the drums with solvent used for the particular stage
- 5.2.5 Allow the drums to dry by applying Nitrogen / Air.
- 5.2.6 Check the drums for any damage if any damage or scratches replace new drums in place of the damage drums.
- 5.2.7 Before unloading check it for cleanliness if it is not clean, clean as per the above procedure.


5.3 SCOOPS AND SCRAPERS

- 5.3.1 Scoop and scraper should be cleaned after usage.
- 5.3.2 Wash the scoop and scraper by using water.
- 5.3.3 Wash with suitable solvent specific for the particular stage and allow them dry (after wiping with a dry cloth)
- 5.3.4 After cleaning, check the cleanliness and visually
- 5.3.5 Put the accessories in poly bag, affix the cleaned status label
- 5.3.6 Keep the scoop and scraper in their dedicated places.
- 5.3.7 Scoops cleaning details should be record by Ware house person after dispensing of raw material only.

5.4 HOSE PIPES:

- 5.4.1 Dedicated hose pipes should be used in manufacturing activities i.e. for transferring a specific material from one equipment to another equipment.
- 5.4.2 All hosepipes shall carry a tag indicating the name of the material for which it is intended.

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- 5.4.3 Clean the hosepipe with water followed by suitable solvent and allow to dry the hosepipe.
- 5.4.4 In case of the pipe is used in transfer of any solvent, they should be cleaned with respective solvent.
- 5.4.5 Upon completion of cleaning of hose pipes, when not in use, the ends of the hose pipes shall be covered with polythene bags to avoid accumulation of dust and store at the designated place keeping the both ends of pipe down.
- 5.4.6 The hosepipes shall be periodically checked and any torn or worn out hosepipes shall be discarded and new ones shall be used.
- 5.4.7 Water hose shall be drained from water pipe and close the ends and put the pipe in dedicated place.
- 5.4.8 Keep the Tubs, Containers and Utensils in designated Place.


5.5 SS SOLID SAMPLER:

- 5.5.1 After sampling, remove the inner part of the sampler from outer part.
- 5.5.2 Clean the both parts of sampler with plenty of water.
- 5.5.3 Clean with soap solution by using bottle cleaning brush.
- 5.5.4 Clean the sampler parts with water until there is no soap solution. [Foaming should not be observed]
- 5.5.5 Clean the sampler parts with methanol and dry in the hot air oven.
- 5.5.6 After drying place the sampler in identified covers and tie the identification tag for status.
- 5.5.7 Record the cleanliness in the cleaning register.

5.6 LIQUID SAMPLER

- 5.6.1 After sampling, clean the sampler with plenty of water.
- 5.6.2 Clean with soap solution.

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- 5.6.3 Clean the sampler with water until there is no soap solution [Foaming should not be Observed]
- 5.6.4 Clean the sampler with Methanol and dry in the Hot Air Oven.
- 5.6.5 After drying cover the two ends with fresh polythene bags and place the sampler in Identified area and tie the identification tag for status.
- 5.6.6 Record the cleanliness in the cleaning register.

6.0 FORMATS / ANNEXURE(S):

- 6.1 Status Label : QA037-FM0169
- 6.2 Cleaning Record : QA037-FM0170

7.0 CHANGE HISTORY:

| Revision No. | Effective Date | Details of Revision | Ref. CCF No. |
|--------------|----------------|---|-------------------|
| 00 | 01.01.2018 | 1. SOP-PD-012-03& QC-006-02 SOP's are merged and new SOP introduced in QA department for all users. | CCF/GEN/ 17037 |

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