



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Swab Sampling for Validation of Clean Surface

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To establish a procedure for Swab Sampling for Validation of Test Surface to Evaluate Cleaning Efficacy.

2.0 RESPONSIBILITY:

Quality Control Chemist / Quality Assurance Chemist.

3.0 ACCOUNTABILITY:

Quality Control Manager / Quality Assurance Manager

4.0 PROCEDURE

For Chemical Evaluation:

4.1 **SWAB** : A clean room laundered polyurethane foam swab molded into a polypropylene stick.

TRANSPORT CONTAINER : Capped test tubes made of glass.

SAMPLING SOLVENT : As mentioned in the validation protocol of analytical method used for analysis of swab samples of respective active ingredients.

4.2 Swab sampling procedure:

4.2.1 Pipette out 10 ml of sampling solvent in transport container.

4.2.2 Remove a swab from its protective bag using a clean latex hand glove.

4.2.3 Avoid touching the swab head to prevent its contamination.

4.2.4 Transfer the swab in transport container (test tube) containing 10 ml of sampling solvent and allow the swab to soak completely.

4.2.5 Take out the swab from sampling solvent and squeeze the tip against inner surface of test tube to remove excess solvent in such a manner that excess sampling solvent drips inside the test tube.

4.2.6 Hold the stem of swab without touching the head of the swab.

4.2.7 Using one side of moistened swab wipe the test surface of 2" x 2" with 10 firm horizontal strokes as illustrated in Fig. 1.

4.2.8 At the end of each stroke, lift the swab carefully.

4.2.9 Turn the swab over to its other side, wipe the test surface of 2" x 2" with 10 firm vertical strokes as illustrated in figure no.2.

4.2.10 At the end of each stroke, lift the swab carefully.



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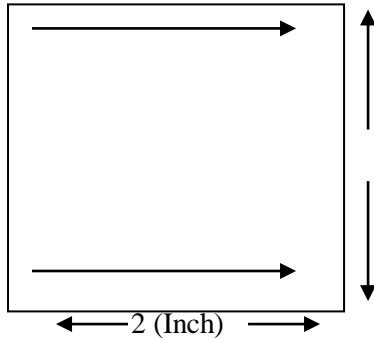


Fig: 1

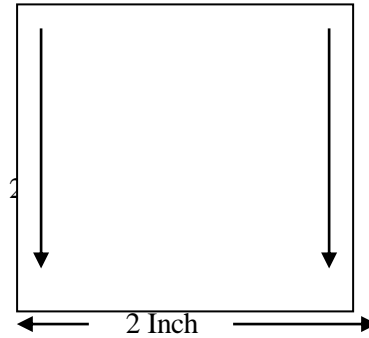


Fig: 2

Hold the stem of the swab without touching the head of the swab and let the swab drop into the transport container. Cap the transport container and send for analysis after labeling the same.

4.3 PROCEDURE FOR MICROBIOLOGICAL EVALUATION:

- 4.3.1 Take a sterile swab to sampling point.
- 4.3.2 Make the swab with (1) sampling point and (2) Date on outer cover.
- 4.3.3 Put on the clean latex hand gloves and disinfect the same with 70% IPA.
- 4.3.4 Take out the sterile swab carefully from the outer cover and swab the complete selected area (10 x 10cm).
- 4.3.5 Replace the swab immediately inside the cover, close it and send for analysis.

4.4 ABBREVIATIONS:

IPA = Iso- Propyl Alcohol

5.0 REASON FOR REVISION:

Harmonization of format.

6.0 TRAINING:

Trainer: Head – Quality Control
Trainees: Quality Control Chemists
Period: One day

7.0 DISTRIBUTION:

Certified Copy No. 1 : Head of Department – Quality Control
Certified Copy No. 2 : Head of Department – Quality Control
Original Copy : Head – Quality Assurance

8.0 ANNEXURES:

Nil.

9.0 REFERENCES

In-house.



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