DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Swab Sampling During Product Changeover	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for swab sampling during product changeover.

2.0 SCOPE:

This SOP is applicable for swabs to be taken from equipment surfaces after during product changeover in manufacturing and packing departments for routine monitoring of cleaning of equipments.

3.0 RESPONSIBILITY:

Officer/Executive- QA

Officer/Executive-QC

Officer/Executive -Production

Head – Quality Assurance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 During product changeover and after cleaning of equipments as per respective SOP's, Production officer In charge shall inform to QA officer with intimation slip for collection of swabs sample as per specified locations (Refer Annexure-I) from different equipment surfaces.

5.2 QA officer shall marks on the test tubes according to locations of swabs and transfer the test tubes into the respective area.

5.3 QA officer shall checks the proper cleaning of the previous product and collect the swab stick in the test tube from QC, which is soaked in purified water or suitable solvent (based on the solubility of that products).

5.4 QA officer shall remove the swab stick from the test tube and shall take swab sample of respective surface area of equipment and put into the respective test tube.

5.5 Cover the test tubes and send it to QC with intimation slip for analysis.

5.6 After getting satisfied results from QC, QA officer shall certify line clearance of this respective area for switching over to next product manufacturing.

5.7 QA shall take the swab 5 x 5 cm of each location

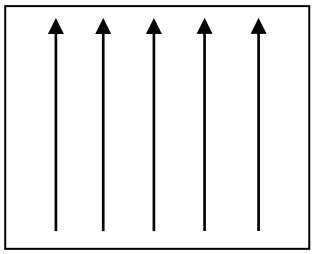
5.8 The detailed procedure is given below:

5.9 Swab samples shall be taken after the final cleaning of the equipment.

5.9.1 **Sampling Pattern**: With the help of swabs, wipe the defined area in both the directions as shown in the figure. Apply swab stroke only one time. Do not rub the surface in to & fro movement. Refer the typical diagram to collect the sample-using swab.

(**Direction of swabbing strokes**)

and



5.9.2 Required number of swabs shall be taken in this manner at defined location as per Annexure –I.

5.9.3 After swabbing the specified area, store swab in a test tube.

5.9.4 Ensure that the test tubes are identified.

6.0 ABBREVIATION (S):

Cm: centimeter

QA: Quality Assurance

QC: Quality Control

SOP: Standard Operating Procedure

7.0 REFERENCE (S):

NA

8.0 ANNEXURE (S):

Annexure –I: Location of swabs to be taken from equipment surfaces

Annexure –II: Detail list of Solubility of active content.

9.0 REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

Annexure I

Swabbing Sites for Routine Cleaning

S.No.	Name of Equipment	Site No.	Sampling Sites
Granulation area:			
1.	Vibro - Sifter	1	Hopper
		2	Chute
2.	Multi-Mill	1	Rotor Blade
		2	Discharge Port
3.	Bin Blender	1	Bottom discharge Port
		2	Inner surface of bin
4.	Roll Compacter	1	Inner surface of outlet
		2	Impeller
Compression area:			
5.	Compression Machine	1	Hopper
		2	Turret
		3	Feed frame
		4	Outlet chute
6.	De duster cum metal detector	1	Inlet
		2	Chute
Coating area:			
7.	Coating solution preparation tank	1	Inner surface
		2	Outlet
8.	Coating Machine	1	Inner surface
		2	Baffle
Inspection area:			
9.	Inspection belt	1	Belt
		2	Hopper
10.	Blister packing machine	1	Hopper
		2	Bowl

Annexure II
Solubility Data of Raw Material

S.No.	Product Name	Active Raw Material	Solubility in