DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Sampling of Rinse Water/Swab	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for sampling of Rinse water/Swab.

2.0 SCOPE:

This Standard Operating Procedure shall be applicable for procedure for sampling of rinse water/ swab of …….

3.0 RESPONSIBILITY:

3.1 Officer/Executive Production shall give intimation to QA for collection of rinse water/swab sample.

3.2 Officer/Executive QA shall be responsible for sampling of rinse water/swab sample for analysis.

3.3 Officer/Executive Production shall send the sample to QC for analysis.

4.0 ACCOUNTABILITY:

Head -Quality Assurance or his/ her designee shall be responsible for compliance of SOP.

5.0 DEFINITIONS:

Not applicable

6.0 PROCEDURE:

6.1 Swab water sampling

6.1.1 Swab water sampling shall be performed after cleaning the equipment's and area for every product to product changeover.

6.1.2 Officer/Executive QA shall receive intimation from production for sampling of swab water of equipment's / areas in production department.

6.1.3 Officer/Executive QA shall take required quantity of sterile swab sticks for particular parts of equipment / area.

6.1.4 Collect the swab sample from clean surface of particular parts of equipment / area surface (approximate-100 sq.cm) 10x10 sq.cm 10 sq.cm in vertical position & 10 sq.cm in horizontal position and label the swab sample duly signed.

6.1.5 Submit the sample to QC department for swab analysis as per **Annexure-I.**

6.1.6 QC shall perform analysis of the sample, prepare the analysis report and same shall be sent to QA department.

6.1.7 If sample does not comply, QC department shall immediately intimate to Head QA / his designee for further action.

6.1.8 QC department shall be followed for swab sample also per **Annexure-I.**

6.2 Rinse water sampling

6.2.1 Rinse water sampling shall be performed after cleaning the equipment.

6.2.2 Officer/Executive QA shall receive intimation from Officer/Executive production for sampling of rinse water of equipment used in production department.

6.2.3 Take required quantity of Water for Injection for particular equipment. Pour into cleaned equipment (contact part of equipment).

6.2.4 Collect rinse water (approximate 200 ml) from equipment's in clean, dry glass bottle / pet and label the bottle, duly filled and signed Label as per **Annexure …...**

6.2.5 Submit the sample to QC department for rinse water analysis as per **Annexure-II**

6.2.6 QC shall perform analysis of the sample, prepare the analysis report and same shall be sent to QA department.

6.2.7 After receiving rinse water analysis report, production department shall affix **'CLEANED'** label as per **Annexure …….**on the equipment's duly filled and signed.

6.2.8 If sample does not comply, QC department shall immediately intimate to Head QA / his designee for further action.

6.3 Annexure-I & Annexure-II is the duplicate logbook one copy is attached in BMR & BPR and second copy is initiator department.

7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
No.	Number
QC	Quality Control
Ar. No.	Analytical Report Number

8.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure-I	Swab Intimation cum Report	
Annexure-II	Rinse water Intimation cum report	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control
- Controlled Copy No. 03Production

10.0 REFERENCES:

In house

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

ANNEXURE-I

SWAB INTIMATION CUM REPORT

From: Production Department		To: QA Department
	Intimated by (Production)	**Intimation Received by (QA)**
Name		
Sign		
Date		
Time		

❖ **Equipment Details (To be filled by Production department)**

Name of Equipment			
Equipment No.			
Previous Product		**Batch No.**	
Equipment to be used for		**Batch No.**	
Name of Contact Parts	**1.**	**5.**	
	2.	**6.**	
	3.	**7.**	
	4.	**8.**	

Sample Quantity:	**Sample collected by QA Sign/Date/Time**

❖ **Sampling Details (To be filled by Quality Control department)**

Sample Received by QC Sign/Date/Time	**A. R. No.**

The equipment Can Be Used 1. _____ 2. _____ 3. _____ 4. _____
5. _____ 6. _____ 7. _____ 8. _____

Not To Be Used1. _____ 2. _____ 3._____4. _____
for further process. 5. _____ 6. _____ 7. _____ 8. _____

Swab Sample Complies / Does Not Comply the standard specifications.

Quality Control
Sign/Date

❖ **If Sample Dose Not Complies (To be filled by QA department)**

Remarks: _____

_____

Manager QA /Head QA
Sign& Date_____

ANNEXURE-II

RINSE WATER INTIMATION CUM REPORT

❖ Equipment Details (To be filled by Production department)			
Name of Equipment			
Equipment ID. No.			
Previous Product		**Batch No.**	
Sample Quantity			
Test			

Intimated by (Production)	Sampled by (QA)	Sample Received by (QC)
Name **Sign/Date/Time**	**Name** **Sign/Date/Time**	**Name** **Sign/Date/Time**

❖ **Sampling Details (To be filled by Quality Control department)**

A. R. No.

The Rinse Water Sample Complies / Does Not Comply the standard specifications.

Quality Control
Sign/Date

❖ **If Sample Dose Not Complies (To be filled by QA department)**

Remarks: _____
_____

Manager QA /Head QA
Sign & Date_____