

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Control SOP No.:				
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>			
Supersedes: Nil	<b>Review Date:</b>			
Issue Date:	Page No.:			

#### 1.0 **OBJECTIVE**:

To provide a procedure for analysis of Wash Water/Swab samples.

#### 2.0 SCOPE:

This SOP is applicable for analysis of Wash Water/Swab samples received in Quality Control Department.

#### 3.0 **RESPONSIBILITY:**

Officer, Executive - Quality Control Head- Quality Control.

#### 4.0 **PROCEDURE:**

#### 4.1 Procedure for Wash water Analysis:

- 4.1.1 After receiving the samples make necessary entry in inward register as per Annexure -IV of SOP.
- 4.1.2 Generate the A.R. no. of wash water as follows

SW-0001/22

SW Swab water (Wash water)

- Dash

0001 Serial number of the sample

/ Slash

- Last two digit of the Year (22 for year 2022) as per SOP
- 4.1.3 Write the A.R. no. on the requisition slip which is received with samples from QA Department.
- 4.1.4 Scan the blank received with the sample from 200 nm to 400 nm on UV-Vis Spectrophotometer as per SOP
- 4.1.4 Then scan sample(s) from 200 nm to 400 nm on UV-Vis Spectrophotometer.
- 4.1.5 Compare the absorbance with the Ready Reference for individual as per Annexure –II.

Acceptance criteria: Absorbance at mentioned  $\lambda$  max should be less than reference standard absorbance as per Annexure –II.

4.1.6 Make entry of status of analysis on the inward register in remarks column and give the results to



#### QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Control SOP No.:				
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>			
Supersedes: Nil Review Date:				
Issue Date:	Page No.:			

production department through received intimation slip.

4.1.7 Prepare data sheet for Ready reference for individual once before starting of routine analysis as per Annexure –I (Data sheet for ready reference).

#### 4.2 Procedure for Swab sample Analysis:

- 4.2.1 Follow the procedure as per point no. 4.1.1 to 4.1.3
- 4.2.2 Cut the Swab stick and transfer the remaining swab to Test tube, add diluent up to 10 ml and shake vigorously/ Vortex to dissolve the content and remove the swab from test tube.
- 4.2.3 Scan the blank received with the sample from 200 nm to 400 nm on UV-Vis Spectrophotometer as per SOP.
- 4.2.4 Then scan sample(s) from 200nm to 400nm on UV-Vis Spectrophotometer.
- 4.2.5 Compare the absorbance with the Ready Reference for individual as per Annexure –II.

Acceptance criteria: Absorbance at mentioned  $\lambda$  max should be less than reference standard absorbance as per Annexure –II.

4.2.6 Make entry of status of analysis on the inward register in remarks column and give the results to production department through received intimation slip.

#### 5.0 ANNEXURE (S):

Annexure –I: Data sheet for ready reference.

Annexure –II: Ready reference for wash water/Swab samples.

#### 6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Allocation of Analytical Reference Number.

SOP: Handling of Finished products, Semi-finished, In process, Validation and Swab Samples

SOP: Procedure for operation and calibration of UV-Visible Spectrophotometer.



QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Control SOP No.:			
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

### **7.0 ABBREVIATION** (S)/**DEFINITION** (S):

SOP: Standard Operating procedure.

A.R. No.: Analytical reference number.

nm: Nano meter

#### **REVISION CARD**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	RFERANCE CHANGE CONTROL No.
1	00			New SOP	



QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Control	SOP No.:		
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

# ANNEXURE I DATA SHEET FOR READY REFERENCE

Preparation of 10 ppm Standard solution of _	
Solution reference no.:	Date of preparation
WS Batch no.:	Validity
Preparation 1)	
Dissolve(10) mg of	in 100 ml of
Pipette 10 ml of above solution in 100 ml of	·
Preparation 2)	
Dissolve (10) mg of	in 100 ml of
Pipette 10 ml of above solution in 100 ml of	
Preparation 3)	
Dissolve (10) mg of	in 100 ml of
Pipette 10 ml of above solution in 100 ml of	·
Take the absorbance from 200nm to 400nm	(λ max=nm)
Standard absorbance for 10 ppm solution (Corn	rection):-
Absorbance of standard x 10 Standard weight	
For preparation 1)	
x10 =	



QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Control SOP No.:			
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

For preparation 2)		
x10 =		
For preparation 3)		
x10 =		
Average standard Absorbance=		
Prepared by: Date:	Checked by: Date:	Approved by: Date:



QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Control	SOP No.:		
Title: Procedure for Wash Water/Swab Sample Analysis	<b>Effective Date:</b>		
Supersedes: Nil	<b>Review Date:</b>		
Issue Date:	Page No.:		

#### **ANNEXURE II**

### READY REFERENCE FOR WASH WATER/SWAB SAMPLES

REF. No.	MATERIAL NAME	λMAX	AVERAGE REF. ABS. (10 ppm)	PREPARED BY/ DATE	CHECKED BY/DATE