



Title: Procedure for Wash Water/Swab Sample Analysis

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
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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

15 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 λ 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



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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 λ 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.

7.0 ABBREVIATION (S)/DEFINATION (S):

SOP: Standard Operating procedure.



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A.R. No.: Analytical reference number.

nm: Nano meter

REVISION CARD

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

ANNEXURE I
DATA SHEET FOR READY REFERENCE

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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 (Correction):-

$$\frac{\text{Absorbance of standard}}{\text{Standard weight}} \times 10$$

For preparation 1)

$$\text{_____} \times 10 = \text{_____}$$

For preparation 2)

$$\text{_____} \times 10 = \text{_____}$$



PHARMA DEVILS

ENGINEERING DEPARTMENT

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For preparation 3)

_____x10 = _____

Average standard Absorbance= _____

Prepared by:
Date:

Checked by:
Date:

Approved by:
Date:

