VALIDATION PROTOCOL FOR DRAIN TIME OF PURIFIED WATER

1.0 Objective:

To validate the Drain time of Purified water and to demonstrate that the Purified water collected after a certain drain time interval from various user points is of required quality.

2.0 Scope:

Applicable to Purified water used for various purposes in Pharma Department.

3.0 Justification:

Justification to be recorded for performing the validation in the Report.

4.0 Site of the Study:

To be recorded in the Validation Report.

5.0 Responsibility:

Representatives from: Production:
Quality Control
Quality Assurance
(Individual names to be recorded)

6.0 Description of the Equipment to be used:

Stop watch: Code No. to be recorded in the validation report.

7.0 Standard Operating Procedure to be followed:

7.1 Sanitization of Purified Water Storage and Distribution system.
(SOP No. to be recorded in the validation report.)

7.2 Operation and Regeneration of Purified water Plant.
(SOP No. to be recorded in the Validation Report.)

7.3 Specification for of Purified water
(Specification No. to be recorded on report.)

8.0 Controls:

8.1 Requirements:

Sanitization of Purified Water Storage and Distribution system should be done as per SOP.
Sanitization Done On: To be recorded in Validation Report
Due On: To be recorded in Validation Report

8.2 Calibration:

Calibration details of stop watch to be recorded in the validation report.

8.3 Training:

Training Personnel details to be recorded in the report.

8.4 Precautions:

Ensure all safety procedures are being followed during sampling namely:

- Use sterile bottle for sampling of Purified water and check the breakage of bottle prior to sampling.
- Prior to sampling check whether the area is sanitized (If applicable).
- Use all necessary precautions viz. nose mask, snood, etc. (wherever applicable) during sampling.
- Use sterile gloves for sampling.

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- Open the stopper of each bottle at specified interval after checking through stop watch during sampling of purified water.
- Immediately close the stopper of the bottle after sampling of required quantity of purified water.

9.0 Validation Procedure:

9.1 Operate the Purified Water system as per the SOP.

9.2 Collect 150 ml of Purified water from the nearest, farthest and any one user point at time intervals of 0 min (initial), 1 min, 2 mins and 3 mins of draining for 3 consecutive working days.

9.3 Visually inspect the Purified water sampled.

9.4 Analyse the sample as per the Quality Control specification for bioload.

9.5 Record the observations and results in the report.

10.0 Acceptance criteria:

10.1 The sample visually inspected should be clear.

10.2 The Purified water collected from the user points should meet the Purified water Specification for bio-load.

S.No.	Test	Limit
1.	Total Viable Count (TVC)	NMT 100 Cfu/ml
2.	Pathogens - Eschericia.coli, Salmonella, Staphylococcus.aureus, Pseudomonas.aeruginosa.	Nil /100 ml

11.0 Details of deviation:

11.1 Deviation:

Any Deviation if observed should be recorded in the Validation Report and should be investigated.

11.2 Out of Specification:

Any Out of Specification (OOS) if observed should be recorded in the Validation Report and investigation should be done.

12.0 Type of validation:

Concurrent validation.

13.0 Frequency of validation:

One validation exercise per year.

14.0 Results and Observations:

Record the observations during the study and results obtained from Quality Control Department in the validation report.

15.0 Summary of validation activity:

Summarize the findings of the validation study to draw an inference.

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16.0 Recommendation:
Record the recommendations based on the interpretation of results in the Validation report.

17.0 Team Approval:
The individuals who have performed the validation study, supervised the validation, completed the records, performed the testing of the product should approve the validation report.

18.0 Review:
The Validation Report should be reviewed by Unit Quality Assurance Head and notified by Unit Head. The report should include any follow-up action if required.

19.0 Approved by:
Validation report should be finally approved by Unit Quality Assurance Head and Notified by Unit Head.

20.0 Attachments (if any):
Annexures (if any) attached to the validation report should be recorded.

21.0 Abbreviations:

SOP	-	Standard Operating Procedure.
No.	-	Number
Sr.	-	Serial
TVC	-	Total viable count
Cfu	-	Colony forming unit
NMT	-	Not more than
Mins	-	Minutes