PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

VALIDATION REPORT 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:

4.0 Site of the Study:

_____

5.0 Responsibility:

Production : _____

Quality Assurance : _____

Quality Control : _____

6.0 Description of the Equipment to be used:

Stop watch.

Code No.: _____

7.0 Standard Operating Procedure (SOP)/Specifications to be followed:

7.1 Sanitization of Purified Water Storage and Distribution system.

SOP No._____.

7.2 Operation and Regeneration of Purified Water SOP No: _____

7.3 Specification for Purified water

Specification No. :_____

8.0 Controls:

8.1 Requirements:

i) Sanitization of Purified Water Storage and Distribution System should be done as per Standard Operating Procedure.

Sanitization Done on: _____

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Due on: _____

ii) Operation and Regeneration of Purified Water Plant should be done as per SOP No.:_____

8.2 Calibration:

Calibration of stop watch done on: _____ due on: _____

8.3 Training:

Name	Training status	Training report availability	Checked by

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.
- 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:

Carry out the experiment as per Validation Protocol.

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 below given Purified water specification limits for bioload :-

S.No.	Test	Limit
1.	Total Viable Count (TVC)	NMT 100 Cfu/ml

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2.	Pathogens - Eschericia.coli, Salmonella, Staphylococcus.aureus, Pseudomonas.aeruginosa.	Absent /100 ml

11.0 Non Compliances:

11.1 Details of Deviations:

Deviation Report dated	Checked by

11.2 Details of OOS results:

OOS Report dated	Checked by

12.0 Type of validation:
Concurrent validation.

13.0 Frequency:
One validation exercise per year.

14.0 Results and Observations:

14.1 Date of Experiment: _____/_____/_____.

S.No.	Sampling point location	Sampling points
1.	Nearest	
2.	Furthest	
3.	Any one user point	

14.2 Visual inspection of Purified water sampled.

S.No.	Sampling points	Sampling Time interval (mins)	Visual Inspection		
			Day-I	Day-II	Day-III

1.		Initial			
		1 min			
		2 min			
		3 min			
2.		Initial			
		1 min			
		2 min			
		3 min			

S.No.	Sampling points	Sampling Time interval (mins)	Visual Inspection		
3.		Initial			
		1 min			
		2 min			
		3 min			

14.3 Bio load Observation:

S.No.	Sampling Points	Sampling Time interval (mins)	Observation					
			TVC (Limit-NMT100 cfu/ml)			Pathogens (Limit-Absent /100 ml)		
			Day I	Day II	Day III	Day I	Day II	Day III
1.		Initial						
		1 min						
		2 min						
		3 min						
2.		Initial						
		1 min						
		2 min						
		3 min						
3.		Initial						
		1 min						
		2 min						
		3 min						

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15.0 Summary of validation activity:

16.0 Recommendations:

17.0 Team Approval:

_____	_____	_____
Production	Quality Assurance	Quality Control
Date:		

18.0 Review:

19.0 Approved by: **Noted by:**

_____	_____
HEAD UNIT QUALITY ASSURANCE	UNIT HEAD

20.0 Attachments (if any):

21. Abbreviations:

No.	-	Number
SOP	-	Standard Operating Procedure
OOS	-	Out of Specification
TVC	-	Total viable count
NMT	-	Not more than
Cfu	-	Colony forming units
ml	-	millilitre