



**PERFORMANCE QUALIFICATION PROTOCOL  
FOR  
DRAIN TIME STUDY FOR WATER SAMPLES**

**PROTOCOL No.:**

**REVISION No.:**

**EFFECTIVE DATE:**

**PAGE No.: 1 OF 37**

**DRAIN TIME STUDY PROTOCOL  
FOR  
COLLECTED WATER SAMPLES**

<b>PROTOCOL No.</b>	
<b>SUPERSEDES No.</b>	NIL
<b>EFFECTIVE DATE</b>	



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**1.0 Pre – Approval:**

The Protocol has been prepared, Reviewed and Approved for implementation by the under signed.

<b>PREPARED BY</b>	<b>SIGNATURE</b>	<b>DATE</b>

<b>REVIEWED BY</b>	<b>SIGNATURE</b>	<b>DATE</b>

<b>APPROVED BY</b>	<b>SIGNATURE</b>	<b>DATE</b>



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**2.0 OBJECTIVE:**

Objective of this protocol is to provide documented evidence through the scientific data to establish and verify that drain time study of different type of water.

**3.0 SCOPE:**

3.1 This procedure is applicable to drain time study of different type of water

**4.0 ACCEPTANCE CRITERIA:**

**5.0 RESPONSIBILITIES:**

5.1 QA shall write the protocol in consultation with QA/QC Manager.

5.2 Microbiologist shall be responsible for preparation of media, culture suspension preparation, preparing the use dilution as per the manufacturers recommendation and also for compilation of data.

5.3 Head QC or designee will check the protocol for its completeness, accuracy, technical excellence and applicability.

5.4 Senior Microbiologist will monitor the analysis.

5.5 Head QA or designee shall be responsible for final approval of protocol.

**6.0 PROCEDURE:**

**6.1 Sampling Procedure**

6.1.1 Clean 500 ml Clear glass bottles with cap for membrane filtration method or pour plate method and rinse with purified water. Close the bottle with cap and wrap the neck with aluminum foil. Sterilize the container at 121 °C (15 lbs) for 30 minutes.

6.1.2 Carry the sampling containers to the sampling point. Sanitize the hands with 70 % v/v IPA. Wear gloves and nose mask before sampling. Open the valve of the sampling point and allow the water to drain as per Table-I.



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**Table- I**

S.No.	Sampling Point Name	Sampling Point ID	Sample quantity	Drain Time	Test
1.	Purified Water Return Loop		500 ml	20 Second	Bioburden
				30 Second	
				60 Second	
				2 Minutes	

**6.2 Analysis for Bioburden:**

6.2.1 Analyze the sample of Purified water for Total Viable Count using filtration technique as per the current version of GTP “Microbial Limit Test of Water”.

**7.0 EVALUATION OF RESULTS:**

It shall meets the specification of its particular water type.

**8.0 REVALIDATION FREQUENCY:**

Revalidation shall be carried out in case of

**9.0 CONCLUSION:**

Summary report will be prepared, which clearly state the successful achievement of objective of validation