



PHARMA DEVILS

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QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

**REQUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DSITRIBUTION
SYSTEM**

**REQUALIFICATION PROTOCOL
FOR
PURIFIED WATER STORAGE &
DSITRIBUTION SYSTEM**



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1.0 PROTOCOL PRE APPROVAL:

Signing of this approval page of Protocol indicates agreement with the requalification approach described in this document. If modification to the requalification approach becomes necessary. The protocol cannot be used for execution unless approved by the following authorities.

This Requalification protocol of Purified water Storage & Distribution System been reviewed and approved by the following persons:

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		PROJECTS / ENGINEERING		
REVIEWED BY		PRODUCTION		
REVIEWED BY		QUALITY CONTROL (MICRO)		
REVIEWED BY		QUALITY CONTROL		
APPROVED BY		QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of this protocol is to perform & evaluate the power failure study of all user point of distribution loop of purified water distribution system. The power failure study of water system is available which was performed during PQ stage for 5 min. Now it is planned to perform the power failure study for 12 hours.

2.2 PURPOSE:

The purpose of this protocol is to execute & evaluate the power failure study which is planned to execute in water system.

2.3 SCOPE:

This document is applicable to power failure study of purified water storage & distribution system at service floor.

2.4 RESPONSIBILITY:

The following shall be responsible:

Quality Assurance officer/ Executive-Preparation of protocol its execution and support

Execution team –for execution of protocol

Projects / Engineering – For execution support and review of protocol/report

Production – For execution support and review of protocol/report

Quality Assurance Head – For adequacy and final approval



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2.5 EXECUTION TEAM:

The satisfactory power failure study of the purified water storage & distribution system shall be verified by executing the requalification studies described in this protocol. The successfully executed protocol documents that the purified water storage & distribution system is working satisfactorily.

Execution team is responsible for the execution of power failure study of purified water storage & distribution system, Execution team comprises of:

NAME	DEPARTMENT	DESIGNATION	SIGNATURE	DATE
	PROJECTS/ ENGINEERING			
	PRODUCTION			
	QUALITY CONTROL			
	QUALITY CONTROL (MICRO)			
	QUALITY ASSURANCE			



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3.0 ACCEPTANCE CRITERIA:

- 3.1 All SOPs for the equipment shall be available
- 3.2 All the functionality of equipment & components shall be available.
- 3.3 The validity of the calibration of test instruments shall be within calibration status with tag.
- 3.4 Capacity of equipment shall be verified.

4.0 REQUALIFICATION CRITERIA:

The purified water storage & distribution system shall be requalified if

- ☞ There are any major changes in system components which affect the performance of the system.
- ☞ After major breakdown maintenance is carried out.
- ☞ After change in the location
- ☞ As per revalidation date and schedule

5.0 REQUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

Equipment Name	:	Purified Water Storage & Distribution System
Supplier/Manufacturer	:	
Capacity	:	7.5 KL
Location	:	
Equipment id	:	

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

- 5.2.1 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.2 Actual observation of the component should be written in specified location
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the Requalification report.
- 5.2.5 Whichever column is blank or not used 'NA' shall be used.



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5.3 Procedure for Power failure study:

Perform the power failure study in distribution loop to evaluate the impact of power failure on Purified Water quality after Power OFF of the purified water distribution pump for 12 hours.

Collect water samples from all the sampling points at interval of 04 hours i.e. sampling from all sampling points shall be performed at 04 hours, 08 hours and 12 hours after switching off the distribution pump and same shall be analyzed as per specification. The power failure study shall be performed after Power OFF of the purified water distribution pump

Note: Purified water distribution loop shall not be started during sampling of power failure study.

On successful completion of sampling for power failure study drain the water from distribution loop and sanitization shall be carried out as per current SOP & observation shall be recorded below table-II

Power failure study

Table – I

Purified water distribution loop off time: _____

S.No.	Sampling Interval	Sampling Done by (Sign/Date)	Checked by (Sign/Date)
1.	04 hours Date: Time:		
2.	08 hours Date: Time:		
3.	12 hours Date: Time:		



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5.4 Sampling Plan:

After completion of sampling from all user points and return loop shall performed for 4 hr, 8 hr, 12 hr time and trend shall be made and evaluate the impact. After successful completion of the activity routine monitoring of purified water user points shall be carried out as per define frequency in SOP.

5.5 Sampling points and Sampling frequency:

The sampling points and their sampling frequencies are mentioned as below.

Sampling point No.	Sampling points Description	Frequency
SP-13B	RM store Janitor room ground floor	4 hours, 8 hours, 12 hours
SP-14B	RM store wash area ground floor	4 hours, 8 hours, 12 hours
SP-15B	Wash area ground floor	4 hours, 8 hours, 12 hours
SP-16B	IPQA ground floor	4 hours, 8 hours, 12 hours
SP-17B	Janitor room first floor	4 hours, 8 hours, 12 hours
SP-18B	IPQA first floor	4 hours, 8 hours, 12 hours
SP-19B	Wash room first floor	4 hours, 8 hours, 12 hours
SP-20B	Coating-VIII First floor	4 hours, 8 hours, 12 hours
SP-21B	Coating Solution preparation-1 (first floor)	4 hours, 8 hours, 12 hours
SP-22B	Coating-IX first floor	4 hours, 8 hours, 12 hours
SP-23B	Coating -X First floor	4 hours, 8 hours, 12 hours
SP-24B	Coating-XI first floor	4 hours, 8 hours, 12 hours
SP-25B	Coating Solution Prep-II (FIRST FLOOR)	4 hours, 8 hours, 12 hours
SP-26B	Pilot Plant FBD (Second Floor)	4 hours, 8 hours, 12 hours
SP-27B	Pilot Plant RMG (Second Floor)	4 hours, 8 hours, 12 hours
SP-28B	Granulation-VI second floor	4 hours, 8 hours, 12 hours
SP-29B	Sifting and milling area-VI second floor	4 hours, 8 hours, 12 hours
SP-30B	Paste preparation – I second floor	4 hours, 8 hours, 12 hours
SP-31B	Sifting and milling area-III second floor	4 hours, 8 hours, 12 hours
SP-32B	Granulation-VII second floor	4 hours, 8 hours, 12 hours



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Sampling point No.	Sampling points Description	Frequency
SP-33B	Paste preparation –II second floor	4 hours,8 hours,12 hours
SP-34B	FBP solution preparation second floor	4 hours,8 hours,12 hours
SP-35B	Granulation-VIII second floor	4 hours,8 hours,12 hours
SP-36B	Bin washing service floor	4 hours,8 hours,12 hours
SP-37B	Unclean Bin Room Area	4 hours,8 hours,12 hours
SP-38B	Janitor room second floor	4 hours,8 hours,12 hours
SP-39B	IPQA second floor	4 hours,8 hours,12 hours
SP-40B	FBP –III second floor	4 hours,8 hours,12 hours
SP-41B	FBP-III Second floor	4 hours,8 hours,12 hours
SP-42B	Blender VI	4 hours,8 hours,12 hours
SP-43B	FBP-V Second floor	4 hours,8 hours,12 hours
SP-44B	Blender –IV second floor	4 hours,8 hours,12 hours
SP-45B	Roll compactor V (Second Floor)	4 hours,8 hours,12 hours
SP-46B	Sifting and milling area- I Second floor	4 hours,8 hours,12 hours
SP-47B	Granulation –V second floor	4 hours,8 hours,12 hours
SP-48B	Return Loop	4 hours,8 hours,12 hours
SP-49B	Coating Area -XIII	4 hours,8 hours,12 hours
SP-50B	Solution Preparation (Inspection –X)	4 hours,8 hours,12 hours
SP-51B	Feed up Water to PSG	4 hours,8 hours,12 hours
SP-52B	FBD-6 Area	4 hours,8 hours,12 hours
SP-53B	Granulation Area -IX	4 hours,8 hours,12 hours
SP-54B	FBP Machine WIP	4 hours,8 hours,12 hours
SP-55B	Solution Preparation -III	4 hours,8 hours,12 hours
SP-56B	Solution Preparation -IV	4 hours,8 hours,12 hours
SP-57B	PSG-III	4 hours,8 hours,12 hours



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5.6 Sanitization procedure:

Sanitize the system with hot water as per current sanitization SOP for distribution system. After completion of sanitization the purified water may be supply to distribution loop for routine activity.

5.7 Sanitization process:

Table II

Date of Sanitization	Sanitization Start On	Sanitization Completed On	Done By (Sign/Date)	Checked By (Sign/Date)

Inference:-----

Reviewed by
(Sign & Date)



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5.8 Acceptance Criteria:

Water, which is collected from different locations from distribution system, shall meet the specified acceptance limits mentioned in given below table.

Acceptance criteria for Purified water:

S.No.	Test	Specification
1.	Description	Clear color less and odorless liquid
2.	pH	Between 5.0 to 7.0
3.	Conductivity at 25°C (µS/cm)	1. *For online monitoring Not more than 1.25 µS/cm 2. #For offline monitoring Stage 1: NMT 1.3 µS/cm Stage 2: NMT 2.1 µS/cm Stage 3: NMT 4.7 µS/cm
4.	Acidity/ Alkalinity	For acidity, the resulting solution should not be red For alkalinity, the resulting solution should not be blue.
5.	Nitrate (ppm)	Not more than 0.2
6.	@Nitrite content (µg/ml) (by HPLC)	Not more than 0.1
7.	Heavy Metals (ppm)	Not more than 0.1
8.	*Total Organic Carbon (ppb) (Alternative Test) **Oxidisable Substances	NMT 500 ppb The solution should remain faintly pink
9.	Total Viable Count (cfu/ml)	NMT 100
10.	Test for specified microorganism	
A.	<i>Escherichia coli</i> ,	Should be Absent
B.	<i>Staphylococcus aureus</i>	Should be Absent
C.	<i>Pseudomonas aeruginosa</i>	Should be Absent
D.	<i>Salmonella species</i>	Should be Absent
E.	<i>Burkholderia cepacia</i>	Should be Absent

* Online measurement.

** In case of instrument breakdown, perform oxidisable substance in place TOC.

In Case of instrument breakdown, perform offline conductivity measurement.

@ shall be performed only on return loop point.



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5.9 Action in case of Failure:

In case of any failure, investigation shall be carried out and rectification or modification shall be done if required. Based upon the data recommendation shall be given. During this period no production activity shall be carried out.



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7.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the requalification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol, (if applicable).

Signatures in the block below indicate that all items in this requalification report of Purified water storage & distribution system have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PROJECTS / ENGINEERING		
		PRODUCTION		
		QUALITY CONTROL (MICRO)		
		QUALITY CONTROL		
		QUALITY ASSURANCE		