



**PHARMA DEVILS**

**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PROTOCOL No.:**

**HYDRO TEST QUALIFICATION PROTOCOL FOR PURIFIED WATER TANK**

# **HYDRO TEST QUALIFICATION PROTOCOL**



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**1.0 PROTOCOL APPROVAL:**

Signing of this approval protocol indicates agreement with the validation approach described in this document. The protocol cannot be used for execution unless approved by the following authorities.

This addendum protocol of purified water system has been reviewed and approved by the following persons.

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		PROJECTS/ ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		



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### 2.1 OBJECTIVE:

The objective of this qualification protocol is to provide documented evidence of hydro test pump used to check the integrity of tank in water system. This qualification document ensures that the Hydro Test pump is properly functioning.

### 2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the hydro test pump is functioning and working properly.

### 2.3 SCOPE:

This Qualification protocol describes the procedure for qualification of hydro test pump and this equipment is applicable for testing the integrity of tank in purified water system.

### 2.4 RESPONSIBILITY:

The following shall be responsible;

Quality Assurance - For Preparation of protocol

Projects / Engineering Head – For Review and execution

Production Head – For execution support

Quality Assurance Head – For adequacy and final approval



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**2.5 EXECUTION TEAM:**

Execution team is responsible for the execution of qualification protocol of hydro test pump. All executors involved with this protocol shall be signed within the prescribed format given below:

NAME	DEPARTMENT	DESIGNATION	SIGNATURE	DATE
	PROJECTS / ENGINEERING			
	PRODUCTION			
	QUALITY ASSURANCE			



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**3.0 ACCETANCE CRITERIA:**

- 3.1 The hydro test pump shall meets with the acceptance criteria mentioned under the topic “Identification of major components”.
- 3.2 The equipment shall be operational as per its specified operating instructions.
- 3.3 All SOPs for the equipment to be verified and checked.
- 3.4 Training is important to all the concerned personnel.
- 3.5 Operational sequence of equipment to be checked for its full range.
- 3.7 Pressure shall constant till 2 hrs and there is no leakage in the equipment.

**4.0 REVALIDATION CRITERIA:**

The Hydro test pump has to be revalidated if:

- ❖ There are any major changes in system components which affect the performance of the system.
- ❖ After major breakdown maintenance is carried out.

**5.0 QUALIFICATION PROCEDURE:**

**5.1 SYSTEM DESCRIPTION:**

EQUIPMENT DESCRIPTION:		
Equipment Name	:	Hydro Test pump
Supplier / Manufacturer	:	.....
Model no.	:	.....
Location	:	Service area



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**5.2 INSTRUCTION FOR FILLING CHECKLIST:**

- 5.2.1 Write down the actual observation in observation column.
- 5.2.2 Give the detailed information in the summary and conclusion part of the addendum Qualification report.
- 5.2.3 Whichever column is blank or not used 'NA' shall be used

**5.3 INSTALLATION CHECKLIST**

S.No.	Statement	Method of Verification	Observation	Verified by (Sign/Date)
1.	Verify the purchase order and write down the PO number.	Verified with PO copy		
2.	Verify there is no damage in any part of pump.	Verified by Visually		
3.	Verify proper identification number given to the pump.	Verified by Visually		

**Inference:** -----  
 -----  
 .....  
 .....

**Reviewed by**  
**(Sign/Date)**



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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of verification	Observation	Verified By (Sign/Date)
	Equipment Name				
Pump	Equipment Name	Hydro test pump	Shall be verified with tag		
	Make	Inder hydraulic	Shall be verified with tag		
	Model	P-231B	Shall be verified with tag		
	Pressure gauge	Make - Baumer		Shall be verified with tag/test certificate	
Range – 0 to 07 kg/cm <sup>2</sup>			Shall be verified visually		

**Inference:** -----  
-----  
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**Reviewed by**  
**(Sign/Date)**





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**5.5 IDENTIFICATION & VERIFICATION OF COMPONENTS:**

Following component to be calibrated before starting the Performance checks

S.No.	Name of Components	Range	Location	Calibration Done on	Calibration Due on	Verified By Sign/Date

**Inference:** -----  
-----  
-----

**Reviewed by**  
(Sign/Date)

**5.6 Identification & Verification of Standard Operating Procedure (SOP):**

The related standard operating procedure has been identified and verified for easy to operate the system.

S.No.	SOP Title	SOP No.	Status	Verified By Sign/Date

**Inference:** -----  
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**Reviewed by**  
(Sign/Date)



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### 5.7 Performance Checks:

- ❖ Operate the hydro testing pump as per the respective SOP and perform the trial on equipment and record the observation in the following table:

#### Observation Table:

Equipment ID	Tank ID	Qty of water in hydro test pump tank	Normal working pressure of tank (kg/cm <sup>2</sup> )	Reading of of pressure apply to tank (kg/cm <sup>2</sup> )	Hold Period start Date/ Time	Reading of pressure of after hold time of 02 hrs.	Hold Period End Date/ Time	Done by sign/date

**Inference:** -----  
 -----  
 -----

**Reviewed by**  
 (Sign/Date)

### 6.0 ABBREVIATION:

- PO : Purchase Order
- SOP : Standard operating procedure
- HTP : Hydro testing pump





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8.0	<b>DEFICIENCY AND CORRECTIVE ACTION:</b>
<b>Description of Deficiency:</b>	
<b>Corrective Action (s) taken:</b>	

**Reviewed By:**

**Date**





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**9.3 FINAL REPORT APPROVAL:**

Verified that all test cases required for addendum of qualification studies, results data attached to this protocol or included in the qualification summary report are completed.

Signatures in the block below indicate that all tests in this addendum qualification report has been reviewed and found to be acceptable, considered to be safe and qualified for routine use:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PROJECTS / ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		