PERFORMANCE QUALIFICATION PROTOCOL FOR MANUFACTURING TANK CAPACITY: 2000 LITER

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR MANUFACTURING TANK	PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To carry out the Performance Qualification of Manufacturing Tank used for manufacturing of liquid Preparation.
- To Provide Documented Verification that the Equipment as connected with ancillary system is suitable for indented purpose and produced product as per pre defined Acceptance Criteria

3.0 SCOPE:

- The scope of this qualification protocol is limited to qualification of Manufacturing Tank Installed in **Manufacturing Room**.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, and Authorization of Performance Qualification Protocol. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity..
Production	• Review & Approval of Performance Qualification Protocol. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol.
Quality Control	• Review & Pre Approval of Performance Qualification Protocol. • Analytical Support (Microbiological Testing / Chemical Analysis)
Engineering	• Review & Pre Approval of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.

5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing Tank
Equipment	
Manufacturer's Name	
Model	
Location of Installation	Manufacturing Room

6.0 SYSTEM DESCRIPTION

Manufacturing Vessel Comprises of Top & Bottom Tori spherical Dish ends (10 %) Welded with Central cylindrical shell. This is principally designed for the preparation and manufacturing of Product.

Bottom Entry Agitator of rating 5 HP, 950 RPM is provided at the bottom dish end of the tank. The bottom entry agitator is provided with mechanical seal to avoid the leakage during operation.

Top dish is provided with nozzles as per the service requirement and on the top dish end manhole with davit arm arrangement is provided for ease in cleaning the vessel. Top dish is provided with two nos. lifting hooks for ease at the time of installation.

Entire vessel is mounted on four legs support. Manufacturing tank is provided with all pipe fittings and valves with TC fittings and silicon gasket. A working platform made with S.S. Dimpled plates and SS 304 railing is also provided. The size of the working platform is 1600mm L x 1175 mm W x1250 mm H. it will have a ladder on one side of 850mm length.

7.0 REASON FOR QUALIFICATION:

- New equipment installed in Ointment Section, Manufacturing Room.

8.0 SITE OF STUDY:

- Manufacturing Room.

9.0 FREQUENCY OF QUALIFICATION

- After Every Two years as per Validation Master Plan.
- After any major breakdown or after major modification
- Relocation of Equipments.

10.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

10.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Completed Yes/No	Checked By Engineering Sign/Date	Verified By QA Sign/Date
1.	Executed and approved Design Qualification cum report.			
2.	Executed and approved Installation Qualification cum report.			
3.	Executed and approved Operational Qualification cum report.			
4.	PQ Protocol approved.			
5.	SOP for Operation & Cleaning of Manufacturing Tank.			
6.	SOP for Preventive Maintenance Manufacturing Tank.			

10.2 Training Record of Validation Team:

- All the persons involved in the execution of qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.
- Verify the training records and record the details in table mentioned in performance qualification report.

11.0 TESTS & CHECKS:

11.1 Equipment Volumetric Capacity Test and Uniformity Of Solution:

11.1.1 Objective:

- The purpose of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement and solution prepared is homogeneous as seen visually and active contents are uniform.

11.1.2 Equipment / Instrument Used:

- Purified Water
- Calibrated Vessel / QC equipment to measure required quantity for charging Water
- Sodium chloride. (0.9%)

11.1.3 Method Applied

- **Minimum Capacity (400 Ltr) at Minimum & Maximum RPM:** Charge 400 liters to 2000 Liter Tank of purified water using calibrated cylinder/ vessel.
- Add NaCl 3.6 Kg (0.9%) to 400 Ltr. charged vessel.
- Operate the equipment as per SOP on operation of manufacturing vessel.
- Agitate the mixture for 10 min. at Minimum RPM (400).
- After the completion of cycle take 100 ml of sample from top and bottom & send to QC lab for assay.
- Above procedure shall be repeated at Maximum RPM (950).

- **Maximum Capacity (2000 Ltr) at Minimum & Maximum RPM:** Charge 2000 liters to 2000 Liter Tank of purified water using calibrated cylinder/ vessel.
- Add NaCl 18.0 Kg (0.9%) to 2000 Ltr. charged vessel.
- Operate the equipment as per SOP on operation of manufacturing vessel.
- Agitate the mixture for 10 min. at Minimum RPM (400).
- After the completion of cycle take 100 ml of sample from top and bottom & send to QC lab for assay.
- Above procedure shall be repeated at Maximum RPM (950).

Acceptance Criteria:

Uniformity of solution

- **For 400 Ltr. And 2000 Ltr:** Assay of NaCl should be between 0.882% W/V – 0.918%W/V.
- Relative standard deviation shall not be more than 2.0 %.
- Equipment should run trouble free without any problems after charging material up to working volume i.e. 2000 Ltr.

12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check
1.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM
2.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Minimum RPM
3.	Equipment Volumetric Maximum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM
4.	Equipment Volumetric Minimum Capacity Test and Verification of Uniformity of Mixing at Maximum RPM

13.0 REFERENCES:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- SOP for "Operation & Cleaning of Manufacturing Tank".

14.0 DOCUMENTS TO BE ATTACHED:

- Test Report from QC lab
- Any other Relevant Documents.

15.0 NON COMPLIANCE:

- In case of any Non-compliance observed during PQ, same shall be handled through SOP for Handling of Non-Compliance.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY

- In case of any deviation observed during PQ, same shall be handled through SOP for Handling of Deviation.

17.0 CHANGE CONTROL, IF ANY

- If any change is required during PQ, same shall be handled through SOP for Change Management.

18.0 ABBREVIATIONS:

%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
Ltr.	:	Liter
RSD	:	Relatives Standard Deviation
LTD.	:	Limited
MFT	:	Manufacturing Tank
Nacl	:	Sodium chloride
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
QC	:	Quality Control
S.S	:	Stainless Steel
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization