PERFORMANCE QUALIFICATION PROTOCOL FOR JACKETED MANUFACTURING TANK SYRUP MANUFACTURING ROOM

EQUIPMENT ID. No.	
LOCATION	**Syrup Manufacturing Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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 **Syrup 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.

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

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM DESCRIPTION

The Manufacturing Tank Comprises of Top & Bottom Torispherical Dish ends (10%) Welded with Central cylindrical shell. It provide with limpet coil at shell for heating & cooling of vessel. It provided with glass wool insulation at shell. This is principally designed for the sugar syrup preparation and manufacturing of liquid syrup.

Bottom Entry Agitator of rating 5 HP, 960 RPM is provided at the bottom dish end of the tank with the help of specially designed lantern stool support. 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.

7.0 REASON FOR QUALIFICATION:

- New equipment installed in Syrup Manufacturing Room.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired

8.0 SITE OF STUDY:

- Syrup 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.

10.3 Calibration of Test Instruments:

- Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

11.0 TESTS & CHECKS:

11.1 Equipment Volumetric Capacity (In Liters) Test:

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 (2395 liters total volume and 2000 liters maximum and 500 ltrs. Minimum Working Volume).

11.1.2 Equipment / Instrument Used:

- Process Water: Calibrated Vessel/ QC equipment to measure required quantity for charging of water.

11.1.3 Method Applied:

- Charge liters of Process Water using calibrated cylinder/vessel. Witness the quantity of Water received by the vessel without overflowing. Operate the equipment at process parameters as per SOP on operation & cleaning of Manufacturing Tank.
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

11.1.4 Acceptance Criteria:

- Quantity of water charged shall not be less than quantity mentioned on Equipment Tag i.e. 2000 liter ± 0.3% (1999.5 to 2000.5 ltr.)
- Quantity of water charged shall not be less than quantity mentioned on Equipment Tag i.e. 500 liter ± 0.3% (499.5 to 501.5 Ltr.)

11.1.5 Result Recording:

- Measure the Equipment Volumetric Capacity (in liters) & calculate the result and record the results in Performance Qualification Report.

11.2 Verification Of Equipments Volumetric capacity By chemical assay Method:

11.2.1 Objective:

- The purpose of this test is to ensure that Equipment Operates trouble free to prepare solution and solution prepared is homogeneous (without Lumps & clear solution) as seen visually and active contents are uniform.

11.2.2 Equipment / Instruments Used:

- Sodium Chloride & Purified water in sufficient quantity to make 2000 Ltr. Solution of 0.9 % NaCl.
- Sample collection using calibrated sampling rod.
- Sample containers

11.2.3 Method Applied:

- Charge 0.9% Nacl (Sodium chloride) in the Manufacturing Tank along with Solvent. Stir the mixture for 15 minutes with minimum and maximum Speed.
- Perform Volumetric Capacity i.e. 500 Ltr. 1000 Ltr. 1500 Ltr. And 2000 Ltr. Test with 0.9% Nacl

with Different speed.

- Take one sample of 100 ml after each interval of capacity and speed for pH, Description and Assay of 0.9% Nacl. Sample to be taken after 15 minutes of mixing at Different Speed i.e. Minimum and Maximum
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

11.2.4 Acceptance Criteria:

- The sample shall be free of lumps as seen visually
- Assay should be 0.882% W/V – 0.912%W/V
- The Equipment should operate trouble free throughout the operation cycle.

11.2.5 Result Recording:

- Record the results of in Performance Qualification Report record the details of the instruments used including its Calibration Status.

11.3 Verification Of Uniformity Of Mixing:

11.3.1 Objective:

- The purpose of this test is to ensure that Equipment Operates trouble free to prepare solution and solution prepared is homogeneous (without Lumps & clear solution) as seen visually and active contents are uniform.

11.3.2 Equipment / Instruments Used:

- Sodium Chloride & Purified water in sufficient quantity to make 2000 Liter. Solution of 0.9 % NaCl.
- Sample collection using calibrated sampling rod.
- Sample containers or sample bags.

11.3.3 Method Applied:

- Charge 0.9% Nacl (Sodium chloride) in the manufacturing vessel along with Solvent. Stir the mixture for 30 minute duration and Defined speed i.e. Min. and max.
- Take the Samples after 5, 10 & 30 minute time interval of mixing of cycle. Sample to be taken at two locations at identified potential areas of poor mixing. Sample to be taken at top and bottom. At different speed.
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent

performance.

11.3.4 Acceptance Criteria:

- At the 05 minutes, take the sample & observe visually .The sample shall be free of lumps as seen visually
- At the 10 & 30 minutes interval of cycle take the sample from manufacturing tank & send the QC Lab for assay & pH.
- The test shall perform at Min and maximum Capacity of Tank.
- The Equipment should operate trouble free throughout the operation cycle.
- RSD should be NMT 2%.

11.3.5 Result Recording:

- Record the results of in Performance Qualification Report record the details of the instruments used including its Calibration Status.

12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check	Execution (Yes/No.)	Remark
1.	Equipment Volumetric Capacity (in liters) Test		
2.	Equipment Volumetric Capacity (in liters) Test by chemical method		
3.	Verification of Uniformity of Mixing		

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.
- Calibration Certificate of test Instruments.

15.0 NON COMPLIANCE:

- In case of any Non compliance observed during PQ, inform to Head QA for necessary action. Document the details observed.
- The Head QA will study the impact of Non compliance. If Non compliance is acceptable and it does not have an impact on performance of the Qualification, prepare final conclusion.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on performance of the Qualification, prepare final conclusion & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on performance of the Qualification, prepare final conclusion & prepare final conclusion.

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
S.S	:	Stainless Steel
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization