PERFORMANCE QUALIFICATION PROTOCOL FOR MANUFACTURING VESSEL CAPACITY: 2000 LITER (FFS LINE)

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING AREA , FFS- LINE**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To carry out the Performance Qualification of manufacturing vessel 2000 Ltr. 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 vessel (Make: Pharmatech Process Equipment Installed in manufacturing Area, FFS Line.

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, Approval of Performance Qualification Protocol. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity..
Production	• Review & Pre Approval of Performance Qualification Protocol. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol.
Quality Control	• 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	SS Jacketed Manufacturing vessel
ID Number	
Capacity	2000 lt.
Gross Capacity	2400lt.
Manufacturer's Name	Pharmatech Process Equipment
S. No.	
Model	cGMP Model.
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area, FFS Line

6.0 EQUIPEMENT DESCRIPTION

SS jacketed Manufacturing Vessel and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

- Shell
- Jacket
- Spiral stiffner
- Insulation &cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge
- Sterile safety valve
- 0.2 micron plain vent filter
- Manual operated diapharagm valve

- Rupture disc
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Auto Ball Valve
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- SS skid with castor wheel
- SS304 PLC panel

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7.0 REASON FOR QUALIFICATION:

- New equipment installed in Manufacturing Area**,** Ground Floor, FFS line. 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:

Manufacturing Area Ground Floor, FFS line.

9.0 FREQUENCY OF QUALIFICATION

- Once in a 2 Yearly as per Validation Master Plan.
- After any major breakdown or after major modification.
- Change in Location.

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	DOCUMENT / SOP NO.	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 vessel				
6.	SOP for Preventive Maintenance Manufacturing vessel				

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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 by:

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 (2400 liters total volume and 2000 liters Working Volume).

11.1.2 Equipment / Instrument Used:

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

11.1.3 Method Applied:

- Charge 2000 litres 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 vessel
- 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)
- Equipment runs trouble free without any problems after charging material up to working volume i.e. 2000Liters.

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 Equipment Volumetric Capacity (In Liters) Test By Chemical assay Method :

11.2.1 Objective:

- The purpose of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement

11.2.2 Equipment / Instrument Used:

- Process Water: Calibrated Vessel/ QC equipment to measure required quantity for charging Water for Injection, Sodium chloride. (0.9%) packs.

11.2.3 Method Applied:

- Charge 400 liters to 2000 Liter of Process Water using calibrated cylinder/ vessel or through load cell. Witness the quantity of Water received by the vessel.
- Add NaCl (0.9%) to 400 Ltr. charged vessel.
- Operate the equipment at process parameters as per SOP on operation of manufacturing vessel.
- After the completion of cycle take 100 ml of rinse sample & send to QC lab for assay.
- Repeat above process by adding water 400 Ltr. in each interval up to manufacturing capacity.

11.2.4 Acceptance Criteria:

- Assay of Nacl should be between 0.882% W/V – 0.912%W/V
- Equipment runs trouble free without any problems after charging material up to working volume i.e. 2000 Litres.

11.2.5 Result Recording:

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

11.3 Verification Of Uniformity Of Solution:

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 & Water for Injection in sufficient quantity to make 2000 Ltr. 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. Agitate the mixture for defined duration & defined RPM.
- Temperature of WFI should be between 60-75 ° C
- Take the Samples at the 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.
- 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 the100 ml sample from manufacturing tank & send the QC Lab for assay (98% to102%) & pH (5-7).
- The Equipment should operate trouble free throughout the operation cycle.

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 Solution		

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

13.0 REFERENCES:

The Principle Reference is the following:

- 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 Vessel".

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
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
FFS	:	Form Fill & Seal
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
Ltr.	:	Liter
MFT	:	Manufacturing vessel
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