PERFORMANCE QUALIFICATION PROTOCOL FOR MANUFACTURING VESSEL CAPACITY: 500 LITER

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING ROOM**
DATE OF	
SUPERSEDE PROTOCOL	**NIL**

PERFORMANCE QUALIFICATION PROTOCOL S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

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)			

PERFORMANCE QUALIFICATION PROTOCOL S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

2.0 OBJECTIVE:

- To carry out the Performance Qualification of manufacturing vessel 500 L used for manufacturing of liquid eye drop 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: ……..) 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, Approval and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing vessel
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Manufacturing Room

6.0 EQUIPEMENT DESCRIPTION

SS jacketed Mfg. tank 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
- Sparger tube
- Rupture disc

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- Halogen lamp
- 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
- Flexible hose for utility
- SS skid with castor wheel
- SS304 PLC panel

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7.0 REASON FOR QUALIFICATION:

- New equipment installed in 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:

Manufacturing vessel (Capacity- 500 L) installed in Manufacturing Room.

9.0 FREQUENCY OF QUALIFICATION

- Yearly as per Validation Master Plan.
- After any major breakdown or after major modification

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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				

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……..

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.

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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 (500 liters total volume and 500 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 500 litres of Process Water using calibrated cylinder/ vessel. Witness the quantity of Water received by the vessel without overflowing.
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

11.1.4 Acceptance Criteria:

- Quantity of water charged l mentioned on Equipment Tag i.e. 500 liter Should be +/- 0.1% (500.00 to 499.99)
- Equipment runs trouble free without any problems after charging material up to working volume i.e. 500 Liters.

11.1.5 Result Recording:

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

11.2 Equipment Volumetric Capacity (In Liters) Test By Chemical 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 50 litres of Process Water using calibrated cylinder/ vessel or through load cell. Witness the quantity of Water received by the vessel.
- Now add Nacl (0.9%) to50 ml 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 50 L at 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. 500 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 500 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 30-45 ° C
- Take the Samples at the after 5(50L.),10 (250 L.) & 30 (500L.) 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 the sample from manufacturing tank & send the QC Lab for assay & pH.
- 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.

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11.4 PERFORMANCE QUALIFICATION OF SPRAY BALL

11.4.1 Objective:

To demonstrate the spray ball of vessel is capable of removing the traces of 1 % of riboflavin & 0.2 % of Mannitol solution from the vessel surface & to check the working of spray ball during running trial.

11.4.2 Material,

Water, Riboflavin, Manitol

11.4.3 UTILITIES

Pump, Hosepipe, U.V. Light, painting brush

Pressure gauge

11.4.4 Method

- Prepare 1 % of riboflavin & 0.2 % of Mannitol solution in one bucket.
- Apply riboflavin solution uniformly on the vessel & nozzle through spray ball.
- Allow the vessel to dry about 10-20 minute
- Open the vessel outlet valve & operate the pump with water @ 1-2 bar pressure for 30 minute at the flow rate of 73 LPM. And that time stirrer should be on position
- Observe the tank visually under U.V. Light
- Adequate precaution shall be taken during observation
- The area where having significant residue of riboflavin , it will glow prominently under the U.V. illumination

11.4.5 Acceptance Criteria ;

Spray pattern of water found all over 360° uniformly & all the surface of vessel internal should be free from riboflavin dye.

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12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check	Execution (Yes/No.)	Remark	Verified By (Sign & Date)
1.	Equipment Volumetric Capacity (in liters) Test			
2.	Equipment Volumetric Capacity (in liters) Test by chemical			
3.	Verification of Uniformity of Solution			
4.	Performance qualification of spray ball efficiency			

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:

- Raw data from QC lab
- Cycle printouts
- Any other Relevant Documents.

15.0 FROM PREDEFINED SPECIFICATION IF, ANY: 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:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
ID	:	Inner Diameter
MFT	:	Manufacturing vessel
PVT	:	Private
LTD.	:	Limited
ID.	:	Identification
L	:	Liter
NaCl	:	Sodium chloride
%	:	Percentage