PERFORMANCE QUALIFICATION PROTOCOL FOR SUGAR MELTING TANK

EQUIPMENT ID. No.	
LOCATION	**Sugar melting Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SUGAR MELTING TANK	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SUGAR MELTING 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 Sugar melting 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 Sugar melting Tank Installed in sugar Melting 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 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	Sugar melting Tank
Equipment	…….
Manufacturer's Name	Punchtab
Model	cGMP
Location of Installation	Sugar melting Room

6.0 SYSTEM DESCRIPTION

SS jacketed Sugar Melting 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 Anchor. The Sugar melting Tank Comprise of the Following Components.

- Shell
- Jacket
- Insulation &cladding
- Stirrer
- Legs
- safety valve
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Variable frequency drive

7.0 REASON FOR QUALIFICATION:

- New equipment installed in Sugar melting 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:

- Sugar melting 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 Sugar melting Tank.			
6.	SOP for Preventive Maintenance Sugar melting 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.

10.4 Utility Requirement:

- Steam : 1.0 to 1.5 kg/cm^2
- Purified Water

11.0 TESTS & CHECKS:

11.1 Verification Of Mixing Efficiency:

11.1.1 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.

11.1.2 Equipment/Instruments Used:

- Sugar & Purified water in sufficient quantity to make 250 Liter. Solution of Sugar.
- Sample collection using calibrated sampling rod.
- Sample containers or sample bags.

11.1.3 Method Applied:

- Switch on the Main Panel and start the Equipment as per respective SOP.
- On the Supply valve of Steam for Jacket through the Valve and Maintain the Temperature up to 70-90°C. and Steam Pressure 1.0 to 1.5 kg/cm^2
- Add the Ingredients as per defined in batch Manufacturing Record.
- Take the Samples after 15, 30 & 45 minute time interval of proper mixing of cycle. Sample to be taken at identified potential areas of poor mixing. Sample to be taken at top and bottom. At Min and Maximum speed.
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

11.1.4 Acceptance Criteria:

- At the 15, 30 & 45 minutes, take the sample & observe visually .The sample shall be free from lumps and visually should be Clear Liquid

11.1.5 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.	Verification of Mixing Efficiency		

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 Sugar melting Tank".

14.0 DOCUMENTS TO BE ATTACHED:

- 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	:	Sugar melting 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