



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK  
CAPACITY: 1000 Ltr.**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>SUGAR MELTING ROOM</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**PROTOCOL CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>Protocol pre-approval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibility</b>	<b>5</b>
<b>5.0</b>	<b>Equipment details</b>	<b>6</b>
<b>6.0</b>	<b>System description</b>	<b>6</b>
<b>7.0</b>	<b>Pre-qualification requirements</b>	<b>7</b>
<b>8.0</b>	<b>Critical variables to be met</b>	<b>8</b>
<b>9.0</b>	<b>References</b>	<b>18</b>
<b>10.0</b>	<b>Documents to be attached</b>	<b>18</b>
<b>11.0</b>	<b>Deviation from pre-defined specification, if any</b>	<b>19</b>
<b>12.0</b>	<b>Change control, if any</b>	<b>19</b>
<b>13.0</b>	<b>Review (inclusive of follow up action, if any)</b>	<b>19</b>
<b>14.0</b>	<b>Conclusion</b>	<b>19</b>
<b>15.0</b>	<b>Recommendation</b>	<b>19</b>
<b>16.0</b>	<b>Abbreviations</b>	<b>20</b>
<b>17.0</b>	<b>Protocol post approval</b>	<b>21</b>



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of manufacturing vessel 1000 Ltr. and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of Manufacturing Vessel (**Make:** .....) installed in the Sugar Melting Area Ground Floor, Liquid Line.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Manufacturing Vessel
- Successful completion of this Protocol Cum Report will verify that Manufacturing Vessel meet all acceptance criteria and ready for Performance Qualification.



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, and Authorization, compilation of the operational Qualification Protocol Cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Approval of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• To co-ordinate and support Operational Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	SS Jacketed Sugar Melting Tank
<b>ID. Number</b>	
<b>Capacity</b>	1000 Ltr.
<b>Gross Capacity</b>	1200 Ltr.
<b>Manufacturer's Name</b>	
<b>Sr. No.</b>	
<b>Supplier's Name</b>	
<b>Location of Installation</b>	Sugar Melting Area, Liquid Line

**6.0 EQUIPEMENT DESCRIPTION:**

Sugar Melting Tank Comprises of jacked, insulated & cladded vessel having bottom entry low shear magnetic stirrer for stirring to perform heating & cooling with stirring operations respectively during the manufacturing process. The vessel will have CIP/SIP provision to clean the vessel respectively. All utility valves will be pneumatically operated & process valves pneumatic & manual operated to fulfill process requirements. Vessel will be supported by 3 legs. The full unit with operating panel & with drain header behind the vessel will be mounted on movable trolley. The vessel will also be facilitated with temperature sensor to online monitor the content's temperature. The operation of Sugar Melting Tank will be from touch screen (HMI) to operate in auto mode & semi -auto mode. The system will have online printing facility to take the printing by connecting Epson make dot matrix printer. This is principally designed for the sugar syrup preparation and manufacturing of liquid syrup. Sugar melting Tank is provided with all pipe fittings and valves with TC fittings and silicon gasket.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Verification of certificate of Measuring Instrument Associated with the Vessel and MOC
- SOP for Operation & Cleaning of manufacturing vessel
- SOP for Preventive Maintenance of manufacturing vessel.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test documents.  
Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	COMPLETED (YES/NO)	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report		
2.	Executed and approved Installation Qualification cum report		
3.	SOP for Operation & Cleaning of manufacturing vessel		
4.	SOP for Preventive Maintenance of manufacturing vessel		

**Inference:**

.....

.....

.....

.....

**Reviewed By  
Manager QA  
Sign/Date: .....**



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.2 Test / Measuring Equipment Calibration:**

<b>INSTRUMENTS NAME</b>	<b>INSTRUMENT I.D.</b>	<b>CALIBRATION ON</b>	<b>DUE ON</b>	<b>OBSERVED BY SIGN/DATE</b>

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**  
 .....  
 .....  
 .....  
 .....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.3 MOTOR FUNCTIONALITY:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Switch ON the main Power Supply	Power flows in to the main panel this is indicating by the three light on the front panel having R Y B lamp indicator		
Switch OFF the main Power Supply	The light on the front panel should not glow.		
To Start Stirrer Press Green push Button	Motor should start and stirrer Start rotating		
To Stop Stirrer Press Green push Button	Motor should Stop and stirrer Stop rotating		
Steam On / Off turn toggle Key From Off mode to On Mode	Steam Solenoid Valve Should start		
Steam On / Off turn toggle Key From Off mode to On Mode	Steam Solenoid Valve Should Stop		
Pressing Emergency push button	Process Should Stop Immediately		
Releasing Emergency push button	Process should Start Immediately		
Noise Level	Below 80 db.		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**  
.....  
.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.4 LAMP FUNCTIONALITY:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Vessel Lamp On / Off turn toggle Key from off mode to on mode	Vessel Lamp Should On		
Vessel Lamp On / Off turn toggle Key from On mode to Off mode	Vessel Lamp Should Off		

**8.5 SAFETY VALVE CHECK:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Start supply of Water into the Jacket and then slowly pump water till it reaches set pressure of safety valve	Water should expelled from the safety valve		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.6 Hydro Test:**

**8.6.1 Objective:** To qualify the Welding Quality in View of Leak of Tightness under Hydraulic Pressured Condition as per ASME Sec. VIII Div. I (2001) code and qualifying the vessel to operate at Specified Design Condition.

**8.6.2 Material :** water

**8.6.3 Utility :** Water Supply ,Compressed Air

**8.6.4 Instrument :** Air Vent Valve

**8.6.5 Method :**

- Fill the Tank with Water
- Blind of all Nozzle ,Except bottom Connection & Top Connection
- Connect water pump to Bottom Connection
- When Water Flow out vent, Close the vent Valve
- Pressurize the shell side up to Hydro test Pressure
- Mark the Pressure on Pressure gauge.
- Check the Same after 30 minute
- Check all weld joint & Temporary Joint for leakage.
- Record all the data on Hydro test in Report.

**8.6.6 Hydro Test Observation:**

HYDRO TEST	START TIME OF THE TEST	END TIME OF THE TEST	OBSERVATION
Main Shell			
Jacket Shell			
<b>Acceptance Criteria:</b> No Leakage Observed with in 30 min.			

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.7 Spray Ball Test :**

**8.7.1 Objective:** To demonstrate that the spray ball of Vessel is Capable of Removing the Traces of 1-5 % of Riboflavin Solution from the vessel Surface & to Check working of Spray ball during running trial.

**8.7.2 Material:** Water, Riboflavin Dye. Hose pipe, Painting Brush, Bucket,

**8.7.3 Method :**

- Fit the Spray ball & its line on Vessel.
- Connect the pump outlet to spray ball line and connect the vessel out let line to drain line.
- Prepared 1-5% Riboflavin solution in one Bucket.
- Apply Riboflavin solution uniformly on the vessel and Nozzle through Painting brush.
- Allow the vessel to dry (5-10 Minute )
- Close the open Connection provide on vessel.
- Open the vessel out let valve and operate the pump with Fresh water at 1-2 Bar for specified time and that time Stirrer should be in ON position.
- Collect 100 Sample from Sampling Valve and Sent to QC for Identification of Riboflavin
- Riboflavin detection test are inspected for remaining riboflavin using a UV lamp at either 365 or 254nm wavelength for riboflavin detection.
- At the same time perform blank for the riboflavin detection test also

DATE OF TEST	ACCEPTANCE CRITERIA	OBSERVATION
	Spray pattern of water found all over 360° uniformly & all the surface of vessel internal should be free from riboflavin	

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.7.4 Operating Parameter**

PARAMETER	OPERATING PARAMETER	OBSERVATION	OBSERVED BY
Pressure	1.5 to 2.0 Bar		
Flow rate	73 LPM		
Time	10 Min		

**8.7.5 Result:**

TEST	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY
Spray Ball Test	Run the Spray ball smoothly and clean the Surface Areas. Riboflavin dye not Detected UV lamp		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.8 Power Failure Verification:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>Main Power Shut Down</b>	Equipment stops in a safe and secure condition.		
<b>Main Power Restored</b>	Equipment can be restarted with no problems or adverse conditions. Press Again Login and cycle restart.		

**Checked By  
Production  
Sign/Date: .....**

**Verified By  
Quality Assurance  
Sign/Date: .....**

**Inference:**

.....

.....

.....

.....

**Reviewed By  
Manager QA  
Sign/Date: .....**





**OPERATIONAL QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.9 Equipment Volumetric Capacity (In Liters) Test:**

**8.9.1 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 Ltr. Total volume and 2000 Ltr. Working Volume of manufacturing vessel)

**8.9.2 Equipment / Instrument Used:**

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

**8.9.3 Method Applied:**

- Charge 1000 Ltrs 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.

**8.9.4 Acceptance Criteria:**

The Quantity of Water Should be  $\pm 0.3\%$  (1999.5 to 2000.5 Ltr.) of Claimed Water.

DATE OF TEST	TRIAL NO.	ACCEPTANCE CRITERIA	OBSERVATION
		Total volume to be 1000 Ltrs	
		Working volume to be 1000 Ltrs	
		Total volume to be 1000 Ltrs	
		Working volume to be 1000 Ltrs	
		Total volume to be 1000 Ltrs	
		Working volume to be 1000 Ltrs	

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
 .....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.10 RPM Verification:**

Date of test	Instrument ID	Date of Calibration	Due date of Calibration	Observation		
				Run-1	Run-2	Run-3

Acceptance criteria: 100, 500, 960 RPM

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**8.11 Temperature Verification:**

Temp. Probe ID	Done date of Calibration	Due date of Calibration	Temp.	Observation (Probe)			Observation (Controller)		
				Run-1	Run-2	Run-3	Run-1	Run-2	Run-3

**Acceptance Criteria:** The temp. Difference Should be  $\pm 1^{\circ}\text{C}$

**Checked By  
Production  
Sign/Date:** .....

**Verified By  
Quality Assurance  
Sign/Date:** .....

**Inference:**

.....  
.....  
.....  
.....

**Reviewed By  
Manager QA  
Sign/Date:** .....

**9.0 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.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Operation and Maintenance Manual.
- Any other Relevant Documents.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:**

.....  
.....  
.....  
.....

**12.0 CHANGE CONTROL, IF ANY:**

.....  
.....  
.....  
.....

**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):**

.....  
.....  
.....  
.....

**14.0 CONCLUSION:**

.....  
.....  
.....  
.....

**15.0 RECOMMENDATION:**

.....  
.....  
.....  
.....



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**16.0 ABBREVIATIONS:**

°C	:	Degree centigrade
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
Lt.	:	Liters
LTD.	:	Limited
SMT	:	Sugar Melting Tank
No.	:	Number
RPM	:	Revolution per Minute
SOP	:	Standard operating procedure
VFD	:	Variable Frequency Drive
WHO	:	World Health Organization



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
JACKETED SUGAR MELTING TANK**

**PROTOCOL No.:**

**17.0 PROTOCOL POST APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			