



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

**PROTOCOL No.:**

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

<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>



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**1.0 PRE – APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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**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 Tank 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 Sugar Melting Tank installed in the Sugar Melting Room.
- 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 Sugar Melting Tank meet all acceptance criteria and ready for Performance Qualification.



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**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, Authorization and 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; Pre 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 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>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Sugar Melting Tank
<b>Equipment</b>	
<b>Capacity</b>	300 LTR.
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Model</b>	cGMP
<b>Location of Installation</b>	Sugar Melting Room

**6.0 EQUIPEMENT 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



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**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 Tank
- SOP for Preventive Maintenance of manufacturing Tank.

**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.



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**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)	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.	SOP for Operation & Cleaning of manufacturing vessel			
4.	SOP for Preventive Maintenance of manufacturing vessel			

**Inference:**

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





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**8.2 Test / Measuring Equipment Calibration:**

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

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

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

**Inference:**

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



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**8.3 Functional & operational verification:**

Checks	Acceptance criteria	Observation	Observed by Engineering Sign/Date
Open Purified Water Valve	Water is Charged in the vessel until valve is open		
<b>Steam inlet valve</b>			
Pressing steam inlet valve symbol	Steam inlet valve should be opened.		
Pressing again after opening	Steam inlet valve should be closed.		
<b>Cooling outlet valve</b>			
Pressing cooling outlet valve symbol	Cooling outlet valve should be opened		
Pressing again after opening	Cooling outlet valve should be closed.		
<b>Jacket vent valve</b>			
Pressing jacket vent valve symbol	Jacket vent valve should be opened.		
Pressing again after opening	Jacket vent valve should be closed.		
<b>Cooling inlet valve</b>			
Pressing cooling inlet valve symbol	Cooling inlet valve should be opened.		
Pressing again after opening	Cooling inlet valve should be closed		
<b>Jacket drain valve</b>			
Pressing cooling inlet valve symbol	Jacket drain valve should be opened		
Pressing again after opening	Jacket drain valve should be closed.		
<b>Heating” Operation</b>			



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Checks	Acceptance criteria	Observation	Observed by Engineering Sign/Date
Heating for entire set time	Boiler steam inlet valve & condensate outlet valve should be opened.		
	As product temp .reaches the set point, heating maintain time should be started.		
	Steam inlet valve should be opened & closed to maintain heating temp.		
	On heating maintain time over, steam inlet valve condensate		
Heating with intermediate stop	Boiler steam inlet valve & condensate outlet valve should be closed.		
<b>“Cooling” Operation</b>			
Cooling for entire set time	Cooling inlet valve & cooling outlet valve should be opened.		
Cooling for entire set time (Continue)	As product temp.reaches the set point, cooling maintain time should be started.		
	Cooling inlet valve should be opened & closed to maintain cooling temp.		
	On cooling maintain time over, cooling inlet valve, cooling outlet valve should be closed.		
Cooling with intermediate stop	Cooling inlet valve & cooling outlet valve should be closed.		
Functioning of Anchor	The Anchor Should Rotate clockwise Direction		
Functioning of Transfer Pump	The Pump should Functioning Properly		



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Checks	Acceptance criteria	Observation	Observed by Engineering Sign/Date
Functioning of Pressure gauge for Jacket	The Pressure Gauge should Work Properly		

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

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

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

**8.4 Power Failure Verification:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions. Press START Button Equipment Start.		

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

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

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



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**8.5 Safety:**

<b>CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided		
Noise Level	Below 80 db		
Operation	Sugar Melting Tank should be in working condition, and it should be repeated during shutting also.		
Variable Frequency Drive	Motor safety from overload		
Main Supply	Main power supply should be always switched off when not in		
Safety valve	Safety against over pressure		
Insulation	For operator safety & Heat loss prevention		
Emergency Button	Protection against abnormal condition		

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

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

**Inference:**

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 .....

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



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**8.6 Utility Verification:**

Operational Checks		Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Electricity	Voltage	415±10% V		
	Phases	3 Phase		
	Frequency	50 Hz		
	Motor	2 HP		
Cooling Water		20 BSP Header at 100 lt./Hr		
Compressed Air Supply		5-6 kg/cm <sup>2</sup>		
Room Condition		Should be able to meet the requirement of Clean Environment.		
Steam		2-2.5 kg/cm <sup>2</sup>		
Service Water		20 BSP line at 2 kg/cm <sup>2</sup>		

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

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

**Inference:**

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 .....

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



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

**8.7.1 Objective:**

- The purpose of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement (350 Ltr. Total volume and 300 Ltr. Working Volume of manufacturing vessel).

**8.7.2 Equipment/Instrument Used:**

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

**8.7.3 Method Applied:**

- Charge 300 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 vessel
- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

**8.7.4 Acceptance Criteria:**

The Quantity of Water Should be  $\pm 0.3\%$  (299.1 to 300.9 Ltr.) of Claimed Water.

DATE OF TEST	TRIAL No.	ACCEPTANCE CRITERIA	OBSERVATION
		Total volume to be 300 liters	
		Working volume to be 300 liters	
		Total volume to be 300 liters	
		Working volume to be 300 liters	
		Total volume to be 300 liters	
		Working volume to be 300 liters	

**Checked By** \_\_\_\_\_  
**Production**  
**Sign & Date**

**Verified By** \_\_\_\_\_  
**Quality Assurance**  
**Sign & Date**

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

**Reviewed By:** \_\_\_\_\_  
**Manager QA**  
**Sign & Date**



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**8.8 RPM Verification:**

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

Acceptance criteria:

**Checked By**  
**Production.....**  
**Sign & Date**

**Verified By**  
**Quality Assurance.....**  
**Sign & Date**

**Inference:**.....  
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**Reviewed By:** \_\_\_\_\_  
**Manager QA**  
**Sign & Date**

**9.0 REFERENCES:**

- Validation Master Plan.
- Design Qualification Protocol Cum Report
- Installation Qualification Protocol Cum Report
- Operating Manual or Instruction Manual.

**DOCUMENTS TO BE ATTACHED:**

- Calibration Certificates of Measuring Devices
- Any other Relevant Documents.

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

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**11.0 CHANGE CONTROL, IF ANY:**

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

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**13.0 CONCLUSION:**

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**14.0 RECOMMENDATION:**

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**15.0 ABBREVIATIONS:**

°C	:	Degree centigrade
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
IQ	:	Installation Qualification
Lt.	:	Liters
LTD.	:	Limited
MFT	:	Manufacturing vessel
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard operating procedure
WHO	:	World Health Organization



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**16.0 POST APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			