



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

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SS JACKETED SUGAR MELTING  
TANK  
CAPACITY: 1000 LITER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Sugar Melting Room</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



PHARMA DEVILS

**INSTALLATION 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 Detail</b>	<b>6</b>
<b>6.0</b>	<b>System Description</b>	<b>6</b>
<b>7.0</b>	<b>Pre Qualification Requirement</b>	<b>7</b>
<b>8.0</b>	<b>Critical Variables to be Met</b>	<b>8-29</b>
<b>9.0</b>	<b>Reference</b>	<b>30</b>
<b>10.0</b>	<b>Documents to be Attached</b>	<b>30</b>
<b>11.0</b>	<b>Deviation from pre-defined specification, if any</b>	<b>30</b>
<b>12.0</b>	<b>Change control, if any</b>	<b>30</b>
<b>13.0</b>	<b>Review (inclusive of follow up action, if any)</b>	<b>30</b>
<b>14.0</b>	<b>Conclusion</b>	<b>31</b>
<b>15.0</b>	<b>Recommendation</b>	<b>31</b>
<b>16.0</b>	<b>Abbreviations</b>	<b>32-33</b>
<b>17.0</b>	<b>Protocol post Approval</b>	<b>34</b>



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**1.0 PROTOCOL PRE- APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



PHARMA DEVILS

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

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To prepare the installation Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for SS jacketed Mfg tank. (**Make: .....**) to be installed, Liquid Line.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of jacketed Sugar Melting Tank



**PHARMA DEVILS**

**INSTALLATION 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 of Installation Qualification Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li> <li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li> <li>• Monitoring of Design Qualification activity.</li> <li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li> </ul>
<b>Production</b>	<ul style="list-style-type: none"> <li>• Review and Approval of Installation Qualification Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li> <li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>• Review of Installation Qualification Protocol cum Report.</li> <li>• To co-ordinate and support the Activity.</li> <li>• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.               <ul style="list-style-type: none"> <li>• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.</li> <li>• Details of Utilities</li> <li>• Material of Construction of all components</li> <li>• Brief Equipment Description</li> <li>• Safety Features and Alarms</li> </ul> </li> <li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li> </ul>



**INSTALLATION 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>	Bright Pharma Engineering Pvt. Ltd.
<b>Sr. No.</b>	
<b>Supplier's Name</b>	Bright Pharma Engineering Pvt. Ltd.
<b>Location of Installation</b>	Sugar Melting Area

**6.0 SYSTEM 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

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

**PROTOCOL No.:**

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document
- Verification of Certificate of material of construction of components.
- Verification of Calibration Certificate of test Instrument.

**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 IQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

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



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks and Location Suitability:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
Physical Damage	Should be no Damage to the jacketed mfg tank with stirrer		
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Syrup Manufacturing		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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

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

**Inference:**

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

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





**PHARMA DEVILS**

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

**PROTOCOL No.:**

**8.2 Utility Verification:**

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Sugar Melting Tank 1000 Ltr.		
Design Code & Guideline	cGMP guideline		

**ELECTRICAL INSTALLATION:**

Electricity	Voltage	415±10% V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

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

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

**Inference:**

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

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



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

**PROTOCOL No.:**

**8.3 Installation Checks:**

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation		
3.	Check the proper electrical installation of		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Verify that major components are securely anchored and protected from shock		
7.	Verify that there is no observable physical damage		
8.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

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

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

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

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



PHARMA DEVILS

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

**PROTOCOL No.:**

**8.4 Verification of Technical Specification:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>Equipment Name</b>	Jacketed Sugar melting Tank		
<b>Make</b>	Bright Pharma Engineering Pvt. Ltd.,		
<b>Sr. No.</b>	.....		
<b>Gross Capacity</b>	1200 Ltr.		
<b>Working Capacity</b>	1000 Ltr.		
<b>Design Code &amp; Guideline</b>	cGMP guideline		
<b>Contact Part</b>	SS 316L		
<b>Non-Contact Part</b>	SS 304		
<b>Overall Dimension</b>	1800 (W) x 1500 (D) x 2300 (H) mm		
<b>Vessel Design Data</b>			
Working Pressure	3.0 Kg/cm <sup>2</sup>		
Design Pressure	3.5 Kg/cm <sup>2</sup>		
Hydro- Test Pressure	5.0 Kg/cm <sup>2</sup>		
Working Temperature	0 to 121°C		
Design Temperature	0 to 135°C		
Vacuum Pressure	760 mm Hg		
<b>Jacket Design Data</b>			
Working Pressure	3.5 Kg/cm <sup>2</sup>		
Design Pressure	4.5 Kg/cm <sup>2</sup>		
Hydro-Test Pressure	6.0 Kg/cm <sup>2</sup>		
Working Temperature	0 to 140°C		
Design Temperature	0 to 150°C		
<b>General Specification</b>			
<b>Vessel Shell</b>			
Shape	Cylindrical		
Shell Size	1250 ID x 900 mm Height		
Thickness	6mm		
MOC	SS 316L		
Make	BPEPL		



PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>Vessel Top</b>			
Shape	Torrispherical dish		
Dish Size	1250 ID x 250 mm Height		
Thickness	6mm		
MOC	SS 316L		
Make	BPEPL		
<b>Vessel Bottom</b>			
Shape	Torrispherical dished		
Dish Size	1250 ID x 250 mm Height		
Thickness	6mm		
MOC	SS 316L		
Make	BPEPL		
<b>Jacket Shell</b>			
Shape	Cylindrical welded over external surface of vessel shell with spiral stiffeners.		
Thickness	4mm		
MOC	SS 304		
Make	BPEPL		
<b>Jacket Bottom</b>			
Shape	Torrispherical Dished end welded over external surface of vessel bottom with spiral stiffeners		
Thickness	4mm		
MOC	SS 304		
Make	BPEPL		
<b>Spiral Stiffeners (Welded on main chamber shell &amp; bottom)</b>			
Thickness	35 x 5 mm thick		
MOC	SS 304		
Make	BPEPL		
<b>Insulation (Bounded on external surface of shell)</b>			
Thickness	50 mm thick		
MOC	Glass Wool		
Make	K-flex		



PHARMA DEVILS

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

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Cladding Shell (Cylindrical welded over shell insulation)</b>			
Thickness	2 mm (14 Swg)		
MOC	SS 304		
Make	BPEPL		
<b>Cladding Bottom (Torrishpherical dished end welded over shell insulation)</b>			
Thickness	2 mm (14 Swg)		
MOC	SS 304		
Make	BPEPL		
<b>Legs (Made of SS pipes)</b>			
MOC	SS 304		
No. of Legs	3 Nos.		
Make	BPEPL		
<b>Man Hole (N1) (Triclover type with blank)</b>			
Man Hole Size	0400 mm TC		
MOC	SS 316L		
Make	BPEPL		
<b>Vessel Lamp (N2) (Combined in 4" DIN with glass &amp; vessel lamp)</b>			
MOC	SS 316L		
Glass (Make:- Diamond Glass)	Toughened glass, 0100 x 10mm thick		
Vessel Lamp (Make:- Bright)	Halogen		
- Operating Voltage	230VAC		
- Power rating	50 Watt		
Make	BPEPL		
<b>CIP/SIP Inlet Connection (N3) {2" x1" TC with Detachable arrangement of spray ball and MBFV}</b>			
MOC	SS 316L		
Make	BPEPL		
Spray Ball (Make:- Jet Spray)	Dynamic 360 degree rotating		
-MOC	SS 316L		
- Flow rate	89 LPM @ 2 bar		
- Process connection	1.5"		



PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>CIP Inlet Valve (Manual Butterfly Valve)</b>			
- Size	1.5"		
-MOC	SS 316L		
- Diaphragm	PTFE backed by EPDM		
- Process Connection	1" TC		
- Air Press. Required	4.5 to 6 bar for actuation		
Make	Cipriani		
<b>Compound Gauge (N 4) {1.5" TC with gauge}</b>			
MOC	SS 316L		
Compound Gauge	Diaphragm Type Bourdon gauge		
- Dial Size	0100 mm		
-MOC	SS 316L		
- Range	-760mm Hg to 4 kg/ern?		
Make	Baumer		
<b>Pressure transmitter (N5) {1.5" TC with pressure transmitter}</b>			
MOC	SS 316L		
Make	Baumer		
<b>Pressure transmitter (Sanitary Diaphragm Type)</b>			
- Model	JumodTRANS		
- Range	-1 to 5 bar		
- Output	4 to 20 mA		
- Process End	1.5" TC		
Make	Jumo		
<b>Sterile safety valve (N6) {1.5"TC with sterile safety valve}</b>			
MOC	SS 316L		
Sterile Safety Valve	Spring Loaded Type		
-MOC	SS 316L		
- Set Pressure	2.5 kg/em-		
- Process Connection	1.5" TC		
Make	BPEPL		
<b>Sugar Charging Inlet (N7){1.5"TC with MBFV }</b>			
MOC	SS 316L		



PHARMA DEVILS

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

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Make	BPEPL		
<b>Sugar Inlet Valve {Manual Butterfly Valve}</b>			
- Size	1.5"		
Make	Cipriani		
-MOC	SS 316L		
- Diaphragm	EPDM		
<b>Ingredient Inlet (N8) {1.5"TC with MBFV}</b>			
MOC	SS 316L		
Make	BPEPL		
<b>Ingredient Valve (Manual Butterfly Valve)</b>			
- Size	1.5"		
-MOC	SS 316L		
- Diaphragm	EPDM		
Make	Cipriani		
<b>Vacuum Inlet (N9) {1.5"TC with MBFV }</b>			
MOC	SS 316L		
Make	BPEPL		
<b>Ingredient Valve (Manual Butterfly Valve)</b>			
- Size	1.5"		
-MOC	SS 316L		
- Diaphragm	EPDM		
Make	Cipriani		
<b>Vacuum Breaker (NI0) {1"TC with MBFV &amp; Filter}</b>			
MOC	SS 316L		
Make	BPEPL		
<b>Ingredient Valve (Manual Butterfly Valve)</b>			
- Size	1"		
-MOC	SS 316L		
- Diaphragm	EPDM		
Make	Cipriani		
<b>Air Filter (5")</b>			
MOC	Sintered SS316L		



PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
- Size	1.5"		
Make	Kumar		
<b>Purified Water inlet (N 11) {1.5"TC }</b>			
- Size	1.5"		
-MOC	SS 316L		
Make	BPEPL		
<b>Extra Connection (NI2) {1.5"TC}</b>			
- Size	1.5"		
-MOC	SS 316L		
Make	BPEPL		
<b>Tank Outlet Valve (N13)</b>			
MOC	SS 316L		
Make	BPEPL		
<b>Tank outlet valve {Manual Flush bottom Valve}</b>			
- Size	1.5"		
-MOC	SS 316L		
- Diaphragm	EPDM		
Make	Flow fit		
<b>Temperature Sensor (NI4) {1.5"TC with Pt-100 type with head mounted transmitter }</b>			
-MOC	SS 316L		
- Range	0 to 200°C		
- Probe Diameter	06mm		
- Probe Length	50 mm long below TC		
- Power Supply	24 V DC, 2 wires		
- Process Connection	1.5" TC		
- Accuracy	Class A		
Make	Radix		
<b>Jacket Safety Valve (NI5) {3/8" BSP (F) coupling with safety valve }</b>			
Safety Valve	Spring Loaded		
-MOC	SS 304		
- Set Pressure	3.5 Kg/cm <sup>2</sup>		
- Process Connection	3/8" BSP (M)		





PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	BPEPL		
<b>Pressure Gauge {1;4" BSP (F) coupling with Pressure Gauge }</b>			
-MOC	SS 304		
- Dial Size	02.5"		
-MOC	SS 304		
- Range	0 to 7 kg/ern?		
- Process Connection	1;4" BSP (M)		
<b>Steam Inlet (NI6) 1.5" TC with valve &amp; steam trap</b>			
MOC	SS 304		
Make	BPEPL		
<b>Steam Inlet Valve (Pneumatically operated Angle Seat valve )</b>			
- Size	1"		
-MOC	SS 304		
- Seating	PTFE		
- Process End	1.5" TC		
- Compo Air Required	4.5 to 6 Kg/ern? for actuation		
Make	Avcon		
<b>Steam Condensate (NI7) (1.5" TC with valve &amp; steam trap)</b>			
MOC	SS 304		
Make	BPEPL		
<b>SteamCond. Valve (Pneumatically operated Angle Seat valve)</b>			
- Size	1"		
-MOC	SS 304		
- Seating	PTFE		
- Process End	1" TC		
- Compo Air Required	4.5 to 6 Kg/ern? for actuation		
Make	Avcon		
<b>Cooling Inlet (NI8) (1.5" TC with valve &amp; steam trap)</b>			
MOC	SS 304		
Make	BPEPL		
<b>Cooling Inlet Valve (Pneumatically operated Angle Seat valve)</b>			



PHARMA DEVILS

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

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
- Size	1"		
-MOC	SS 304		
- Seating	PTFE		
- Process End	1.5" TC		
- Compo Air Required	4.5 to 6 Kg/ern? for actuation		
Make	Avcon		
<b>Cooling Outlet (N19) (1.5" TC with valve &amp; steam trap )</b>			
MOC	SS 304		
Make	BPEPL		
<b>Cooling Outlet Valve (Pneumatically operated Angle Seat valve)</b>			
- Size	1"		
-MOC	SS 304		
- Seating	PTFE		
- Process End	1.5" TC		
- Compo Air Required	4.5 to 6 Kg/ern <sup>2</sup> for actuation		
Make	Avcon		
<b>Jacket Air vent (N20) (1.5" TC with valve &amp; steam trap )</b>			
MOC	SS 304		
Make	BPEPL		
<b>Jacket Air vent Valve (Pneumatically operated Angle Seat valve)</b>			
- Size	1"		
-MOC	SS 304		
- Seating	PTFE		
- Process End	1.5" TC		
- Compo Air Required	4.5 to 6 Kg/ern? for actuation		
Make	Avcon		
<b>Jacket Drain (N21) (1.5" TC with valve &amp; steam trap )</b>			
MOC	SS 304		
Make	BPEPL		
<b>Jacket Drain Valve (Pneumatically operated Angle Seat valve )</b>			
- Size	1"		
-MOC	SS 304		



PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
- Seating	PTFE		
- Process End	1" TC		
- Compo Air Required	4.5 to 6 Kg/ern? for actuation		
Make	Avcon		
<b>CIP Drain (N22) (1.5" TC with valve &amp; steam trap )</b>			
MOC	SS 304		
Make	BPEPL		
<b>CIP Drain Valve (Manual Butterfly Valve )</b>			
- Size	1.5"		
-MOC	SS 316L		
- Diaphragm	EPDM		
Make	Cipriani		
<b>Flow Switch (N23) (1A" BSP Sanitary Coupling with level switch)</b>			
-MOC	SS 304		
Connection	114" BSP		
Set Flow	0.4 to 4 LPM		
Model	WFS-06-S-1		
Maximum Pressure	10 Kg/cm sq.		
Electric	230 V ACI 1 A		
Make	BPEPL		
<b>Solenoid Coil Seal cooling for stirrer (N24) {3/8" BSP Sanitary Coupling with level switch}</b>			
Size	3/8"		
MOC	Brass		
Type	9230D 104/BRIS6/E/BSP		
Make	Avcon		
<b>Stirrer (Propeller Type On Inclined Portion.)</b>			
Model	5 HP / 3.75 Kw		
Motor Rating	CI		
Maximum Speed	960		
- Accuracy's	Class A		
Elect. Connections.	415 V, 3 Phase		
Frequency	50Hz		



PHARMA DEVILS

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

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Type	Vertical Flange		
Protection	IP - 55		
Stirrer Shaft	38mm		
Make	Hindustan		
<b>Stirrer Design (Propeller type with 4 Blade )</b>			
-MOC	SS 316L		
Sweep Dia	150mm		
<b>Shaft Seal (Double Cartridge Mech. Seal )</b>			
-MOC	SS 316L		
Seal Size	38 mm dia.		
Seal Face Inboard	S.C vs. S.c.		
Seal Face Outboard	TC vs. Carbon		
Seal Cooling Media	Water		
Make	Sigma Seal		
<b>Control Panel (Make Precise)</b>			
Size	600 (W) x 300 (D) x 1000 (H) mm Approx.		
MOC	SS 304		
3 Phase Indication (Make MIMIC)	R YB Lamps		
Main Switch (Make Salzer)	3 Pole, 25 A		
<b>HMI (Panel flush mounted)</b>			
Model	TP700 Comfort		
Size	7" color touch screen		
Power Supply	24VDC		
Communication	Modbus Protocol		
Make	Siemens		
<b>Control Start (Make Teknic)</b>			
Control Start (Make Teknic)	Illuminated green push button		
Control Stop (Make Teknic)	Red push button		
Emergency Stop (Make Teknic)	Push button		
Filter Pads (Make Teknic)	100 x 100mm		



PHARMA DEVILS

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

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Exhaust Fan (04" )</b>			
Power Supply	230V AC		
Make	Rexnord		
<b>Stirrer VFD (Mounted inside the control panel )</b>			
Model	V-20 Series With filter		
HP Rating	5.0HP		
Make	Siemens		
<b>PLC (Mounted inside the control panel)</b>			
Model	S71200		
Power Supply	24VDC		
Make	Siemens		
<b>Control MCB (Make Siemens)</b>			
Control MCB (Make Siemens)	2 pole, 6A		
<b>Stirrer MCB (Make Siemens)</b>			
Stirrer MCB (Make Siemens)	3 pole, 20A		
<b>Plug Point MCB (Make Siemens)</b>			
Plug Point MCB (Make Siemens)	2 pole, 6A		
<b>SMPS (Make Meanwell)</b>			
SMPS (Make Meanwell)	24 V DC power supply of 6.5 Amp.		
<b>Single Phase Preventer (Make: OIC)</b>			
Single Phase Preventer (Make: OIC)	3 Ph., 4 Wire		
<b>PLC Based Relay Cards (Make Phoenix)</b>			
PLC Based Relay Cards (Make Phoenix)	24 VDC, 1CHO		
<b>Pneumatic Coil (Mounted inside the control panel )</b>			
Model	305.M58		
Size	1/8"		
Electrical supply	230 V AC		
Make	Pneumax		
<b>Air Pressure switch (For plant compressed air supply to valves )</b>			
Type	UT-10		
Range	0 to 10 bar		
Electrical supply	24 VDC		
Make	Baumer		



PHARMA DEVILS

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

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Terminal (Make: Connectwell)	Single deck		
Main Incomer (Make Salzer)	25A,3P		
<b>Finishing</b>			
Vessel Internal Finishing	Ra::::: 0.5 urn, Mirror Polish		
Vessel External Finishing	Ra::::: 0.8 urn, Matt Polish		
Movable Trolley	Ra < 1.2 urn, Matt Polish		
Make	BPEPL		
Bottom entry mixer	Propeller Type Stirrer Make: Bright		
Process pneumatic & manual valves	2-way diaphragm valves Make: Cipriani		
Utility pneumatic valves	2-way angle seat valves, Make: Avcon		
Vacuum breaker filter	Model: 5" SS Sintered Vent Filter, Make: Kumar		
Compound Gauge	Sanitary bourdon gauge, Dial size-04" Make: Baumer		
Pressure Gauge	Bourdon gauge, Dial size-02.5",0 -7 kg/ern", Make: Baumer		
Sterile Safety Valve	Sanitary, spring loaded Make: BPEPL		
N on Sterile Safety Valve	Non Sanitary, spring loaded Make: BPEPL		
Vessel Lamp	Halogen Make: Bright		
Temperature sensor on shell	Pt-100, 0-200 °C, W' BSP Make: Radix		
Spray Ball	360° self-rotating Make: Jet Spray		
Tank outlet valve	Make: Flofit		
Pressure Transmitter	Sanitary diaphragm Make: Jumo		



**PHARMA DEVILS**

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

**PROTOCOL No.:**

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

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

**Inference:**

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

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



PHARMA DEVILS

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

**PROTOCOL No.:**

**8.5 MATERIAL OF CONSTRUCTION:**

S.No.	COMPONENTS	MOC	OBSERVATIONS	OBSERVED BY ENGINEERING SIGN/DATE
1.	Vessel Shell	SS 316L		
2.	Vessel Bottom	SS 316L		
3.	Vessel Top	SS 316L		
4.	Contact Parts	SS 316L		
5.	Non-Contact Parts	SS 304		
6.	Jacket Shell	SS 304		
7.	Jacket Bottom	SS 304		
8.	Spiral Stiffeners	SS 304		
9.	Insulation	Glass Wool		
10.	Cladding Shell	SS 304		
11.	Cladding Bottom	SS 304		
12.	Legs	SS 304		
13.	Spray ball	SS 316 L		
14.	Agitator	SS 316 L		
15.	Top Dish Nozzle	SS 316L		
16.	Vessel Lamp	SS 316L		
17.	CIP/SIP Inlet Connection	SS 316L		
18.	Compound Gauge (N 4)	SS 316L		





PHARMA DEVILS

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

**PROTOCOL No.:**

S.No.	COMPONENTS	MOC	OBSERVATIONS	OBSERVED BY ENGINEERING SIGN/DATE
19.	Pressure transmitter (N5)	SS 316L		
20.	Sterile safety valve (N6)	SS 316L		
21.	Sugar Charging Inlet	SS 316L		
22.	Ingredient Inlet (N8)	SS 316L		
23.	Vacuum Inlet (N9)	SS 316L		
24.	Vacuum Breaker (NI0)	SS 316L		
25.	Purified Water inlet (N11)	SS 316L		
26.	Extra Connection (NI2)	SS 316L		
27.	Tank Outlet Valve (N13)	SS 316L		
28.	Temperature Sensor (NI4)	SS 316L		
29.	Jacket Safety Valve	SS 304		
30.	Steam Inlet (NI6)	SS 304		
31.	Steam Condensate (NI7)	SS 304		
32.	Cooling Inlet (NI8)	SS 304		
33.	Cooling Outlet (N19)	SS 304		
34.	Jacket Air vent (N20)	SS 304		
35.	Jacket Drain (N21)	SS 304		
36.	CIP Drain (N22)	SS 304		
37.	Flow Switch (N23)	SS 304		



**PHARMA DEVILS**

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

**PROTOCOL No.:**

<b>S.No.</b>	<b>COMPONENTS</b>	<b>MOC</b>	<b>OBSERVATIONS</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
38.	Solenoid Coil Seal cooling for stirrer (N24)	Brass		
39.	Shaft Seal	SS 316L		
40.	Stirrer	SS 316L		
41.	Control Panel	SS 304		

**Checked By  
Production**

**Sign/Date:** .....

**Verified By**

**Quality Assurance**

**Sign/Date:** .....

**Inference:**

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

**Reviewed By  
Manager QA**

**Sign/Date:** .....



PHARMA DEVILS

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

**PROTOCOL No.:**

**8.6 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		
Variable Frequency Drive	Motor safety from overload		
Main Supply	Main power supply should be always switched off when not in use.		
Safety valve	Safety against over pressure		
Air pressure switch	Protection for low air pressure for pneumatic valves		
Rupture Disc	Safety against Over pressure		
Insulation	For operator safety & Heat loss prevention		
Emergency Button	Protection against abnormal condition		
Instrument air pressure	Low air pressure protection		
Overload Relay	For motor & equipment protection		
Temperature Controller	To Control the temperature of vessel		
Steam Control Valve	For Controlling On / Off Action of Steam Depending on the set point.		
<b>Critical Alarms</b>			
Air pressure low	Entire process will trip with hooter activation and alarm		



PHARMA DEVILS

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

**PROTOCOL No.:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Emergency pressed	display. The same will log in alarm history as well as in print. On acknowledging msg., hooter will be silent. On reset of air pressure, alarm will disappear & the process will resume on manual intervention.		
Single phase fail			
Stirrer overload			
Flow Switch for Seal Cooling			
<b>Non-Critical Alarms</b>			
No Water Flow to Seal	Stirring, heating & cooling process will not start in semi-auto mode mfg. "No Water flow to seal"		
	Hooter will activate with alarm display		
	<b>On</b> acknowledging msg., hooter will be silent & alarm will disappear.		
No Heating	During heating in auto as well as in semi auto mode Mfg. process, if product temperature doesn't increase for set scan time, hooter will activate with alarm display.		
	The same will be printed and printing will stop.		
	<b>On</b> acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.		
No Heating (Continue)	Process will continuously check for healthy condition.		
	<b>On</b> reset of healthy condition, alarm will disappear & process and printing will resume automatically.		
No Cooling	During heating in auto as well as in semi auto mode Mfg. process, if product temperature doesn't increase for set scan time, hooter will activate with alarm display.		
	The same will be printed and printing will stop.		



PHARMA DEVILS

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

**PROTOCOL No.:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
	<b>On</b> acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.		
	Process will continuously check for healthy condition.		
	<b>On</b> reset of healthy condition, alarm will disappear & process and printing will resume automatically.		
Product Temp. high	During heating in auto as well as in semi auto mode Mfg. process, if product temperature exceeds up to upper limit as per set upper tolerance, raw steam inlet valve will close.		
	Hooter will activate with alarm display		
	The same will be printed and printing will continue.		
	<b>On</b> acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.		
	Process will continuously check for healthy condition of reaching heating set point.		
	<b>On</b> reset of healthy condition, alarm will disappear & raw steam inlet valve will function to maintain the same.		
Product Temp. low	During heating in auto as well as in semi auto mode Mfg. process, if product temperature falls below lower limit as per set lower tolerance, raw steam inlet valve will open.		
	Hooter will activate with alarm display		
	The same will be printed and printing will continue.		
	<b>On</b> acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.		



**PHARMA DEVILS**

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

**PROTOCOL No.:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
	Process will continuously check for healthy condition of reaching heating set point. <b>On</b> reset of healthy condition, alarm will disappear & raw steam inlet valve will function to maintain the same.		

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

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

**Inference:**

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

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



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

**PROTOCOL No.:**

**9.0 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

**10.0 DOCUMENTS TO BE ATTACHED:**

- MOC & Calibration certificate
- P & ID
- Any other relevant Documents

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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

**12.0 CHANGE CONTROL, IF ANY:**

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

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

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



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

**PROTOCOL No.:**

**14.0 CONCLUSION:**

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

**15.0 RECOMMENDATION:**

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

**16.0 ABBREVIATIONS:**

- AISI : American Iron & Steel Institute
- BSP : British Standard Pipe
- cGMP : Current Good Manufacturing Practices
- D : Depth
- db : Decible
- LPH : Liter per Hours
- LPM : liter per Minute
- SMT : Sugar Melting Tank
- mm : Millimeter
- MOC : Material of Construction
- OD : Outer Diameter
- PLC : Programmable Logic Controller
- PO : Purchase Order
- PT-100 : Platinum-100
- TC : Triclover
- VFD : Variable Frequency Drive





**PHARMA DEVILS**

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

**PROTOCOL No.:**

**17.0 PROTOCOL POST APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			