



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
SS JACKETED MANUFACTURING VESSEL (2000 LITER)**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
SS JACKETED MANUFACTURING
VESSEL
CAPACITY: 2000 LITER
(FFS LINE)**

EQUIPMENT ID. No.	
LOCATION	MANUFACTURING AREA , FFS LINE
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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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)			



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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: Pharmatech Process Equipment .2000 ltr,)** to be installed.

- 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 manufacturing vessel



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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:

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



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5.0 EQUIPMENT DETAILS:

Equipment Name	SS Jacketed Manufacturing vessel
ID Number	
Capacity	2000 ltr.
Gross Capacity	2400 ltr.
Manufacturer's Name	Pharmatech Process Equipment
S.No.	
Model	cGMP Model.
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area, FFS Line

6.0 SYSTEM DESCRIPTION:

The Manufacturing Vessel is the Jacketed, Insulated & Cladding vessel having Bottom entry low shear magnetic mixer to perform heating & cooling with stirring operations respectively during the mixing Process .the vessel is incorporated with high shear mixer tank plate for future installation of mixer, if required .the respective electrical components have been organized in the control panel except VFD .it's also designed of having compatible with clean in process and steam in process with in-built facilities of the same .some process valves are manually operated & some are pneumatically operated as per process Requirements. All utility valve are pneumatically operated to perform the heating & cooling operation automatically & control the Same.

- Shell
- Jacket
- Insulation & cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge



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PROTOCOL No.:

- Sterile safety valve
- 0.2 micron plain vent filter
- Manual operated diaphragm valve
- Rupture disc
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Variable frequency drive
- Load cell
- PLC panel

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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
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	Manufacturing Room, FFS Line		
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:

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**Reviewed By
(Manager QA)
Sign/Date:**



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**INSTALLATION QUALIFICATION
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PROTOCOL No.:

8.2 Utility Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Manufacturing vessel 2000 lt		
Model	cGMP Model		
ELECTRICAL INSTALLATION:			
Electricity	Voltage	415±10% V	
	Phases	3 Phase	
	Frequency	50 Hz	
Electrical connections have been provided and	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:

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**Reviewed By:
(Manager QA)
(Sign & Date)**



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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:

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**Reviewed By
(Manager QA)
Sign/Date:**



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8.4 Verification of Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Gross Capacity	2400 lt.		
Working Capacity	2000 lt.		
S.No.		
Contact Part	SS316 L		
Non Contact Part	SS304		
Impeller	Type : Magnetic Stirrer Make : Kweng Mounting : Bottom Sweep Dia : 195 mm MOC : SS316 L Model : BAGI -5K		
Gear Box	Make : Bonfiglioli Type : Worm with body flange Model : W63 U 7P90 B5 B3 Ratio : 7:1		
Motor	Make : Siemens Type : Non Flame Proof Rating : 1.5 KW Power Supply : 415 VAC, 50 Hz, 3 Phase RPM : 2800 Mounting : Flange Mounted Sr.No : 0783		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Spray Ball	Make : Leacher Sr.No : 569.139.1 Y.AL.00.3 Type : Self Rotating , 360° Rotating Detachable. Dia : 61 mm MOC : SS 316 L Water Flow : 73 LPM @ 2.01		
Manual Diaphragm Valve	Make : Gemu Sr.No : 67325D88405E02TS 1537 Type : Manual Operated Diaphragm Valve Size : 25 mm in Dia Thickness : 8mm MOC : Contact Part SS316 L, Non Contact Part SS 304		
Compound Gauge	Make : Baumer S.No. : Type : Manual Operated Diaphragm Valve Size : 4 mm in Diameter Thickness : 8mm MOC : Contact Part SS316 L Non Contact Part SS 304 Mounting : 38 mm T/C end Range : -760 to 10		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Sterile Safety Valve	Make : Pharmatech S.No. : 530/16 Type : Sterile Diaphragm Size : 9.3 mm in Dia. (Inlet) / 12.5 mm in Dia. (outlet) MOC : Contact Part SS316 L		
Manual Diaphragm Valve	Make : Gemu S.No.: Type : Manual Operated Diaphragm Valve Size : 25 mm in Diameter Thickness : 8mm MOC ; Contact Part SS316 L, Non Contact Part SS 304 End Connection : T/C end Application : For WFI		
Plain Vent Filter	Make : Pall Type : Emflon, code 7, Hydrophobic Size : 5 inch long Filter Area : 0.29 M ² MOC : Housing SS 316 L , Cartridge Double Layer PTFE Gasket : Silicon Mounting : 25 mm T/C Model : Cartridge		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Manual Diaphragm Valve	Make: Gamu Type : Diaphragm PTFE with EPDM Back up End Connection : T/C end Size : 25 mm in Dia Qty : 2 Nos MOC ; Contact Part SS316 L Non Contact Part SS 304 Sr. No. : 67325D88405E02TS 1537		
Plain Vent Filter	Make: Pall Type : Emflon ,code 7, Hydrophobic Rating : 0.2 Micron Filter Area : 0.29 M ² MOC ; Housing SS316 L Cartridge Double Layer PTFE Gasket : Silicon		
Manual Diaphragm Valve	Type : Manual Operated Size : 25 mm in Dia MOC : Contact Part SS316 L, Non Contact Part SS 304 Diaphargm PTFE with EPDM Backup End Connection : T/C end Application : for vent Filter Isolation Qty : 2 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Manual Diaphragm Valve	Make : Gemu Type : Manual Operated Size : 12 mm in Dia MOC : Contact Part SS316 L Non Contact Part SS 304 Diaphragm PTFE with EPDM Backup End Connection : T/C end Application : for Nitrogen Inlet		
Manual Diaphragm Valve	Make : Gemu Type : Manual Operated Size : 38 mm in Dia MOC : Contact Part SS316 L Non Contact Part SS 304 Diaphragm PTFE with EPDM Backup		
Halogen Lamp	Make : Lumiglass Type : NFLP Halogen Lamp with bracket Bulb : 12 volt/50 W Hallogen Mounting : on light Glass		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Rupture Disc	Make : Fike Size : 1.5 Inch T/C MOC : SS 316 L Gasket : PTFE End Connection : T/C Ended Operating Pressure : FV to 3 Bar Operating Temperature : -20 to 180° C Burst Pressure : 3.5 kg/cm ² @ 180° C Sr.No : 1572257		
Temperature Sensor with Transmitter	Make : Radix Type : PT 100 Mounting : Dr. Ingold MOC : Sensor –SS 316 L Range : 0-200 ° C Accuracy : Class A Sheath Dia & Length : 6 X 600 mm Connection : 3 Wire		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Temperature Sensor with Transmitter	Make : Radix Type : PT 100 Mounting : Mini T/C MOC : Sensor –SS 316 L Range : 0-200 ° C Accuracy : Class A Sheath Dia & Length : 8 X 65 mm Connection : 3 Wire		
Flush Bottom Valve	Make : Gemu Type : manual operated, with Manual Sample Valve MOC : Contact Part SS316 L Non Contact Part SS 304 Out let Size : 38 mm Diaphragm : PTFE backed by EPDM Backup Sample Valve : 12 mm in Dia Design Temperature : -80 to 200 °C Design Pressure : -1 to 10 Bar End Connection : T/C Ended Mounting : At Bottom of tank		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Air Vent Ball for Jacket Vent	Make : Micro MOC : SS 304 Type : Pneumatic Operated ball Valve Size : 15 NB End Connection : T/C Ended		
Pressure Gauge for Jacket	Make : Baumer MOC : SS 304 Type : Bourdon perforation, Size : 100 mm in dia End Connection : ½ inch BSP Threded		
Safety Valve for Jacket	Make : Fainger Leser Type : Conventional FLP 549 MOC : SS 304 Over Pressure : 10 % of Pressure Set Pressure : 3.18 bar End Connection : Screwed		
Ball Valve for Compressed Air inlet Jacket side	Type : Pneumatic operated Valve, Make : Micro MOC : SS 304 Size : 15 NB		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Ball Valve for Compressed Air Inlet & Cooling Water Supply & Return	Type : Pneumatic operated Valve, Make : Micro MOC : SS 304 Size : 40 NB End Connection : Flanged end		
Steam Trap Unit for Jacket Side	Make : Rex Type : Thermodynamic Model : Optiseal vent filter Cartridge MOC : Body SS 420 Strainer SS 304 Size : 20 NB End Connection : ¾" BSP Threaded		
Ball Valve for Steam Trap Unit	Make : Micro Size : ¾" NB End Connection : TC Ended Qty : 2 Nos		
Piping for Steam Strap unit	Make : Pharmatech Type : ERW MOC : AISI 304 End Connection : TC Ended		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Variable Frequency Drive	Make : ABB Rating : 2HP Power Supply : 380- 500 V AC + 10 % /-15% , 3 phase. Output Frequency : 50.... 60Hz ± 5% Protection : IP20 Ambient Temperature : - 10 to 55 ° C Ambient Humidity : Max 95 % non Condensing		
Load Cell	Make : Mettler Model : SBH-2000 Capacity : 2 Ton/Each Least Count : 1 kg Accuracy : ±0.1 % MOC : SS 304 Qty : 3 Nos Indicator : IND 331		
Flexible Hose	Make : Shanti Size : 25 mm Dia MOC: SS wire Braided Length : 500 mm Qty : 2Nos		
Flexible Hose For Spare	Make : Ami Polymer Size : 25 mm in Dia MOC : SS 304 Length : 500 mm Qty : 3 Nos		
Skid	Make : Pharmatech MOC: SS304 Size : 1900 (L) x 1550 (W)		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Control Panel	Make : Rittal Type : Dust Proof Mounting : Suitable MOC: SS304 Gasket : Rubber Finish : Matt		
PLC	Make : Allen Bradley Type : Programmable Logical Controller Model : ML-1400 Power Supply : 24 VDC User data Space : 10 K Port : Serial Ethernet Software : RS logic 500 No. of DI : 20 No. of DO : 12 Oper Tem. : -20 °C to + 65°C		
HMI	Make : Allen Bradley Type : Colour Touch Screen Model : PVP-600 Power Supply : 18-30 VDC Size : 5.7 ” Resolution : 320 x 240 , 18 -bit color Graphics. Back light: CC FL, 50, 000H Software : RS View Factory Common Port : RS232, USB and Ethernet port		
Printer	Make : Epson Type : Dot Matrix /Online printer Model : LX-310 Power Supply : 230 VAC, Single Phase		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
FRL Unit	Make : Festo Model : FRC ¼ -D-MINI Range : 0-16 Bar Mounting : Panel Mounted		
Hooter	Make : Reputed make Type : Panel Mounted Size : 96 x 96 mm Mounting : Panel Mounted		

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 MATERIAL OF CONSTRUCTION:

S.No.	COMPONENTS	MOC	OBSERVATIONS
1	Vessel shell	AISI 316L	
2	Jacket shell	SS 304	
3	Legs	SS 304	
4	Impeller	AISI 316L	
5	Spray Ball	SS 316L	
6	non contact part	SS 304	
7	Contact part	SS 316L	
8	Safety Valve non contact part	SS 304	
9	Safety Valve Contact part	SS 316L	
10	vent filter housing	SS316 L	
11	Manual Diaphragm valve (Contact Part)	SS316 L	
12	Manual Diaphragm valve (Non Contact Part)	SS304	
13	Rupture Disc	SS316 L	
14	Temperature Sensor	SS316 L	
15	Pressure gauge for jacket	SS304	
16	Control Panel	SS304	
17	Safety valve for jacket	AISI304	

**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 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (Panel and Motors) and operator should be provided		
Guards	Guards for all Moving Parts		
Noise Level	Below 80 db		
Main Supply	Main power supply should be always switched off when not in use.		
Safety valve	Safety against over pressure		
Emergency stop	Protection from abnormal condition		
Air pressure switch	Protection for low air pressure for pneumatic valves		

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

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

Inference:

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(Manager QA)
Sign/Date:.....**



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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
- Any other relevant Documents



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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

AB	:	Allen Bradley
AC	:	Alternate current
AISI	:	American Iron & Steel Institute
ASME	:	American Society of mechanical Engineering
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
D	:	Depth
db	:	Decible
DQ	:	Design Qualification
EPDM	:	Ethylene Propylene Dyne monomer
H	:	Heigh
HMI	:	Humen Machine Interface
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
JMT	:	Jacketed Manufacturing Tank
Kg	:	Kilograms
KW	:	Kilo Watt
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
OD	:	outer Diameter
PEEK	:	Polyether Ether ketone
PG	:	Pressure Gauge
PLC	:	Programmable Logic Controller
PNP	:	Positive Neutral Positive
PT-100	:	Platinum-100
PTFE	:	Poly tetra Fluoro Ethylene
PVT.	:	Private



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QA	:	Quality Assurance
RPM	:	Revolution Per Minute
SF	:	Steri Flange
SIP	:	Sterilization in Place
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
V	:	Volt
VFD	:	Variable Frequency Drive
W	:	Width
WFI	:	Water for injection
WHO	:	World Health Organization



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17.0 PROTOCOL POST 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)			