

PHARMA DEVILS

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

# DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL

## **CAPACITY: 2000 Liter**

## (FFS LINE)

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



PROTOCOL No.:

SS JACKETED MANUFACTURING VESSEL (2000 LITER)

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PROTOCOL No.:

SS JACKETED MANUFACTURING VESSEL (2000 LITER)

#### **PROTOCOL PRE- APPROVAL:** 1.0

#### **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 Manufacturing tank (2000 ltr.) procured from Pharmatech Process Equipment at the site.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design 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:

DEPARTMENTS	RESPONSIBILITIES
	<ul> <li>Preparation, Review and Approval of Design Qualification Protocol cum Report.</li> <li>Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li> </ul>
Quality Assurance	<ul> <li>Co-ordination with Production and Engineering to carryout Design Qualification.</li> <li>Monitoring of Design Qualification activity.</li> </ul>
	Review of Design Qualification Protocol cum Report after Execution.
Production	<ul> <li>Review of Design Qualification Protocol cum Report.</li> <li>Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li> <li>Review of Design Qualification Protocol cum Report after Execution.</li> </ul>
Engineering	<ul> <li>Review of Design Qualification Protocol cum Report.</li> <li>Assist in the Preparation of the 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.</li> <li>GA Drawing</li> <li>Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.</li> <li>Details of Utilities</li> <li>Identification of components for Calibration</li> <li>Material of Construction of all components</li> <li>Brief Equipment Description</li> <li>Safety Features and Alarms</li> <li>Review of Design Qualification Protocol cum Report after Execution.</li> </ul>



#### 5.0 **PROJECT REQUIREMENTS:**

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented. The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical products in accordance with cGMP principles.

#### 6.0 BRIEF EQUIPMENT DESCRIPTION:

The Manufacturing Vessel is the Jacketed, Insulated & Cladding vessel having Bottom entry low sher 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
- Spray ball
- Compound gauge
- safety valve
- 0.2 micron plain vent filter
- Manual operated diapharagm valve



- Rupture disc
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.

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- Safety valve for jacket.
- PG For Jacket
- Auto Ball Valve
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- PLC panel



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#### 7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification.

#### 8.0 CRITICAL VARIABLES TO BE MET:

#### 8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The purpose of manufacturing vessel is mixing of pharmaceutical product with magnetic stirrer.	<ul> <li>Manufacturing vessel shall be</li> <li>Able to dissolve the Solid content in the Solvent Media to provide solution</li> <li>Leak free</li> <li>Jacketed to control the temperature of the solution</li> </ul>	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

#### 8.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	415 Volts AC, 50 Hz & 3 phase	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement



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### 8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Gross Capacity	2400 lt.	Design Requirement
Working Capacity	2000 lt.	Design Requirement
Sr.No	15-16/SJ/000279	Design Requirement
Contact Part	SS316 L	Design Requirement
Non Contact Part	SS304	Design Requirement
Impeller	Type: Magnetic StirrerMake: KwengMounting: BottomSweep Dia: 195 mmMOC: SS316 LModel: BAGI - 5K	Process Requirement
Gear Box	Make: BonfiglioliType: Worm with body flangeModel: W63 U 7P90 B5 B3Ratio: 7:1Outer Driving Head Torque: 10 NmSr. No : 1500000 77403130001	Design Requirement
Motor	Make : SiemensType : Non Flame ProofRating : 1.5 KWPower Supply : 415 VAC, 50 Hz, 3 PhaseRPM : 2800Mounting : Flange MountedSr.No : 0783	Design Requirement



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PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : Leacher	
	Sr.No: 569.139.1 Y.AL.00.3	
	<b>Type</b> : Self Rotating , 360° Rotating Detachable.	
Spray Ball	Dia : 61 mm	
	<b>MOC</b> : SS 316 L	Design Requirement
	Water Flow: 73 LPM @ 2.0 bar	
	<b>END Connection :</b> <sup>3</sup> / <sub>4</sub> <sup>**</sup> BPS	
	<b>Part No.</b> : 569.139.1 Y. AL	
	Make : Gemu	
	Sr.No : 67325D88405E02TS 1537	
	Type         : Manual Operated Diaphragm Valve	
	Size : 25 mm in Dia	
Manual Diaphragm Valve	Thickness : 8mm	Design Requirement
	MOC ; Contact Part SS316 L	
	Non Contact Part SS 304	
	End Connection : T/C end	
	Application : For CIP at Spary ball	
	Make : Baumer	
	Sr.No : 0716-PG-150023	
	Type         : Manual Operated Diaphragm Valve	
	Size : 4 mm in Dia	
Commence I Comme	Thickness : 8mm	
Compound Gauge	MOC ; Contact Part SS316 L	Design Requirement
	Non Contact Part SS 304	
	Mounting : 38 mm T/C end	
	Range : -760 to 10 kg/Cm2	
	Size : 4" In Dia	



PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : Pharmatech	
	<b>Sr.No. :</b> 530/16	
	Type         : Sterile Diaphragm	
Sterile Safety Valve	Size : 9.3 mm in Dia (Inlet) / 12.5 mm in Dia	
	(outlet)	Process Requirement
	MOC ; Contact Part SS316 L	
	Non Contact Part SS 304	
	Set Pressure : 3.25 bar	
	Make : Gemu	
	<b>Sr.No</b> : 67325D88405E02TS 1537	
	Type         : Manual Operated Diaphragm Valve	
	Size : 25 mm in Dia	
Manual Diaphragm Valve	Thickness : 8mm	Process Requirement
	MOC ; Contact Part SS316 L	-
	Non Contact Part SS 304	
	End Connection : T/C end	
	Application : For WFI Inlet	
	Make : Pall	
	Type : Emflon, code 7, Hydrophobic	
	Size : 5 inch long	
	Filter Area : 0.29 M <sup>2</sup>	
	MOC : Housing SS 316 L , Cartridge Double	
Plain Vent Filter	Layer PTFE	Design Requirement
	Gasket : Silicon	
	Mounting: 25 mm T/C	
	Model: Cartridge AB05HTPFR2PVH4	
	Housing : VSVNLI05G723H4	



PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make: Gamu	
	<b>Type</b> : Diaphragm PTFE with EPDM Back up	
	End Connection : T/C end	
Manual Diaphragm Valve	Size: 25 mm in Dia Qty: 2 Nos MOC; Contact Part SS316 L	Design Requirement
	Non Contact Part SS 304	
	Sr. No. : 67325D88405E02TS 1537	
	Make: Pall	
	<b>Type</b> : Emflon ,code 7, Hydrophobic	
	Rating: 0.2 Micron	
	Filter Area : 0.29 M <sup>2</sup>	
Plain Vent Filter	MOC ; Housing SS316 L	Design Requirement
	Cartridge Double Layer PTFE	2
	Gasket : Silicon	
	Mounting : 25 mm T/C	
	Model : Cartidge AB05HTPFR2PVH\$	
	Housing : VSVNLI05G723H4	
	<b>Type :</b> Manual Operated <b>Size :</b> 25 mm in Dia	
	MOC : Contact Part SS316 L	
Manual Diaphragm Valve	Non Contact Part SS 304 Diaphargm	Design Requirement
	PTFE with EPDM Backup	Design Requirement
	End Connection : T/C end	
	Application : for vent Filter Isolation	
	Make : Gemu Type : Manual Operated Size : 12 mm in Dia MOC : Contact Part SS316 L	
Manual Diaphragm Valve	Non Contact Part SS 304 Diaphargm	Design Requirement
	PTFE with EPDM Backup	
	<b>End Connection :</b> T/C end	



PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : GemuType : Manual OperatedSize : 38 mm in DiaMOC : Contact Part SS316 L	
Manual Diaphragm Valve	Non Contact Part SS 304 Diaphargm	
	PTFE with EPDM Backup	
	End Connection : T/C end	
	Application : for Dip Tube Outlet.	
Halogen Lamp	Make : LumiglassType: NFLP Halogen Lamp with bracketBulb: 12 volt/50 W HallogenMounting: on light Glass	Design Requirement
<b>F</b>	MOC : Stainless Steel	Design Requirement
	Model : USL 13	
	<b>Art No.</b> 3540.215.00	
	Make : Fike	
	Size : 1.5 Inch T/C	
	<b>MOC</b> : SS 316 L	
	Gasket : PTFE	
Rupture Disc	End Connection : T/C Ended	Design Requirement
	<b>Operating Pressure :</b> FV to 3 Bar	
	<b>Operating Temperature : -</b> 20 to180° C	
	Burst Pressure : 3.5 kg/cm <sup>2</sup> @ 180° C	
	Sr.No : 1572257	
	Make : Radix	
	<b>Type</b> : PT 100	
	Mounting : Dr. Ingold	
Temperature Sensor with	MOC : Sensor –SS 316 L	
Transmitter	<b>Range</b> : 0-200 ° C	Design Requirement
	Accuracy : Class A	
	Sheath Dia & Length : 6 X 600 mm	
	<b>Connection :</b> 3 Wire	



PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : Radix	
	<b>Type</b> : PT 100	
	Mounting : Mini T/C	
Temperature Sensor with	MOC : Sensor –SS 316 L	
Transmitter	<b>Range</b> : 0-200 ° C	Design Requirement
	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	Design Requirement
Air Vent Ball for Jacket Vent	Make : Micro MOC : SS 304 Type : Pneumatic Operated ball Valve Size : 15 NB End Connection : T/C Ended	Design Requirement
Pressure Gauge for Jacket	Make : Baumer MOC : SS 304 Type : Bourdon perforation, Size : 100 mm in dia	Design Requirement
	End Connection : <sup>1</sup> / <sub>2</sub> inch BSP Thresded Range :0-7 kg /Cm <sup>2</sup>	
	Accuracy : ±1.0 FSD	



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : Fainger Leser	
	Type : Conventional FLP 549	
	<b>MOC</b> : SS 304	
	<b>Over Pressure</b> : 10 % of Pressure	
Safety Valve for Jacket	Set Pressure : 3.18 bar	Process Requirement
	End Connection : Screwed	
	<b>Inlet Connection rating :</b> <sup>3</sup> / <sub>4</sub> " BSP (M)	
	<b>Outlet Connection :</b> 1 inch BSP (F)	
	<b>Sr.No. :</b> 10972692	
	Type : Pneumatic operated Valve,	
Ball Valve for Compressed	Make : Micro	
Air inlet Jacket side	<b>MOC</b> : SS 304	Design Requirement
All linet Jacket Side	<b>Size :</b> 15 NB	
	End Connection : Flanged end	
	<b>Type</b> : Pneumatic operated Valve,	
	Make : Micro	
Ball Valve for Compressed	<b>MOC</b> : SS 304	
Air Inlet & Cooling Water	<b>Size :</b> 40 NB	Process Requirement
Supply & Return	End Connection : Flanged end	
	Qty: 3 Nos	
	Make : Micro	
	Make : Rex	
	Type : Thermodynamic	
Steam Trap Unit for Jacket	Model: Optiseal vent filter CartrigeMOC: Body SS 420	
Side	Strainer SS 304	Design Requirement
	Size : 20 NB	
	<b>End Connection</b> : <sup>3</sup> / <sub>4</sub> "BSP Threaded	
Ball Valvo fan Staam Tuar	Make : Micro Size : <sup>3</sup> / <sub>4</sub> " NB	
Ball Valve for Steam Trap	End Connection : TC Ended	Design Requirement
Unit	Qty: 2 Nos	



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**ACCEPTANCE CRITERIA CRITICAL VARIABLES** REFERENCE Make : Pharmatech **Type** : ERW **Piping for Steam Strap unit** Process Requirement MOC : AISI 304 End Connection : TC Ended Make : ABB Rating : 2HP **Power Supply :** 380- 500 V AC + 10 % /-15% , 3 phase. **Output Frequency** : 50....  $60Hz \pm 5\%$ Variable Frequency Drive **Design Requirement Protection :** IP20 Ambient Temperature : -10 to 55 ° C Ambient Humidity : Max 95 % non Condensing **EMC** : Filter Inbuilt Make : Mettler Model: SBH-2000 Capacity: 2 Ton/Each Least Count : 1 kg Design & Process Load Cell Accuracy :  $\pm 0.1$  % Requirement **MOC :** SS 304 Qty: 3 Nos **Indicator :** IND 331 Make : Shanti Size : 25 mm Dia **Flexible Hose MOC:** SS wire Brained Design Requirement Length: 500 mm Qty: 2Nos Make : Ami Polymer Size : 25 mm in Dia **MOC :** SS 304 **Flexible Hose For Spare** Design Requirement Length: 500 mm Qty: 3 Nos



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<b>CRITICAL VARIABLES</b>	ACCEPTANCE CRITERIA	REFERENCE
Skid	Make : Pharmatech	
	MOC: SS304	Design Requirement
	Size : 1900 (L) x 1550 (W)	
Control Panel	Make : Rittal	
	Type :Dust Proof Mounting : Switchle	
	Mounting : Suitable MOC: SS304	Design Requirement
	Gasket : Rubber	
	Finish : Matt	
	Make : Allen Bradley	
	Type : Programmable Logical Controlier	
	<b>Model</b> : ML-1400	
	Power Supply : 24 VDC	
PLC	User data Space : 10 K	Design Requirement
	Port : Serial Ethernet	
	Software : RS logic 500	
	No. of DI : 20	
	No. of DO : 12 <b>Oper Tem. :</b> -20 °C to + 65°C	
	<b>Oper Tem. :</b> -20 C to + 05 C	
	Make : Allen Bradley	Process Requirement
	Type : Colour Touch Screen	
	Model : PVP-600	
	Power Supply : 18-30 VDC	
TINAT	Size : 5.7 "	
HMI	<b>Resolution :</b> 320 x 240, 18 –bit color Graphics.	
	Back light: CC FL, 50, 000H Software : RS View Factory	
	<b>Common Port</b> : RS232, USB and Ethernet port	
	<b>Relative RH</b> : $5 - 95\%$	
	<b>Oper Tem.</b> : 0-55 °C	
	Make : Epson	Process Requirement
	<b>Type :</b> Dot Matrix /Online printer	
<b></b>	<b>Model :</b> LX-310	
Printer	<b>Power Supply :</b> 230 VAC, Single Phase	
	Location : On SS Printer Trolley	
	Common Pin : 25 pin –RS 232	



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Make : Festo	Process Requirement
	Model : FRC ¼ -D-MINI	
FRL Unit	<b>Range :</b> 0-16 Bar	
	Mounting : Panel Mounted	
	Make : Reputed make	Process Requirement
Hooter	Type : Panel Mounted	
	<b>Size :</b> 96 x 96 mm	

## 8.4 MATERIAL OF CONSTRUCTION

S. No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Vessel shell	SS316L
2.	Jacket shell	SS 304
3.	Spray ball	SS 316L
4.	Rupture Disk	SS 316L
5.	Safety valve	SS 316L
6.	Compound Gauge	SS316 L
7.	Pressure gauge for jacket	SS304
8.	Manual Ball Valve	SS304
9.	Steam Trap unit	SS304
10.	SS Skid	SS304
11.	Control Panel	SS304
12.	Contact part	SS316 L
13.	Non Contact part	SS304
14.	Gasket	PTFE



8.5

#### DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)

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**SAFETY:** 

#### **CRITICAL VARIABLES ACCEPTANCE CRITERIA** REFERENCE Electrical Wiring And Electrical wiring should be as per approved drawings. Safety Requirement Earthing Double external Earthing to control machine, panel and operator should be provided Noise Level Below 80 db Safety Requirement Holding vessel should be in working condition, and it Operation Safety Requirement should be repeated during shutting also. Variable Frequency Drive Motor safety from overload Safety Requirement Main power supply should be always switched off Main Supply Safety Requirement when not in use. Safety valve Safety against over pressure Safety Requirement Protection for low air pressure for pneumatic valves Air pressure switch Safety Requirement **Rupture Disc** Safety against Over pressure Safety Requirement For operator safety & Heat loss prevention Insulation Safety Requirement **Emergency Button** Protection against abnormal condition Safety Requirement Instrument air pressure Low air pressure protection Safety Requirement

### 8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Manufacturing	Selection of Vendor is done on the basis of	
vessel.	review of vendor. Criteria for review	
	includes Vendor Background (General /	
	Financial), Technical know -how, Quality	cGMP Requirement
	Standards, Inspection of Site, Costing,	
	feedback from Market .	

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

Verified By (Quality Assurance) Sign & Date .....



PHARMA DEVILS 9.0 **DOCUMENTS TO BE ATTACHED:** Technical details for Equipment Requirement with Engineering Drawings. • Approved Design and Specifications. • Purchase Order Copy Any other relevant Documents 10.0 **REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):** ..... ..... ..... ..... ..... ..... 11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS: ..... 

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## 12.0 RECOMMENDATION:




**13.0 ABBREVIATIONS:** 

AC	:	Alternate current
AISI	:	American Iron & Steel Institute
ASME	:	American Society of mechanical Engineering
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
CIP	:	Clean in Place
D	:	Depth
db	:	Decible
DIN	:	Deustsches Institut for Normuung
DQ	:	Design Qualification
EHEDG	:	European Hygienic Engineering & Diagram
EPDM	:	Ethylene Propylene Dyne monomer
GA	:	General Arrangement
Н	:	Heigh
HMI	:	Humen Machine Interface
HP	:	Horse Power
Hz	:	Hertz
JMT	:	Jacketed Manufacturing Tank
Kg	:	Kilograms
KW	:	Kilo Watt
LPH	:	Liter per Hours
LPM	:	liter per Minute
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
OD	:	outer Diameter
PEEK	:	Polyether Ether ketone
PG	:	Pressure Gauge

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PLC	:	Programmable Logic Controller	
РО	:	Purchase Order	
PT-100	:	Platinum-100	
PTFE	:	Poly tetra Fluoro Ethylene	
QA	:	Quality Assurance	
Ra	:	Roughness Analysis	
RPM	:	Revolution Per Minute	
SS	:	Stainless Steel	
TC	:	Triclover	
Temp.	:	Temperature	
URS	:	User Requirement specification	
V	:	Volt	
VFD	:	Variable Frequency Drive	
W	:	Width	
WFI	:	Water for injection	



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PROTOCOL No.:

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## 14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			