



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC EXTERNAL AMPOULES WASHING,
DRYING & SELF ADHESIVE LABELING MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC EXTERNAL AMPOULES
WASHING, DRYING & SELF ADHESIVE
LABELING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing Hall, Ampoules Line
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	PROTOCOL PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	SYSTEM DESCRIPTION	6-8
7.0	PRE-QUALIFICATION REQUIREMENTS	9
8.0	CRITICAL VARIABLES TO BE MET	10-19
9.0	REFERENCES	20
10.0	DOCUMENTS TO BE ATTACHED	20
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	20
12.0	CHANGE CONTROL, IF ANY	20
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	21
14.0	CONCLUSION	21
15.0	RECOMMENDATION	21
16.0	ABBREVIATIONS	22
17.0	PROTOCOL POST APPROVAL	23



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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AUTOMATIC EXTERNAL AMPOULES WASHING,
DRYING & SELF ADHESIVE LABELING MACHINE**

PROTOCOL No.:

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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PROTOCOL No.:

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine (**Make:** Aseptic Technology inc.) to be installed in Packing hall.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine.



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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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none"> • Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post approval of Installation qualification Protocol cum Report after execution.
Production	<ul style="list-style-type: none"> • Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.



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PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine
Equipment ID.	
Manufacturer's Name	Aseptic Technology inc.
Machine No.	
Model No.	EWL-400
Supplier's Name	Aseptic Technology inc.
Location of Installation	Packing Hall, Ampoules line

6.0 SYSTEM DESCRIPTION:

INFEED TRAY

This machine is equipped with In-feed Tray system for loading of Ampoules. The Ampoules are loaded into the SS Tray and from this tray the Ampoules are passed to the In-feed Feed worm.

STAR WHEEL ASSEMBLY

A star wheel is made of Aluminum casting material. Star wheel is transfer the Ampoule one by one for washing and drying.

TANK ASSEMBLY

This machine is equipped with of SS304 Tank for Re- Circulated Water. And one for Purified water According to the washing cycle the piping are provided. Along with the Tanks Grundfoss Pumps & Require Heating arrangement are provided.

Purified water received from Loop is used for Final washing and this water collected into Re cycle Tank.

This re cycle water is filtered through suitable Filtration system and again used for washing at First station and finally washed water goes to Drain

AIR KNIFE ASSEMBLY

Air knife is made of Aluminum material with black anodizing. Air Knife is blowing the dry air on Ampoule for Drying the Ampoule. Also the machine is equipped with Blower. This is connected at the out-feed end after the washing is over. This ensures that proper drying takes place as the machine is



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running at the high speed.

OUT FEED FEEDWORM ASSEMBLY

Out feed worm is made of Delrin material. Feed worm is feed the Ampoule One by one in collection tray.

LABEL DISPENSING DEVICE

It works on the basic principle of to apply sticker label on Ampoule, which is previously sensed by the Ampoule sensor, after getting the signal from the Ampoule sensor, it allows the label to come out from the label roll up to the label length which is feed in the HMI Unit of the machine. And label sensor sense the gap between the two labels and allows only single label to come out. The control of label dispensing device is on Servo Motor, Servo Drive, Ampoule Sensor and label Sensor.

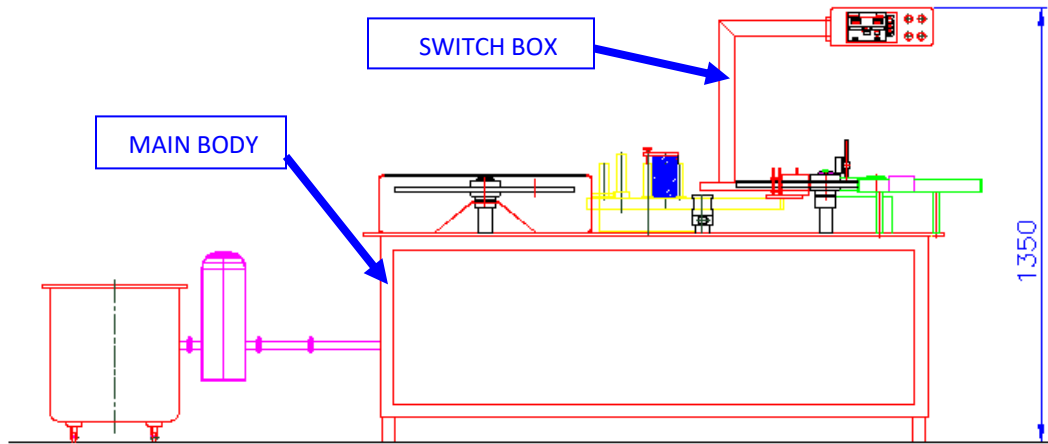
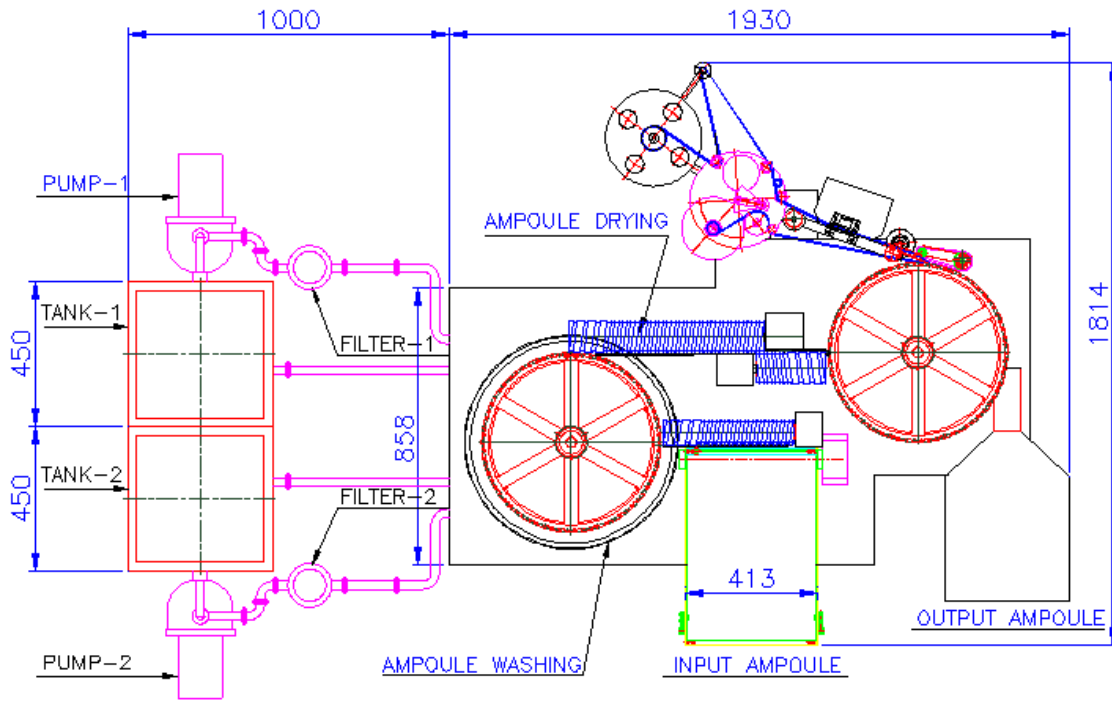
PRESSING DEVICE

It works on the basic Principle to press the sticker label on the Ampoule, which is previously applied by the label dispensing device. When sticker label is applied the applicator simultaneously Ampoule enters in to the pressing belt assembly and it will start move in rotary motion between the pressing belt and pressing pad. This allows the label to stick firmly on Ampoule and resulting wrinkle free Labeling.



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GA of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine:



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PROTOCOL No.:

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Technical specification of equipment.
- MOC Certificate of components.

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.



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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DRYING & SELF ADHESIVE LABELING MACHINE**

PROTOCOL No.:

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Hall		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
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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PROTOCOL No.:

8.2 Technical Specification :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Basic Machine			
Equipment Name	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine		
Machine No	EW-501/04/15-16		
Model No.	EWL-400		
Basic Unit	Machine with change part of 1ml Ampoules & Label		
Model	EWL-400		
Machine Capacity	350 Ampoules /min. for 1 ml ampoules .(Machine Speed Depend on Ampoules Size)		
Washing ,Drying & Labeling Operation	Single Track		
Process			
Washing & Drying Process	First Wash through Re-circulated Water through tank.		
	Second Wash Fresh Purified Water through Purified Water tank.		
	Air blow to dry unit through blower.		
	Air knife to complete drying of unit		
Water Storage Tank			



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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AUTOMATIC EXTERNAL AMPOULES WASHING,
DRYING & SELF ADHESIVE LABELING MACHINE**

PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
SS jacketed tank (for Re-circulated Water)	MOC: SS316 Pump: (Make: Grundfoss) Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater		
SS jacketed tank (for Purified Water)	MOC: SS316 Pump: (Make: Grundfoss) Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater		
Height Adjustment			
Height Adjustment	Manual		
PLC			
Type	PLC with color HMI touch Screen		
Make	ALLEN BRADLEY		
Sr.No.	1766-L32BXB		
Volt	24VDC.		
HMI			
Make	ALLEN BRADLEY		
Power Supply	24VDC.		
Sr.No	2711P-T6C20D8		
Other Feature			



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PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Fault Indication System	Fault is indicated in HMI screen.		
Gear Box	Make Bonfiglioli gear box with motor for machine.		
Drying System	Blower Provided For Ampoule Drying.		
User Friendly	Machine can be easily set for other size of Ampoule.		
Motor (Main)			
Make	Bonfiglioli		
Capacity	0.37 KW		
RPM	1370 RPM		
Sr.No.	BN71B4		
Gear Box			
Make	Bonfiglioli		
Ratio	RATIO-14:1		
Sr.No.	VF44F1 14 P71B5B3		
AC Drive Main			
Make	Allen Bradley		
Capacity	0.5HP.1Phase to 3Phase.		
Sr.No.	22F-A2P5N103		
Servo Motor			
Make	Allen Bradley		
Sr.No.	TL-A2540P-BJ32AA		
Capacity	0.86KW,		
RPM	5000 RPM		
Servo Gear Box			
Make	Shimpo		
Ratio	RATIO-5:1		



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PROTOCOL CUM REPORT
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Sr.No.	VRSF-5C-19DB19		
Servo Drive			
Make	Allen Bradley		
Capacity	800 WATT		
Sr.No.	2071-AP8		
PUMP (PW)			
Make	Grundfos		
Sr.No.	CM3-3 A-R-G-V-AQQVF-A-A-N		
Capacity	0.46KW,0.62HP		
PUMP (RE.CIR)			
Make	Grundfos		
Capacity	0.46KW,0.62HP		
Sr.No.	CM3-3 A-R-G-V-AQQVF-A-A-N		
Blower			
Make	Ambica		
Sr.No	90L		
Capacity	3HP, 2.2KW		
RPM	2910RPM,		
Modbus Module With 485			
Make	Allen Bradley		
Power Supply	24VDC.		
Sr.No.	1763-NC01		
Out Put Module			
Make	Allen Bradley		
Sr.No.	1762-OW8		
Volt	24 volt		
Temperature Module			
Make	Allen Bradley		
Sr.No.	1762-IT4		
Volt	24 volt		
Temperature Sensor			
Make	Emtech Controls		



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PROTOCOL CUM REPORT
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AUTOMATIC EXTERNAL AMPOULES WASHING,
DRYING & SELF ADHESIVE LABELING MACHINE**

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Type	RTD		
Water Level Sensor			
Make	Mts Engineering		
Model	SMT-16S		
Volt	24VDC		
Heater			
Make	Trilok		
Capacity	2000 WATT		
Proximity (Door Open)			
Make	Omron		
Sr.No.	E2B-M12KN05-WP-B1		
Ampoule Sensor			
Make	Panasonic		
Model	FX-301-P		
Label Sensor			
Make	Leuze		
Model	GS 61/6.3		
Transformer			
Make	Camo Care		
Model	1500VA		
Capacity	230/200VAC,		
Pressure Switch (Pw Water)			
Make	Danfoss		
Model	KP35		
Range	0.2 TO 7.5 BAR.		
Pressure Switch (Re.Cir Water)			
Model	KP35		
Range	0.2 TO 7.5 BAR.		
Pressure Switch (Air)			
Make	Danfoss		
Model	KP35		
Range	0.2 TO 7.5BAR.		
Solenoid Valve (Pw Water)			
Make	Rotex		
Sr.No.	24103-12-4G-B13		
Solenoid Valve (Re.Cir Water)			
Make	Rotex		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Sr.No.	24101-12-4G-B12		
Solenoid Coil (Pw & Re.Cir Water)			
Make	Rotex		
Sr.No.	I-24V-DC-22		
Valve (Air)			
Make	SMC		
Sr.No.	VXD232AA		
Range	0.5MPA		
Solenoid Coil (Air)			
Make	SMC		
Volt	24 VDC		

**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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PROTOCOL No.:

8.3 MATERIAL OF CONSTRUCTION:

COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Machine frame structure	MS. Angle Duly Cladded with SS.304 Sheet		
External cladding	SS 304, (No Painted Surface)		
Star Wheel	Aluminum Casting		
In Feed & Out worm	Delrin		
In Feed Tray	SS 304		
Out Feed Tray	SS 304		
Water Tank	SS 316		

**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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 PROTOCOL CUM REPORT
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PROTOCOL No.:

8.4 Safety Feature:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be Properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Earthing	Proper Earthing should be provided.		
Sensor	Sticker Sensor sense the presence of container for labeling. Label Sensor sense the presence of upcoming label for labeling.		

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

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

Inference:

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



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 PROTOCOL CUM REPORT
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PROTOCOL No.:

8.5 Utility Verification List:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	Voltage : 220 V Phase : Single Phase Frequency : 50 HZ		
Air Supply (Optional For Pneumatic Rejection System)	4 To 6 Kgs / Cm ² Thro' FRL at Constant Pressure.		

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
Sign/Date:

Inference:

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



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PROTOCOL No.:

9.0 REFERENCES:

The Principle References 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:

- Certificate of MOC.
- Any other Relevant Document

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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PROTOCOL CUM REPORT
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PROTOCOL No.:

16.0 ABBREVIATIONS:

ALM	:	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
DQ	:	Design Qualification
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
IQ	:	Installation Qualification
Kg	:	Kilogram
KW	:	Kilo Watt
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
MS	:	Mild Steel
No	:	Number
RPM	:	Revolution per minute
SS	:	Stainless steel
VFD	:	Variable Frequency Drive
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)			