INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL-120

EQUIPMENT ID. No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of **Integrated 3 Piece Vial Filling Line** Model No. **CFL-120** 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 **Integrated 3 Piece Vial Filling Line** Model No. **CFL-120**) to be installed in the **Vial Filling & Dropper Fixing Room**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vial Filling & Stoppering Machine.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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	• 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 Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VFS Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Filling & Dropper Fixing Machine
Equipment ID.	…
Manufacturer's Name	Techline Industries
Supplier's Name	Techline Industries
Location of Installation	Vial Filling Room

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

6.0 SYSTEM DESCRIPTION:

The Line consists of four parts / machines

1. Bottle Orienting & Feeding Machine
2. 6 Head Filling Machine
3. Dropper Fixing
4. Screw Capping Machine

Bottle Orienting & Feeding Machine:

Orientator is a simple mechanical feeding system for plastic vials. The machine is equipped with multi-pocket Pick-up Star wheel. This star wheel picks up and feeds vials one by one into the feeder star wheel through a chute. A mechanical inverter is used to invert the vials which are coming upside down. And a feeder star wheel transfers vials from the Orientator to the Turn table. Another star wheel is used to transfer vials from Turn table to Filling station. Two IR sensors are used in between Orientator and Filling station to maintain trouble free running of the machine.

Head Filling Machine:

Filling machine consists of syringe less “Pressure and Time Setting” Filling System with the Pre and Post Nitrogen Flushing attachment. This machine consists of 18 head filling station in which 6 heads re used for filling and remaining 12 heads are used for pre and post Nitrogen flushing. An indexing mechanism is used for transferring vials from Orientator to filling station with the help of a intermediate turn table. Filling volumes can be adjusted independently on PLC screen while the machine is running.

Dropper Fixing & Screw Capping Machine:

It is a eight head rotary screw capping machine. It works on rotary basis in which screw capping is done in a continuous running system. The whole machine is driven on a single motor. A vibrator is used for feeding caps and cap dispenser is used for placing caps. Screwing cap is done by most advanced Bush type capping head. This machine is provided with 8 heads to achieve required output. Vial transfer from inlet conveyor to outlet conveyor is achieved by means of star wheel. Enough height adjustment is given on the capping head to suit different size of vials.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction 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 FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

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	Vial Filling & Dropper Fixing Room		
Room Condition	RH : NMT 55% TEMP : 23 ± 2 ºC		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
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Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.2 EQUIPMENT VERIFICATION

TECHNICAL SPECIFICATIONS

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	CFL-120		
Dimensions	2700 mm L x 1800mm H x 1400 mm W		
Orientator Pockets	Qty. 36 Nos.		
Storage Capacity of Orientator Hopper	200 to 300 vials (for 5 ml)		
Diameter of Orientator Bowl	700 /725 mm.		
Filling Heads	6 Nos.		
Nitrogen Pre Gassing	6 Nos.		
Nitrogen Post Gassing	6 Nos.		
Turn tables	5 Nos.		
Turn tables size	Φ225- Qty.1No Φ325- Qty. 1No Φ400- Qty 3 Nos.		
Dropper Feeder Bowl size	Φ350mm		
Storage Capacity	500 Droppers.		
Cap Feeder Bowl Size	Φ450mm		
Storage Capacity	300 Caps		
ORIENTATOR			
Motor	Make :Siemens RPM: 1400 Power : 1 HP,AC, 3 Phase		
Gear Box	Make : Greaves Size : A200 Ratio :60:1, worm reduction		
Gear Box To Feeder Wheel	19T x ½''-28T x ½'' sprocket		
Feeder wheel to Main star wheel shaft	19T x 3/8'' -68 x 3/8'' sprocket		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
FILLING			
Machine Type	CFL-120		
No. of Heads	6		
Speed	80-120 VPM		
Bottle Feeding	By Turn Table		
Bottle Transferring	By Star Wheel		
Feed Height of the Machine	800-850 mm (Adjustable ± 5mm)		
Compressed Air Required	50 LPM at 1 Kg Pressure		
Bottle Feeding	By Turn Table		
Bottle Transferring	By Star Wheel		
Motor	Make :Siemens RPM: 1400 Power : 1/2 HP,AC 3 Phase		
Gear Box	Make : Greaves Size : A200 Ratio :30:1 Worm reduction		
From Clutch to Indexer inlet	19T - 32T (1/2″ P)		
DROPPER FIXING			
Machine Type	CFL-120		
Speed	80-120 VPM.		
Dropper Feeding	By Vibratory Bowl Feeder		
Bottle Feeding	By Turn Table		
Bottle Transferring	By Star Wheel		
Cap Pressing	By Plunger		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Motor	Make :Siemens RPM: 1500 Power : 1 HP,AC 3 Phase		
Gear Box	Make : Greaves Size : A237 Ratio :60:1 Worm reduction		
From clutch to main shaft	19T - 22T (1/2" P)		
From main shaft to Inlet star wheel shaft	92Tx2M Spur Gear		
From Inlet star wheel to Outlet star wheel shaft	19T - 19T (1/2" P)		
SCREW CAPPING			
Machine Type	CFL-80		
No. of Heads	8		
Speed	80-120 VPM		
Cap Feeding	By Vibratory Bowl Feeder		
Bottle Feeding	By SS Slat Conveyor		
Bottle Transferring	By Star Wheel		
Feed Height of the Machine	800-850 mm (Adjustable ± 5mm)		
Motor	Make :Siemens RPM: 1500 Power : 1 HP,AC 3 Phase		
Gear Box	Make : Greaves Size : A237 Ratio :30:1 Worm reduction		
From clutch to main shaft	19T - 22T (1/2" P)		
From main shaft to gear housing shaft	17T - 22T (1/2" P)		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
From gear housing shaft to outlet star wheel shaft	19T - 57T (3/8" P)		
From infeed star wheel shaft to outlet star wheel shaft	19T - 19T (1/2" P)		
Coupling size	110-Love Joy Coupling. Qty. 4 Nos.		
Clutch	Dia.50 x 100 mm long Taper cone clutch Qty.4 Nos		
TURN TABLE 1&2			
Motor	RPM: 20 Power : 1/4 HP, AC 3 Phase.		
SPROCKET DETAILS			
From motor to TT-1	15T - 22T (3/8" P) Sprocket		
From TT-1 to Idler shaft	20T - 20T (3/8"P) Sprocket		
Idler Shaft to TT-3	1:1 Gear (62Tx2M) Sprocket		
TURN TABLE 3,4 & 5			
Motor	RPM: 20 Power : 1/4 HP,AC 3 Phase		
From motor to TT-3	15T - 22T (3/8"P) Sprocket		
From TT-3 to TT-4	20T - 20T (3/8"P) Sprocket		
From TT-4 to TT-5	20T - 20T (3/8"P) Sprocket		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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Sign/Date: ……

Inference:

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(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.3 INSTALLATION CHECKS

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
BOTTLE ORIENTING & FEEDING MACHINE			
1.	All the M.S base bolts provided for packing purpose to be replaced by SS base bolts with rubber pad.		
2.	Set the height of the machine by adjusting the base bolts to match the height.		
3.	Also proper leveling of the machine should be done using appropriate sprit level by adjusting the base bolts.		
4.	Carefully examine the wiring diagram of the machine before making any connection.		
5.	Connect the cables to the panel to their respective connectors.		
6.	Check wires for proper polarity of the AC motor.		
7.	Connect the sensor cables to the terminal in the panel.		
8.	Make sure that ‘earthing’ is provided.		
9.	After all wires connected, connect the mains cable.		
6 HEAD FILLING MACHINE			
1.	Get buffer tank nozzles and silicon tubes sterilized before fitting with the machine.		
2.	Clean all the SS guides, bridge plates and star wheel with IP solution.		
3.	Carefully examine the wiring diagram of the machine before making any connection.		
4.	Connect the cables to the panel to their respective connectors.		
5.	Check wires for proper polarity on the AC motor		
6.	Connect the sensor cable to the connectors on the machine.		
7.	Make sure that earthing is provided.		
8.	After all wires connected, connect the mains cable.		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
DROPPER FIXING			
1.	Place the vibratory bowl feeder of dropper at its location.		
2.	Fix the chute for dropper at its respective mounting location.		
3.	Carefully examine the wiring diagram of the machine before making any connection.		
4.	Connect the cables to the panel to their respective connectors.		
5.	Check wires for proper polarity on the AC motor.		
6.	Identify the vibrator sockets and connect it respectively.		
7.	Connect the sensor cable to the connectors on the machine.		
8.	Make sure that earthing is provided.		
9.	After all wires connected, connect the mains cable.		
SCREW CAPPING MACHINE			
1.	All the M.S base bolts provided for packing purpose to be replaced by SS base bolts with rubber pad.		
2.	Set the height of the machine by adjusting the base bolts to match the height of dropper fixing machine.		
3.	Proper leveling of the machine to be done using appropriate sprit level by adjusting the base bolts.		
4.	Place the vibratory bowl feeder of cap at its respective locations.		
5.	Fix the chute for cap at its respective mounting locations.		
6.	Carefully examine the wiring diagram of the machine before making any connection.		
7.	Connect the cables to the panel to their respective connectors.		
8.	Check wires for proper polarity on the AC motor.		
9.	Identify the vibrator sockets and connect it respectively.		
10.	Connect the sensor cables to their respective terminals.		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
11.	Make sure that earthing is provided.		
12.	After all wires connected, connect the mains cable.		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.4 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Bottom & Top frames	SS-304 Square pipe and angles.		
Main plate	M.S with SS304 Cladding		
Orientator Hopper	SS304		
Orientator Disc	SS304		
Orientator bridge plate	SS304		
Orientator Star wheel cavities	DELRIN		
Inverter Plate	SS304		
Timer mechanism	SS304		
Filling Nozzles	SS316L		
Other Liquid contact parts	SS316L		
All liquid contact hoses	SILICON		
Vertical Housings of DF and SC	S.S. 304		
Top and Bottom discs of DF & SC	S.S. 304		
Plunger Housings of DF & SC	Aluminium with Gunmetal		
Dropper Fixing Head and Feeder bowl	SS316		
Other Dropper contact Parts	SS316		
Cap Feeder bowl and Chute	SS304		
Capping head	SS-304 with PU bush		
Other Cap contact parts	SS304		
All turntable discs	SS304		
Star wheel Bridge Plates	SS304		
Main shaft	EN-8		
Main Housings	M.S With S.S-304 outer cover		
Other shafts	E.N-8.		
Other Bearing housings	M.S		
Taper roller & Ball bearings	KOYO/ SKF MAKE		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Feeder Star wheels	Delrin		
Cabin Door	Acrylic		
Main Panel	SS304		
Remote panels	SS304		
All covers & guards	SS304		
All guides	Delrin		
Main Panel	SS304		
Mounting plate	SS304		
Remote panels	SS304		
All covers & guards	SS304		

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Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.5 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 440 V Phase : 3 Phase Frequency : 50 HZ		
Room Condition	Temperature : 23 ± 2 ºC RH : NMT 55 %		
Air supply(Nitrogen gas for dosing)	0.5 kg/cm^2		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.6 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Hardware Emergency switch at Operator Console	For Operator Safety.		
Nitrogen pressure drop interlock	For safety of the batch		
Liquid low level – Machine stop	For safety of the batch & the process.		
Dropper low level – Machine stop	For safety of the batch & the process.		
No Cap- Machine stop	For safety of the batch & the process		
Motor overload Relay	For Motor & equipment protection.		
Air Regulator for Nitrogen & Compressed Air	Control the velocity of Nitrogen & Compressed air		
No Vial No Filling Sensor	To avoid the wastage of product.		
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Earthing	Earthing to be provided to Control Panel.		
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		
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		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Earthing	Earthing to be provided to Control Panel.		
Joints	Welding of joints without any welding burrs.		
Mechanical Safety Clutch	Provided with gear box		
All Drive Arrangements	With all covers and guards		

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Inference:

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Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.7 Control Panel Check

Test Particulars	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check that Machine is connected with control panel. Record the details of PLC	Machine should be connected with control panel. PLC make, model no. , serial no should be checked and verified		
Check the input output against Wiring Diagram visually during installation	All the input output shall meet the Requirements		

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(Production)
Sign/Date: ……

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

Inference:

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

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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
Hr	:	Hour
Kg	:	Kilogram
mm	:	Millimeter
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification
KG	:	Kilogram
TFM	:	Three piece filling machine
IQ	:	Installation Qualification
No	:	Number
V	:	Volt
HZ	:	Hertz
°C	:	Centigrade
%	:	Percentage
L	:	Length
W	:	Width
H	:	Height
Ml	:	Mililiter
HP	:	Horse power
AC	:	Alternating Current
NLT	:	Not Less Than
NMT	:	Not More Than
Db	:	Decibel

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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)			