



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACKING MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STRIP PACKING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 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 provide documented evidence for the Installation Qualification of Strip Packing 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:

- To verify the critical dimensions of the unit and record Serial Numbers / Model Number of critical components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.
- To Calibrate Temperature and Pressure Measurements of Control System, Recorder, Gauges and displays.



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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, 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.
Production	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in Sampling Booth Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Strip Packing Machine
Equipment ID.	
Manufacturer's Name	Sharma Engineering Works
Model	GMP Model
Supplier's Name	Sharma Engineering Works
Location of Installation	Strip Packing Area

6.0 SYSTEM DESCRIPTION:

Feeding System:

Product is fed into the hopper from where it is guided into the Bowl mounted on a Vibrator. The product on the Bowl is evenly distributed and guided through the tracks on the Bowl into the Chute Channel and the feed rate of the Product from the Bowl to the Chute Channel is controlled by the Vibrator. The Product from the Chute is released onto the Sealing Roller by the Cam Operated Release Pin.

Sealing System:

The set of Sealing Rollers draws the heat sealing Packing Material (Foil) from 2 sets of front adjustable type of friction brake system Foil Holder Assembly and Foil running tubes. The sealing Rollers are heated to the required temperature by the Cartridge Heaters inserted into the individual Rollers. Adequate pressure is applied onto the Sealing Rollers so that both the foils get sealed at the time of contact while passing through the sealing roller. At this stage the product which is released onto the cavity of the rollers gets packed and sealed in the foils. Batch Coding Unit: The left hand Foil before being drawn by the Sealing Rollers passes through the Batch Coding unit where the Batch Code, Manufacturing date etc. is printed on the Foil.

Batch coding unit:

The left hand foil before being drawn by the sealing rollers passes through the batch coding unit where the batch code, manufacturing date etc is printed on the foil.

Cutting System:

The Packed and sealed Strip from the Sealing Roller passes through the Brush and Slitter Shaft which cuts the Strips vertically. These vertically cut strips then passes through the Cam operated Cutter Assembly which Cuts the Strips Horizontally into the desired Strip Length. The desired Strip Length can be achieved by using the appropriate Cutting Gears and Toe Cams as per the pre defined Calculations.



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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.



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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 grouted & mounted properly		
Leveling	The equipment should be balanced and leveled properly		
Edges of parts	All the edges of metal parts should be grinded and no sharp edges should be there		
Welding of Joints	The welding joints should not have any burrs		
Place of Installation	Packing		
Room Condition	Temperature: NMT 25 ⁰ C		
	RH : NMT 22%		
Illumination in area	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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8.2 Technical Specification:

NAME OF COMPONENT	DESCRIPTION	OBSERVATION
Equipment Supplier	Sharma Engineering Works	
TYPE	Centre Electromagnetic Vibrator Feeding. M.S. fabricated body with adequate inspection windows, painted to pale cream to smooth finish. Hopper mounted on Telescopic adjustable stand made of S.S. Cladding all over the body of the machine of S.S.304 and all contact parts of S.S. 316 only	
Overall dimensions	W 600 mm x D 1220 mm x H 2000 mm	
Drive	0.75 H.P. 3 ph. 415 V. 1385 R.P.M./TEFC Electrical motor (Remi Make) Oil immersed Reduction Gear Box., Universal Mounting Type (Bonfiglioli Make). Variable Frequency Drive-VFD (Mitsubishi Make) for speed variation.cam operated cutter assembly with spring loaded brake belt. Set of draw brushes fitted on brush shaft to draw out sealed strip from rollers with vertical slitters fitted on slitter shaft to slit sealed strip.	



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NAME OF COMPONENT	DESCRIPTION	OBSERVATION
Heater	Cartridge Heaters for heating sealing rollers as per our catalogue specifications. Temperature is controlled by 2 sets of Digital Electronic Temperature Controller (Selectron make) to control both sealing rollers.	
Temperature Controller	Make : Thermotech	
Heating Controller	Sr. No. : 10-02 Model : TC 203AX Class : 1.5	
S.S. Packing Material Holder Assembly	2 sets of front adjustable type of friction brake system with foil running tube.	
ON/OFF Switch	Make : Tecknic 2LHBR-230	
Green Push Button	Make : Tecknic With one light laminar	
Red Push Button	Make : Tecknic Without light.	
Yellow Push Button	Make : Tecknic Without light.	
Red Emergency Stop Push Button	Make : Tecknic Type : Mushroom Head	



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Special Electrical Control Panel of S.S. consisting of:	“ON”, “OFF”, “INCH” controls and extra “INCH” Control near Clutch handle. DOL Air Brake contactor for heater, Amp Meter for heater, Indication lamps and MCB’s and Digital Counter cum Speed indicator to indicate the speed (cuts/min.) with proxy sensor.	
Batch Coding Unit	Ceramic Roller type, nylon stereo rings or flat stereo drum mounted on	
Polycarbonate Cabinet	Cabinet mounting on S.S. angles & S.S. frames for protection of Sealing Rollers, Brush Shaft & Cutter	

**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 MOC Verification List:

S.No.	Components	MOC	Observation	Observed By (Engineering) Sign/Date
1.	All Contact Parts. a) SS Hopper. b) Chute	SS Sheet 18 swg of SS 316.		
2.	Non Contact Parts. a) SS Cladding. b) Control Panel. c) Side covers.	SS Sheet 18swg of SS 304. SS Sheet 18swg of SS 304. SS Sheet 18swg of SS 304.		
3.	M.S.Parts. Batch Printing Bracket and Cutter parts.	M.S with Powder Coating / Plating.		
4.	Front guard.	Polycarbonate-10mm thick.		
5.	Draw Brushes.	Goat Hair (Not Food Grade) the brushes do not come in contact with the tablets.		
6.	Gasket.	Gasket on covers not food grade.		

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 Utility Verification List:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Electricity	<ul style="list-style-type: none"> • Voltage:415 • Phases:3 phase • Frequency:50 Hz 		
AC Inverter Drive	Shall be properly connected and identified		
Light Indication for Machine working condition	Shall be properly connected and identified		

**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 Safety:

Checks	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 & Balancing	Equipment should be properly balanced & leveled		
Earth safety relay	If improper earthing halts the process		
Emergency Switch	Should be provided at approachable distance		
Motor overload relay	If overload the switchgear trip.		

**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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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.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition /March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, General, April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacturer, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

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



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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

°C	:	Temperature in Celsius
AC	:	Alternatic Current
AMPS	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
KVA	:	Kilo Volt Ampere
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
PQ	:	Performance Qualification
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Mili meter
MCB	:	Miniature circuit break



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17.0 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)			