



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
COMPRESSION MACHINE**

PROTOCOL No.:

INSTALLATION QUALIFICATION

NAME OF THE ITEM: COMPRESSION MACHINE

FUNCTIONAL AREA: COMPRESSION

PROTOCOL No. :



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1.0 Protocol APPROVAL:

Prepared By:

Functional area	Name	Signature	Date
Engineering			

Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			



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2.0 Objective:

The purpose of this document is to provide an outline for the inspection of equipment for static attributes to verify that;

- The system is constructed according to the design specifications described in the Design Qualification.
- The system is installed according to the design specifications and manufacturer's recommendations.
- Each installed sub-component has been checked physically and verified the same in accordance with the approved design and equipment data sheets/ specifications.
- The system meets the current Good Manufacturing Practice (cGMP) & Safety requirements.
- No un-authorized or unrecorded modifications have taken place.

Instructions:

- For each data sheet, record the requested information in black ink.
- In the "Verified" column, indicate that the item is inspected and verified according to pre-laid Specifications. Verification can be by a visual examination referring literature and using a measuring device, etc.
- After each data sheet is completed, put signature and date in the assigned space.
- Where the required information is not available 'Not Available' shall be entered accordingly. A single diagonal line shall be scribed through unused boxes and comments sections and "N/A" meaning "not applicable" entered, along with initials and date of the person who enters the line.
- After installation, check all instruments and components are installed as per the P&ID. Use a copy of this diagram as checklist and after completion of checking, attach this verified copy duly signed and approved along with this report.
- After completion of installation vendor should issue the commissioning report, which has to be authenticated by the engineering department.



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3.0 Responsibilities:

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff. When the work is carried by contract/ consulting staff, all the work is to be performed.

3.1 Engineering Department

- Prepares the Installation qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on equipment Qualification.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- Ensures compliance with design specifications for equipment / system.
- Distributes the draft protocol for review and collates comments.
- Makes any necessary corrections to the protocol and answers queries from the reviewers.
- Distributes the finalized protocol for review and approval signatures.
- Execution of IQ protocol.
- Develop departmental SOPs, log books, where appropriate.
- Review of protocol, the completed qualification data package, and the final report.

3.2 Head/Designee Engineering, production and quality assurance

- Review of protocol and the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

3.2 Head/designee Engineering, Manufacturing and Quality

- Approval of protocol and the completed qualification data package, and the final report.
- Assist the equipment user in the execution of the protocol.
- Verification that the protocol test requirements are completed and properly documented for approval.
- Assist in the resolution of validation variances.



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4.0 Equipment Description & Identification:

4.1 Scope and Purpose:

For new installation, modification, replacement or relocation of any component of Compression Machine.

Room name	Room No.	Equipment No.
Compression-I	BAB/.....	

4.2 Name of the Equipment : Compression Machine

4.3 Make /Redesigned by :

4.4 Model No. / TYPE :

4.5 Serial No. :

4.6 Equipment Identification No.:

4.7 Equipment Location :

Remarks (if any): _____

Verified By & Date:



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5.0 List of Reference Documents & Drawings:

S.No.	Name	Document number	Location	Checked by
1.	User Requirement Specifications (URS)			
2.	Purchase Order			
3.	SAT Report			
4.	Operating and Maintenance Manual			
5.	P & I Diagram			
6.	Mechanical Drawing			
7.	Electrical Diagram			
8.	General Arrangements / schematic line diagram			
9.	Utility diagram			
10.	Civil layouts			

Remarks (if any): _____

Verified By & Date:



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PROTOCOL No.:

6.0 Verification of Equipment on Receipt:

S.No.	Title	Observation	Checked by
1.	Purchase Order Number and date		
2.	Was the Machine Properly Protected From Heat, Rain & Dirt etc. During Transportation?		
3.	Physical verification of machine and its components for any damage		
4.	Nature of damage, if any		
5.	Corrective action in case of any damage.		
6.	Availability of accessories as per packing list received		

Remarks (if any): _____

Verified By & Date:



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7.0 Verification of Major Components:

The principal components of the machine are listed in the following table. Visually inspect the components as installed and verify that it is as specified in the acceptance criteria.

7.1 Sub – Component Check List:

S.No.	Description	Specifications	Observation	Remarks	Checked By with date
1.	Main Drive Motor	10 HP / 7.5 kW, 415V, 50 Hz, 3 Phase, 1455 RPM. Make – C&G			
2.	Feeder Drive Motor (02 Nos.)	0.25 HP / 0.18 kW, 1350 RPM, 415V, 50 Hz, 3 Phase. Make – BBL			
3.	Hydraulic Motor	1 HP / 0.75 kW, 1410 RPM, 50 Hz, 3 Phase, 415V, Make – C & G			
4.	ACVFD for Main Motor	Make – Allen Bradley Specification: 10 HP, 415 V, 3 Ph, Model – Powerflex 40, Sr.No. BD017NOW1250169			
5.	ACVFD for Feeder Motor	Make – Allen Bradley Specification: 1 HP, 415 V, 3 Ph Model – Powerflex 4, Sr.No. 1) FD2P5NOW1320170 2) FD2P5NOW1290584			
6.	PLC	Make – Allen Bradley Model – 1762 L40 BXB 1200 Micrologix Sr.No. C91245105347			
7.	MMI	Make – Proface Specs: 24 V DC, 6” Colour Model: AGP 3301 S1-D-24, Rating Class: 2 Sr.No. 102236J011898			
8.	Lubrication Pump	Make – Cenlub Model – CIL-F-5356/11			
9.	Accumulator	Make – Cadmach Type – Mechanical Spring Loaded.			
10.	Electromagnetic Clutch	Make – Golden 20 EBA, 24VDC			
11.	MCB – (All in Control panel)	Make – IndoKopp Type: Gold Line			
12.	Contactora – Main Motor	Make – Sprecher & Schuh, CA3-23-10, 23 Amps. /24VAC			
13.	Contactora – Feeder Motor	Make – Sprecher & Schuh, CA3-12-10, 12 Amps. / 24VAC			



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S.No.	Description	Specifications	Observation	Remarks	Checked By with date
14.	Contactora – Hydraulic Motor	Make – Sprecher & Schuh, CA3-12-10, 12 Amps. / 24VAC			
15.	Overload Relay for Hydraulic Motor	Make – Sprecher & Schuh CT3-12, 1.6 to 2.5 Amps.			
16.	Relay	Make – PLA 3 c/o, 24VAC			
17.	Electronic Overload Relay	Make – Samwha EOCR Ltd. Model – EOCR-SS-05 N 220			
18.	Timer (Turret Delay in Mechanical Override)	Make – Bhartia Cutler Hammer 24VAC			
19.	Control Transformer	Make – Narmada. Natural Air cooled			
20.	Monoblock Rectifier Bridge	Make – Semikron MD5 BU 1016			
21.	SMPS	Make – Omron Model: PL065-S8JX-050-24CD			
22.	Emergency Push Button	Make – Teknic 22.5φ (02 Nos.)			
23.	Cooling Fan for Control Panel	Make – Rexnord 4”			
24.	Illuminated Push Button	Make – Teknic			
25.	Key Actuator Switch	Make – Teknic 6 Amps.			
26.	Potential-meter	Make – Pankaj 10KΩ, 3Watts, Dual Stage			
27.	Main Isolator Switch	Make – Salzer 32 Amps, 3 Pole			
28.	Hydraulic Pressure Sensor	Make – IFM Model – PA 3022			
29.	Tablet Counting Proxy	Make – P & F Type: NBB5-18GM50-E2			
30.	Power Plug	Three Phase Make – BCH			
31.	Micro Switch for Guards	Make – ESSEN MS-7			



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7.2 Component Location List

S.No.	Component	Location	Observation	Remarks	Checked By with Date
1.	Hopper	On the Roof top of the machine			
2.	Hopper Lid	On the Top end of the hopper			
3.	Force Feeder Assembly	On the Feeder platform in the working zone			
4.	Upper Pressure Roll Assembly	On the Top Rear side of the machine, held on the Roll Carriers			
5.	Upper Tamping Roll Assembly	On the Top right side of the machine, within the working zone.			
6.	Lower Pressure Roll Assembly	On Bottom Rear side of the machine, held on the Roll Carriers			
7.	Lower Tamping Roll Assembly	On the Bottom Right side of the machine.			
8.	Main Drive Motor	Base Cabinet			
9.	Feeder Motor	Within the bottom Cabinet			
10.	Tablet Counting Proximity	On the Upper cam disc assembly			
11.	All electrical components.	Within the Control Panel on Front side of machine			
12.	Mechanical Override	On the Panel			
13.	MMI	On the Panel			
14.	Electromagnetic Clutch Assembly	Within the base cabinet, on RHS of the machine behind the hand wheel.			
15.	Weight Adjustment Dial	On the either Side of the machine			
16.	Tablet Thickness Control Dial	On the Front Side of the machine			
17.	Tamping Thickness Control Dial	On the Front Side of the machine			
18.	Upper Punch Penetration Control Dial	On the Front Side of the machine			
19.	Hydraulic Power Pack Assembly	Base Cabinet			
20.	Hydraulic Cylinder	Base Cabinet			



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8.0 Physical Verification of Area:

S.No.	Title	Observation	Checked by
1.	Name of Room and Identification No, where the machine to be installed		
2.	Dimension of the equipment (As per Machine Drawing/ Manual)		
3.	Verify that there is sufficient space for easy movement of man and material after installation		
4.	Verify that foundation arrangement has been made for proper fixing of equipment		
5.	Other provisions: (if any)		
	Equipment lifting and positioning arrangement		
6.	Verify that provisions for required utilities are provided.		
	Electricity		

Remarks (if any): _____

Verified By & Date:



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9.0 FAT Compliance

S.No	Observation	Verification	Remark

Remarks (if any): _____

Verified By & Date:



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10.0 Verification Of Installation:

S.No.	Checks to be performed:	Observation	Remarks	Signature with Date
1.	Check for the Dimensional accuracy			
2.	Check for the receipt of the consignment in good condition			
3.	Check for any scratches on the machine body			
4.	Identify the hoppers with their lids			
5.	Identify the Force Feeder in the working zone			
6.	Check for the three piece turret in the working zone			
7.	Check for the Main rolls in proper condition			
8.	Check for the electrical panel. All Electrical connections should be as per the Circuit Diagram.			
9.	Check for the condition of the MMI			
10.	Check for all dials.			
11.	Check for all driving component in the base cabinet.			
12.	Check for the dust extraction nozzles.			
13.	Check for the anti – vibrating mounts.			
14.	Check for proper base skirting.			
15.	Check for the good condition of guards.			

Remarks:

Verified By & Date:



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11.0 Verification of Special Features in the Equipment

11.1 Safety requirements:

S.No.	User requirement	Acceptance criteria	Observations	Checked By & Date
1.	Safety Interlock	All guards are properly interlocked.		
2.	Alarm / Fault administration	Respective alarm should blow in respective fault.		
3.	Earthing	Touch the tester to body of machine bulb of tester should not glow		
4.	Emergency switch	Should be stop immediately		

Remarks (If any): _____

Verified By & Date:

11.2 Automation control and Electrical connections:

S.No.	User Requirement	Acceptance Criteria	Observations	Checked By & Date
1.	Motors	With Test Certificate		
2.	Pressure Gauges	With Calibration Certificate		

Remarks (If any): _____

Verified By & Date:

11.3 Location of the Control Panel:

S.No.	User requirement	Acceptance criteria	Observations	Checked By & Date
1.	Near to Machine	Should be operational smoothly		

Remarks (If any): _____

Verified By & Date:



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12.0 Identification of the Instruments to be calibrated:

Identify and record all the instruments associated with the equipment/system and determine the criticality of the instrument. All the identified instruments must be calibrated prior to the start of OQ.

S. No.	Instrument to be Calibrated	Location of Instrument	ID	Manufacturer	Model	Range		Identified By & Date
						Instrument Range	Working Range	
1.	Pressure Gauge							

Remarks (If any): _____

Verified By & Date:



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13.0 Material of Construction:

List down and verify that the construction material of equipment components that come into contact with the product are as specified by the Manufacturer and satisfy the User Requirement. All certificates related to material of construction should be attached.

Component	Specified	Observed	Certificate No.	Acceptable?	
				Yes/No	Initial & Date
Turret	SG 600/3				
Die Table	SS316 L				
Press roll	OHNS				
Feeder	Gun Metal				
Paddle for Force Feeder	SS 316 L				
Hopper	SS 316 L				
Butterfly Valve	SS 316 L				
Discharge Chute	SS 316 L				

Remarks (if any): _____

Verified By & Date:



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14.0 Utilities/ Services Connection Check:

Verify the installed service connections to the component against the supplier's specification.

Utility	Specified	As Found	Confirmed by/ Evidence	Acceptable?	
				Yes/No	Initial & Date
Electricity	415 Volts AC 3 Phase, 50 Hz,				
Air	4-6 kg/cm2				

Remarks (if any): _____

Verified By & Date:

15.0 Manufacturer's Certificates:

Review and attach all manufacturers' certificate(s) as per DQ and also attach any other certificate.

Sr. No.	Details of Certificate	Remarks	Checked By & Date
1	Material of Construction		
2	Calibration of Hydraulic Pressure gauges		
3	Sensors		
4	RPM / HP of Motors		

Remarks (if any): _____

Verified By & Date:



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15.1 Identification of Training Need For Operating Personnel:

S.No.	Training Title	Identified By & Date

Remarks (If any):

Verified By & Date:

16.0 Deficiency Sheet:

Report any deficiencies from the acceptance criteria or from protocol instructions in the deficiency report form of Appendix 1. Record the total number of deficiencies reported during the installation qualification activities of this Protocol. Record the deficiency number and Title in the Table below. Include all deficiency Report Forms in Appendix 1. Indicate the status of each variance as 'Closed' only when the deficiency is resolved.

Deficiency No.	Deficiency Title	Status

Total No. Of Deficiencies: _____

Remarks (If any):

Verified By & Date:



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17.0 List of Appendix:

Appendix No.	Document Title

Remarks (If any):

Verified By & Date:

18.0 Deficiency and Corrective Action Report Form

This Deficiency and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deficiency Sheet within the protocol.

Deficiency Report Number:	
Protocol Section No.:	Date of Test:
Description of Test Result:	
Immediate Action Taken:	
Corrective Action Taken / Planned:	



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Deficiency Reported By:

Name:

Signature:

Date:

Corrective action must be taken prior to approval of IQ or OQ? :

Head - Engg. Signature

Date:

Head-User dept. signature

Date

QA Signature:

Date:

Corrective Action Implemented:

Corrective Action Implemented By:

Name:

Signature:

Date:

(Attach comments and supporting documentation as necessary)

Was a re-test or amendment necessary due to the Deficiency?

Date of re-test:

Is Deficiency Closed (Yes/No):

QA Signature:

Date:

18.0 Summary & Conclusion:

Prepared By: _____
Name & Department

_____ Sign. / Date



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20.0 Approval of Installation Qualification:

Functional Area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			