PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ROLL COMPACTOR MACHINE	PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Roll Compactor Machine has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW :

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Roll Compactor Machine and define the qualification requirements and acceptance criteria for the Roll Compactor Machine. Successful completion of these qualification requirements will provide assurance that the Roll Compactor Machine was installed in Granulation.

The objective of the installation qualification is to prove that each activity proceeds as per design specification and the tolerances prescribed there in the document and is the same at utmost transparency.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Roll Compactor Machine received matches the Design specification and also to ensure that it is properly and safely installed. The equipment shall be used for compression of different powders to be used in the formulation. The equipment shall operate under dust free environment and conditions as per the cGMP requirements.

2.3 SCOPE:

This Protocol is applicable to installation of Roll Compactor Machine in Granulation.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

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

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory installations of the Roll Compactor Machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Roll Compactor Machine is installed satisfactorily. Execution team is responsible for the execution of installation of Roll Compactor Machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Roll Compactor Machine shall meet the system description given in design qualification.

3.2 The Roll Compactor Machine shall meet with the acceptance criteria mentioned under the topic "Identification of major components".

3.3 All material of constructions of the contact parts to be checked as per the specifications.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out
- As per revalidation date and schedule

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

1.	Equipment Name	:	Roll Compactor Machine
2.	Supplier / Manufacturer	:	CIP MACHINERIES PVT. LTD.
3.	Model	:	200 /75 GMP
4.	Serial No.	:	------
5.	Overall Dimension in MM (L X W X H)	:	1135 (L) X 727 (W) X1380 (H)
6.	Location	:	GRANULATION
7.	Capacity	:	75-100 Kg/hr.

Process Equipment Description:

To compact the powder for improving the bulk density, achieving better granulation of sieve analysis, reducing process cost & improving product quality etc. Complete machine can be divided in to following sub sections:

- Main (Material contact portion)- Hopper, Roller, Precompression chamber, Feed screw & Discharge Chute
- Machine Base floor mounted

OPTIONAL- Provision for chilled/ cool water made which can be supplied to sensitive areas like rolls, bowl & hopper.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

5.2.1 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

5.2.6 Whichever column is blank or not used ‘NA’ shall be used.

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5.3 INSTALLATION CHECKLIST:

S.No.	Statement	Method of verification	Actual Observation	Verified by (sign/date)
01.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
02.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
03.	Verify that major components are securely anchored and shock proof.	Physically		
04.	Verify that there is no observable physical damage.	Physically		
05.	Verify that there is sufficient room provided for servicing.	Physically		
06.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
07.	All access ports are examined and cleared of any debris.	Physically		
08.	Safe electrical connections.	Physically		
09.	Wiring diagram affixed to inside section of control panel.	Physically		
10.	Equipment identification nameplate visible.	Physically		
11.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Equipment Description	Name	Roll Compactor Machine	Physically		
	Spec.	Flame proof construction	Physically/ Technical Specification		
	Capacity	75-100 Kg	Physically/ Technical Specification		
	Model	200/75 GMP Model	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
	Overall Dimensions	As per actual (LxWxH)	Physically		
	Roll RPM	5 to 25	Physically/ Technical Specification		
	Feed Screw RPM	10 to 60	Physically/ Technical Specification		
Roller	Material	OHNS	Test certificate		
	Inner Surface	Grinding/ Polishing	Physically/ Technical Specification		
	Outer Surface	Hard chrome plated mirror polish	Physically/ Technical Specification		
Pre-compression Chamber	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
Feed Screw	Material	SS 316	Test certificate		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Scrappers	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Side Walls	Material	SS 316	Test certificate		
	Inner Surface	Dull Finish	Physically/ Technical Specification		
	Outer Surface	Dull Finish	Physically/ Technical Specification		
Charging Hopper	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Main Hopper	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Discharge Chute	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Vibrator Plate	Material	SS 316	Test certificate		
	Inner Surface	Dull Finish	Physically/ Technical Specification		
	Outer Surface	Dull Finish	Physically/ Technical Specification		
Top Plate	Material	SS 316	Test certificate		
	Inner Surface	Mirror Finish	Physically/ Technical Specification		
	Outer Surface	Mirror Finish	Physically/ Technical Specification		
Main Body	Material	SS 316	Test certificate		
	Inner Surface	Dull Finish	Physically/ Technical Specification		
	Outer Surface	Dull Finish	Physically/ Technical Specification		
Control Panel	Material	SS 316	Test certificate		
	Inner Surface	Dull Finish	Physically/ Technical Specification		
	Outer Surface	Dull Finish	Physically/ Technical Specification		
Roll Drive Electric Motor (main motor)	Machine No.	To be recorded	Physically/ Technical Specification		
	Power	5 HP	Physically/ Technical Specification/ Test certificate		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	RPM	960	Physically/ Technical Specification/ Test certificate		
	Volt	440, 50 Hz, AC	Physically/ Technical Specification/ Test certificate		
Feed Screw Drive Electric Motor	Machine No.	To be recorded	Physically/ Technical Specification		
	Power	2 HP	Physically/ Technical Specification/ Test certificate		
	RPM	1440	Physically/ Technical Specification/ Test certificate		
	Volt	440, 50 Hz, AC	Physically/ Technical Specification/ Test certificate		
Feed Screw Drive Electric Gear Box	Make	Shanti	Physically/ Technical Specification		
	Ratio	30:1	Physically/ Technical Specification		
	Sr.No	To be recorded	Physically/ Technical Specification		
ACVFD Main Motor	Make	Allen Bradley	Physically/ Technical Specification		
	Sr.No	To be recorded	Physically/ Technical Specification		

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System components	Design specification		Method Of Verification	Actual Observation	Checked By Sign/Date
FEED SCREW ACVFD Motor	Make	Allen Bradley	Physically/ Technical Specification		
	Sr.No	To be recorded	Physically/ Technical Specification		

Remark: ----------

Reviewed by (Sign/Date)

5.5 Verification of Material of Construction:

S.No.	Component	MOC	Method of verification	Actual Observation	Checked By Sign / Date
1.	Rollers	OHNS	Molybdenum kit/ Test Certificate		
2.	Shaft	SS 316	Molybdenum kit/ Test Certificate		
3.	Pre-compression Chamber	SS 316	Molybdenum kit/ Test Certificate		
4.	Feed Screw	SS 316	Molybdenum kit/ Test Certificate		
5.	Scrapper	SS 316	Molybdenum kit/ Test Certificate		
6.	Side Walls	SS 316 cladded	Molybdenum kit/ Test Certificate		
7.	Charging Hopper	SS 316	Molybdenum kit/ Test Certificate		
8.	Main Hopper	SS 316	Molybdenum kit/ Test Certificate		
9.	Discharge Chute	SS 316	Molybdenum kit/ Test Certificate		
10.	Vibrator Plate	SS 316 cladded	Molybdenum kit/ Test Certificate		
11.	Top Plate	SS 316	Molybdenum kit/ Test Certificate		
12.	Control Panel	SS 316	Molybdenum kit/ Test Certificate		
13.	Main body	SS 316 cladded	Molybdenum kit/ Test Certificate		
14.	Outside Doors & covers	SS 316	Molybdenum kit/ Test Certificate		

Remark: ----------

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

UTILITY	Method of verification	Actual Observation	CHECKED BY (SIGN/DATE)
Electricity: 3 Phase, 440 Volts, 50 Hz	Physically with clamp meter		

Remark: ----------

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Earthing	To avoid electrical shocks due to leakage current	Physically		
Emergency stop button	To stop the machine if problem appears in running condition	Physically		
Hydraulic Lift	To avoid the lift during operation condition	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Roll Compactor Machine.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

Remark: ----------

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF COMPONENT (S) TO BE CALIBRATED:

Identified that the drafted calibration procedures for different identified components in Roll Compactor Machine are adequate and appropriate covering the operating range(s).

Name Of Components	Range	Make	Location	Identified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing and Document Detail	Verified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS:

Following Abbreviations are used in the installation qualification protocol of Roll Compactor Machine.

MOC: Material of construction

HP: Horse Power

kW: Kilowatt

Hz: Hertz

V: Volts

SS: Stainless Steel

AC: Alternating Current

5.12 DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S):

Following deficiency was identified and corrective actions taken in consultation with the validation team.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

5.13 Annexure (S):

Annexure No.	Details Of Annexure

Remarks (if any)**:**

Done By & Date: **Verified By & Date:**

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/ Date

6.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol (If applicable). Signature in the block below indicates that all items in this qualification report of Roll Compactor Machine have been reviewed and found to be acceptable and that all variations or discrepancies (If applicable) have been satisfactorily resolved. After the successful installation qualification of the Roll Compactor Machine, the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		