PHARMA DEVILS	PERFORMANCE 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 Performance Qualification protocol of Roll Compactor has been reviewed and approved by the following signatories:

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

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established /predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The equipment shall be used for compact the powder for improving to the bulk density, achieving better granulation of sieve analysis which improves product quality. Drive part of the equipment includes motor and gearbox, which provides necessary torque required to rotate the blade.

The Scope of this protocol is limited to the performance qualification of Roll compactor of Granulation .

Once the performance qualification of Roll compactor has been completed successfully, the equipment shall be released for the daily production.

2.4 RESPONSIBILITY:

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

Execution Team (Comprising members from Production, Quality control , 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 analysis of sample shall be carried out by quality control department if applicable.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / 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 operation of the Roll compactor shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Roll compactor is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Roll compactor. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 GENERAL CONSIDERATION/PREREQUISITE:

3.1 Approved Standard operating procedure of the Roll compactor shall be available.

The maximum and minimum speed of the screw feeder and compact roller of the equipment shall be verified by taking the batch/lot suit the requirement of flakes hardness which is physically verified.

3.2 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.

3.3 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.

3.4 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be requalified if

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

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 Methodology:

The principle of Roll compactor is to compact the powder for improving to the bulk density, achieving better granulation of sieve analysis & improves product quality.

Drive part of the equipment includes motor and gearbox, which provides necessary torque required to rotate the blade of the hopper (i.e. screw roller) & rotate the compaction roller.

All the raw materials after sifting through the specified sieve are collected s.s. container lined with double poly bag.

All the sifted material are mixed manually by means of geometrically mixing/blender and collect the material in s.s. container lined with double poly bag.

The Roll Compactor is charged with the material and operate the Compactor roller at the speed till the required hardness of flakes is obtained. The flakes, which are obtained, is then milled at required size of mess & sieved through sifter. The undersized material is then again passing through the compactor roller in cycle. The cycle is continued till all the materials get the required size of granules and fines.

Sample is collected at each cycle and check the over and under size granules.

The required granules is then collected & utilized in the batch production.

The PQ of the Roll compactor shall be carried out and record observation of all trial in observation part of protocol at specified location

6.0 ACCEPTANCE CRITERIA:

6.1 The percentage of over and under size granules i.e. granules & fines shall be 60 % ± 10% & 40 % ± 10% of the batch quantity respectively.

6.2 The flakes obtained after compaction of materials should be hard enough so that it doesn't crumble easily and after breaking of flakes, Granules should be formed.

7.0 MATERIAL REQUIRED FOR COMPACTION:

S.No.	Ingredients	Weight (in Kg)
1	Paracetamol IP	4.5
2	Microcrystalline cellulose (pH 102) IP	122.324
3	Anhydrous Lactose (DCL-21) IP	201.105
4	Starch IP	87.422

Reviewed by

(Sign/Date)

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8.0 OBSERVATION OF PERFORMANCE QUALIFICATION:

Range for Speed of Compactor roller: 5 -25 RPM

Minimum Speed of Compactor roller: _____ RPM

Maximum Speed of Compactor roller: _____ RPM

Range for Speed of screw feeder: 10 – 60 RPM

Minimum Speed of screw feeder: _____ RPM

Maximum Speed of screw feeder: _____ RPM

S.No.	Speed Details	Ampere Reading Observation	Flakes Observation	Verified By
1	Minimum Speed of screw feeder & Minimum Speed of Compactor roller	---------- Amp. ---------- Amp.		
2.	Maximum Speed of screw feeder & Maximum Speed of Compactor roller	---------- Amp. ---------- Amp.		

9.0 WEIGHT CALCULATION OF OVER & UNDER SIZE GRANULES:

1st Cycle

Wt. of oversize granules pass through 60 #			Balance ID No.:		Date:
S.No.	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Done By	Checked By
Wt. of under size granules pass through 60 #					

2nd Cycle

Wt. of oversize granules pass through 60 #			Balance ID No.:		Date:
S.No.	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Done By	Checked By
Wt. of under size granules pass through 60 #					

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3rd Cycle

Wt. of oversize granules pass through 60 #			Balance ID No.:		Date:
S.No.	**Gross Wt. (Kg)**	**Tare Wt. (Kg)**	**Net Wt. (Kg)**	**Done By**	**Checked By**
Wt. of under size granules pass through 60 #					

Total wt. of oversize granules = **(1)**_ _ _ _ _ + **(2)**_ _ _ _ _ + **(3)**_ _ _ _ _ = _ _ _ _ _ _ _ **Kg**

Total wt. of undersize granules = **(1)**_ _ _ _ _ + **(2)**_ _ _ _ _ + **(3)**_ _ _ _ _ = _ _ _ _ _ _ _ **Kg**

A) % of oversize granules = $\frac{\text{Total wt. of oversize granules}}{\text{Wt. of Material (Used for compaction)}}$ **X 100**

= = _ _ _ _ _ _ _ **%**

B) % of undersize granules = $\frac{\text{Total wt. of undersize granules}}{\text{Wt. of Material (Used for compaction)}}$ **X 100**

= = _ _ _ _ _ _ _ **%**

INFERENCE:

Checked By:

Date:

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

Following deficiency was verified and corrective actions taken.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by:
(Sign/Date)

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11.0 Annexure (s):

S.No.	Annexure No.	Title of Annexure

Remarks (if any)**:**

Done By & Date:
(Sign/Date)

Verified By & Date:
(Sign/Date)

12.0 PERFORMANCE QUALIFICATION FINAL REPORT:

12.1 SUMMARY:

12.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

12.3 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 the qualification report have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. The equipment can be taken for production.

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