PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM TRAY DRYER	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 Qualification protocol of Vacuum Tray Dryer has been reviewed and approved by the following persons:

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 the performance.
- To make an impact assessment of the critical components of the equipments on the material.
- 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 gives the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The performance of the equipment is verified by taking the raw materials for drying before sifting and drying is performed by setting the inlet temperature and LOD of individual material is checked by withdrawing the sample at predefined interval of time till the desired LOD is achieved by using Moisture analyzer.

The equipment performance is challenged by drying the raw materials of the desired LOD are achieved by using Moisture analyzer.

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 Scope of this protocol is limited to the performance qualification of Vacuum tray dryer of VTD area.

Once the performance qualification of Vacuum tray dryer has been completed successfully, the equipment shall be taken for routine use.

2.4 Responsibility:

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

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

- Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system requalification.
- 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.
- Production/QA person will take the sample for testing the water activity of individual raw material. The production person shall perform cleaning of the equipment.

Head– Engineering:

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

Head – Quality Control:

- Review of protocol, the completed requalification data package, and the final report Approval.

Head – Production:

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

Head – Operation/ Quality Assurance:

Head– Engineering:

- Review and Approval of protocol, the completed requalification data package, and the final report.

2.5 Execution Team:

The satisfactory Performance of the Vacuum tray dryer shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents indicate that the Vacuum tray dryer is operational and providing the conditions as per user requirements.

Execution team is responsible for the execution of qualification of Vacuum tray dryer. All executors involved with this protocol shall sign within the prescribed format given below:

NAME	DEPARTMENT	DESIGNATION	SIGNATURE	DATE

3.0 GENERAL CONSIDERATION/PREREQUISITE:

3.1 Approved Standard operating procedure of the equipment shall be available.

3.2 All the measuring Devices shall be verified for its validity of calibration.

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

3.3 All the functional checks shall be carried out.

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

3.5 The minimum and maximum capacity of the equipment shall be verified by taking the lot to suit the requirement.

3.6 The analytical test results and other reports related with the equipment shall be attached with the performance qualification of the equipment and finally verified.

3.7 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 revalidated if:

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

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 METHODOLOGY:

- The principle of Vacuum tray dryer is to dry the thermal sensitive materials in an air tight chamber by the use of vacuum pump, condenser & receiver. On creating vacuum by locking the chamber, the vapours are drawn from the material placed on the trays inside the chamber. The vapours drawn by the vacuum pump are passed through this & are condensed when cold water is circulated through the shell & the condensate is collected at the receiver.
- The Dispensing, Mfg and drying process shall be carried out as per procedure mentioned in Batch No.: ---------- for Drying.
- The materials are taken to the VTD-1 area loaded on to the trays of the Vacuum tray dryer.
- The materials shall be dried at 45 ^{0}C - 55 ^{0}C for 3 hours or more.
- The sample shall be withdrawn and analyzed for LOD after the defined time. The procedure shall be followed as per the Batch Mfg record no. ----------.
- **Minimum capacity- 96 kg & Maximum capacity- 144 kg**

6.0 ACCEPTANCE CRITERIA:

6.1 LOD of individual material should be NMT 3.0 % w/w

7.0 Drying detail:

Lot/Batch details: _____

Observation of minimum batch size

Stage	Time (min.)	Time		Temperature (ºC)		LOD Observed	Done By
		From	To	Inlet	Outlet		

Remarks (if any)**:**

Checked By & Date: **Verified By & Date:**

8.0 Drying detail:

Lot/Batch details: _____

Observation of maximum batch size

Stage	Time (min.)	Time		Temperature (°C)		LOD Observed	Done By
		From	To	Inlet	Outlet		

Remarks (if any)**:**

Checked By & Date: **Verified By & Date:**

9.0 DEFICIENCY AND CORRECTIVE ACTIONS:

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

Description of deficiency:

Deviation Accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

10.0 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:**

Checked By & Date:
(Sign/Date)

Verified By & Date:
(Sign/Date)

11.0 PERFORMANCE QUALIFICATION FINAL REPORT:

11.1 SUMMARY:

11.2 CONCLUSION:

Prepared By:
(Sign/Date)

Verified By:
(Sign/Date)

12.0 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 of Vacuum tray dryer have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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