



**PHARMA DEVILS**

**OPERATIONAL 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 Operation Qualification protocol of Vacuum Tray Dryer has been reviewed and approved by the following persons:

| <b>FUNCTION</b> | <b>NAME</b> | <b>DESIGNATION</b> | <b>DEPARTMENT</b>    | <b>SIGNATURE</b> | <b>DATE</b> |
|-----------------|-------------|--------------------|----------------------|------------------|-------------|
| PREPARED<br>BY  |             |                    | QUALITY<br>ASSURANCE |                  |             |
| REVIEWED<br>BY  |             |                    | QUALITY<br>ASSURANCE |                  |             |
|                 |             |                    | ENGINEERING          |                  |             |
|                 |             |                    | PRODUCTION           |                  |             |
| APPROVED<br>BY  |             |                    | HEAD<br>OPERATION    |                  |             |
|                 |             |                    | QUALITY<br>ASSURANCE |                  |             |



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to Vacuum Tray Dryer, define the qualification requirements, acceptance criteria for the machine, to prove that each operation proceeds as per design specification and the tolerances prescribed in the document.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Vacuum Tray Dryer received matches the Design specification and also to ensure that it is properly and safely installed.

**2.3 SCOPE:**

The Scope of this protocol is limited to the operational Qualification of Vacuum Tray Dryer at VTD. Once the operational qualification of Vacuum Tray Dryer has been completed successfully, the equipment shall be preceded for the performance qualification.

**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 operational checks, calibration, SOP verification, verification of safety features,



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verification of utility supply shall be carried out by engineering persons and production person.

- 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.





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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The equipment shall be operational as per its specified operating instructions.
- 3.2 All SOP's for the equipment to be verified and checked.
- 3.3 Training is important to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 RPM of motor should be in the range of  $\pm 5\%$  deviation.

**4.0 REQUALIFICATION CRITERIA:**

The machine shall be revalidated if:

- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components to be replaced which affect the performance of equipment.
- As per requalification date and schedule.



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**5.0 OPERATIONAL QUALIFICATION PROCEDURE:**

**5.1 SYSTEM DESCRIPTION:**

|   |                       |   |                                       |
|---|-----------------------|---|---------------------------------------|
| 1 | Equipment Name        | : | Vacuum Tray Dryer                     |
| 2 | Supplier/Manufacturer | : | Millennium Equipment Private Limited. |
| 3 | Model                 | : | .....                                 |
| 4 | Serial no.            | : | .....                                 |
| 5 | Location              | : | VTD-1                                 |
| 6 | Capacity              | : | 96 -144 kg                            |

**5.1.1 Brief Process Description:**

The purpose of vacuum tray dryer is suitable for drying of thermal sensitive material that easily resolve, polymerized or deteriorated under high temperature. Sterilization can be conducted prior to drying process during which no matter is allowed to enter the product. Vacuum. The Vacuum Tray Dryer consists of an airtight chamber which is connected to a vacuum pump through a shell, condenser and receiver at bottom. The vacuum line is connected to the pump from the receiver. The chamber accommodates trays filled with material and on locking vacuum can be created. The vapours drawn by vacuum pump passes through this and are condensed when cold water is circulated through the shell. Condensate is collected in the receiver.

**5.1.2 MACHINE DESCRIPTION:**

The Vacuum Tray Dryer consists of an airtight chamber which is connected to a vacuum pump through a shell, condenser and receiver at bottom.

**Vacuum Chamber:** Trays are placed in the vacuum chamber and vacuum is created. It consists of main body, door, heating shelf and trays.

**Condensor:** the vapour drawn by vacuum pump passes through this tube and condensed when cold water is circulated through the shell.

**Receiver:** Condensate solvent will be collected in this receiver.



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**5.2 INSTRUCTION FOR FILLING THE CHECKLIST:**

- 5.2.1 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.2 For identification of the components of the equipment and utilities actual observation should be written in specified location.
- 5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.
- 5.2.4 Whichever column is blank or not used 'NA' shall be used.

**5.3 TEST INSTRUMENT DETAILS:**

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation.

| S.No. | Name of Instrument | Inst. ID. Number | Calibration done on | Calibration Due date | Certificate Number |
|-------|--------------------|------------------|---------------------|----------------------|--------------------|
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |
|       |                    |                  |                     |                      |                    |

**Checked by Date:**

**Remark:** -----  
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**Reviewed by (Sign/Date)**







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**5.5 VERIFICATION OF FUNCTIONAL CHECKS:**

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

**5.5.1 Verification of functionality of major components:**

| Function of Components                                                        | Procedure for verification                                                                                                                   | Specification                                                                                                                                                                 | Observation | Verified By Sign/Date |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------------------|
| Opening and closing of door assembly.                                         | Open and close the door manually.                                                                                                            | Door should be properly closed and locked, so that vacuum can be created in the vacuum chamber.<br><br>Similarly door should be easily opened to load materials in trays.     |             |                       |
| Vacuum Pump and motor.                                                        | Switch on/off the machine.                                                                                                                   | Vacuum pump should be operational and vacuum created 750 mm of Hg(operating vacuum) should be indicated on the gauge.<br><br>Check for smooth running without noise and jerk. |             |                       |
| FLP digital temperature indicator cum controller for steam inlet temperature. | Set the inlet temperature for the following values and check the actual temperature displayed on the indicator.<br><br>Set Values:<br><br>50 | Temperature should be achieved within the range of $\pm 2^{\circ}$ c.                                                                                                         |             |                       |



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| Function of Components | Procedure for verification                                         | Specification                                                                 | Observation | Verified By Sign/Date |
|------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------|-----------------------|
|                        | 70                                                                 |                                                                               |             |                       |
|                        | 100                                                                |                                                                               |             |                       |
| Vacuum release valve   | Turn on/off the valve manually and check visually on vacuum gauge. | Vacuum should be released on opening the valve(as indicated in vacuum gauge). |             |                       |

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.5.2 Verification of operational keys functionality:**

| Componentsof operating Panel | Procedure for Verification        | Specified Function                                                               | Observation | Verified By Sign/ Date |
|------------------------------|-----------------------------------|----------------------------------------------------------------------------------|-------------|------------------------|
| Main supply ON/OFF switch.   | Switch on the main power supply.  | Power supply to control panel should start and RYB indicator should glow.        |             |                        |
|                              | Switch off the main power supply. | Power supply to control panel should stop and RYB indicator should stop glowing. |             |                        |



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| <b>Components of operating Panel</b>                                      | <b>Procedure for Verification</b>                                                                                                        | <b>Specified Function</b>                                           | <b>Observation</b> | <b>Verified By Sign/ Date</b> |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|-------------------------------|
| FLP digital temperature indicator cum controller for product temperature. | Set the temperature for increase and decrease in temperature by means of push buttons for set, increase, decrease and enter push button. | Inlet temperature should increase and decrease as per set value.    |                    |                               |
| START/STOP push button.                                                   | Press the START push button and check visually.<br><br>Press the STOP push button and check visually.                                    | Drying operation should start.<br><br>Drying operation should stop. |                    |                               |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 VERIFICATION OF SUPPORTING UTILITIES:**

| S.No. | Utility                                                                             | Method of Verification      | Observation | Checked By Sign/Date |
|-------|-------------------------------------------------------------------------------------|-----------------------------|-------------|----------------------|
| 1.    | <b>Electricity:</b><br>3 phase, 440V, 50Hz supply with neutral and proper earthing. | Physically with clamp meter |             |                      |
| 2.    | <b>Heating/cooling system</b><br>Steam :3.5 bar<br>Cold water :3.5 bar              | Physically                  |             |                      |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.7 VERIFICATION OF SAFETY FEATURE:**

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

| <b>Safety features description</b> | <b>Procedure for verification</b>                                     | <b>Specification</b>                                                                               | <b>Observation</b> | <b>Verified By Sign/Date</b> |
|------------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------|------------------------------|
| Earthing                           | Check whole body with multimeter for any current leakage.             | No current leakage should be observed.                                                             |                    |                              |
| Sealing system                     | Check physically for suction of air by starting the drying operation. | Consists of inflatable gasket in between door and main body. So that vacuum is created in chamber. |                    |                              |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):**

The following Standard Operating Procedures were identified as important for effective performance of Vacuum Tray Dryer .

| S.No. | SOP Title | SOP Number | Verified By Sign/Date |
|-------|-----------|------------|-----------------------|
|       |           |            |                       |
|       |           |            |                       |
|       |           |            |                       |

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

Reviewed by (Sign/Date)

**5.9 TRAINING RECORD OF PERSONNEL (S):**

| S.No. | Name of Personnel | Designation | Sign. & Date | Trained By | Remark |
|-------|-------------------|-------------|--------------|------------|--------|
|       |                   |             |              |            |        |
|       |                   |             |              |            |        |
|       |                   |             |              |            |        |
|       |                   |             |              |            |        |
|       |                   |             |              |            |        |

Remark: -----  
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Reviewed by (Sign/Date)







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**5.11 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was identified and corrective actions taken in consultation with the Engineering Department.

**Description of deficiency:**

**Corrective action(s) taken:**

**Deviation accepted by  
(Sign/Date)**

**Deviation Approved by:  
(Sign/Date)**



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**6.0 OPERATIONAL QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**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. Verified that all amendments and discrepancies (if applicable) are documented, approved and attached to this protocol. Signatures in the block below indicate that all items in this operational qualification report of Vacuum Tray Dryer have been reviewed, found to be acceptable and all variations or discrepancies (if applicable) have been satisfactorily resolved.

| <b>FUNCTION</b>        | <b>NAME</b> | <b>DESIGNATION</b> | <b>DEPARTMENT</b>    | <b>SIGNATURE</b> | <b>DATE</b> |
|------------------------|-------------|--------------------|----------------------|------------------|-------------|
| <b>REVIEWED<br/>BY</b> |             |                    | QUALITY<br>ASSURANCE |                  |             |
|                        |             |                    | ENGINEERING          |                  |             |
|                        |             |                    | PRODUCTION           |                  |             |
| <b>APPROVED<br/>BY</b> |             |                    | HEAD<br>OPERATION    |                  |             |
|                        |             |                    | QUALITY<br>ASSURANCE |                  |             |