



PHARMA DEVILS

**INSTALLATION 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 Installation 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		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY 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 the Vacuum Tray Dryer and define the installation qualification requirements and acceptance criteria for the Vacuum Tray Dryer. Successful completion of these installation qualification requirements will provide assurance that the Vacuum Tray Dryer was installed as required in the manufacturing area.

The Qualification of Vacuum Tray Dryer performed in view of VTD area.

2.2 PURPOSE:

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

2.3 SCOPE:

This Protocol is applicable to installation of Vacuum Tray Dryer in Production, VTD area of the manufacturing facility.

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.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Vacuum Tray Dryer shall meet the system description given in design qualification.
- 3.2 The Vacuum Tray Dryer shall meet with the acceptance criteria mentioned under the ,
“Identification of major components”.
- 3.3 The Vacuum Tray Dryer system shall be operated by PLC.
- 3.4 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 : Vacuum Tray Dryer
2.	Supplier/Manufacturer : Millennium Equipment Private Limited.
3.	Model :
4.	Serial no. :
5.	Location : VTD
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.



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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.

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:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number.	Physically		
2	Verify that there is no observable physical damage.	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe.	Physically		
6	Verify that the equipment is properly earthed.	Physically		
7	Verify that utility line is properly connected.	Physically		
8	Verify the proper leveling of equipment.	Physically		
9	Verify that there is sufficient space provided for operation, cleaning and preventive maintenance.	Physically		
10	Equipment/system identification no. Is visible.	Physically		

Remark:-----

Reviewed by (Sign/Date)



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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	Vacuum Tray Dryer	Visually from name plate.		
	Make	MEPL	Visually from name plate.		
	Model	MEVTD 48G	Visually from name plate.		
	Size (WXDXH) mm	(2400 X 1900 X 2100)	Physically by measuring tape.		
	Construction	FLP Construction	Visually/ Technical specification.		
	Design pressure	5 Kg/cm ²	Visually from name plate/ Technical specification		
	No of trays	48	Physically		
	No of shelf	17	Physically		
	Tray size (LXWXH) mm	812 X 406 X 31	Physically by measuring tape.		
Supporting column/Legs	Size (Diameter X Height)mm	170 X 300	Physically		
	Qty.	04 No.	Physically		
Main body/ Vacuum chamber	Size (WXDXH) mm	1060 X 1275 X 1800	Physically by measuring tape.		
	MOC	SS 316	Molybdenum kit / Technical certificate		
Main body/ Vacuum chamber	Surface finish	Inside: mirror Outside: matt	Visually/ Technical certificate/ Technical specification		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Standard features	Vacuum measuring port, temperature port, validation port, rupture disc, vacuum release valve, nitrogen purging valve, drain valve, Bull-eye window should be available.	Visually		
Door	Qty.	01	Visually		
	Position	Front	Visually		
	Surface finish	Inside: mirror Outside: matt	Technical certificate/ Technical specification		
	Shape	Hemisphere flat	Visually		
	MOC	SS 316	Technical certificate		
Door	Sealing	Silicon gasket food grade	Technical certificate		
	Standard features	Bull-eye window, handle, name plate should be available.	Visually		
	Size(WXDXT hickness) mm	835 X1250 X18	Physically by measuring tape.		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Heating selfs	Qty.	17	Visually		
	Position	Inside vacuum chamber	Visually		
	MOC	SS 316	Technical Certificate		
	Surface Finish	Mirror polish	Technical Certificate		
	Standard features	Inlet and outlet nozzles	Visually		
	Size(WXDXT hickness) mm	835X1250X 18	Physically by measuring tape		
Trays	Qty.	48	Physically/ Technical Certificate		
	Tray size (LXWXH) mm	812 X 406 X 31	Physically by measuring tape		
	MOC	SS 316	Moly kit/ Technical certificate		
	Surface finish	Mirror polish	Visually/ Technical certificate		
Condenser	Qty.	01 No.	Visually		
	Make	MEPL	Visually/ Technical Certificate/ Technical specification		
	Specification	Shell and tube single pass.	Physically/ Technical Certificate		
	Position	Left side of vacuum chamber.	Visually		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	MOC	SS 304	Molybdenum kit/ Technical Certificate		
	Surface finish	Mirror polish	Technical specification /Technical certificate.		
	Standard features	Chilled water inlet and outlet nozzles.	Visually		
Receiver	Qty.	01 No.	Visually		
	Make	MEPL	Visually/ Technical Certificate/ Technical specification		
	Specification	Horizontal with dished ends.	Physically/ Technical Certificate		
Receiver	MOC	SS 304	Molybdenum kit/ Technical Certificate		
	Surface finish inside	Mirror polish	Technical Certificate/ Technical specification		
	Standard features	Isolation valve, drain valve, view glass, vacuum connection nozzle should be available.	Visually		
Rupture Disc/ explosion vent	Qty.	01 No.	Visually		
	Size	300 x 300mm	Physically by measuring tape/ Technical specification		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Make	BS&B	Visually/ Technical specification		
	Sr. No.	030000121481 4	Visually/ Technical certificate		
	MOC	SS316	Molybdenum kit/ Technical Certificate		
	Brusting temperature and pressure	0.25kg/cm ² with vacuum support 150°c.	Technical Certificate		
Vacuum guage	Qty.	01	Visually		
	Position	Top front center on vacuum chamber	Visually		
	Range	0-760mm Hg	Visually		
FLP digital temperature indicator cum controller	Qty.	01	Visually		
	Make	Creative	Visually		
	Model	CTI-01F	Visually		
	RANGE	-50°c - 200°c	Visually/ Technical Certificate		
	Sr. No.	01510			
	Function	For product temperature	Visually		
FLP digital temperature indicator	Qty.	01	Visually		
	Make	Creative	Visually		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Model	CTI-01F	Visually		
	Range	-50°C - 200°C	Visually		
	Sr. No.	1506	Visually		
FLP temperature sensor	Qty.	01	Visually		
	Make	Creative	Visually		
	Range	-50°C - 300°C	Visually		
	Sensor MOC	SS 316	Visually		
Nozzles	Location	Steam/ heat water inlet and outlet, condenser chilled inlet and outlet, vacuum connection, chamber drain valve, receiver drain valve, vacuum release/ Nitrogen purge.	Visually		
Vacuum Pump	Make	To be recorded	Visually		
	Model	To be recorded	Visually		
	Sr. No.	To be recorded	Visually		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Motor	Make	To be recorded	Visually		
	Model	To be recorded	Visually		
	Sr. No.	To be recorded	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
CONTACT PARTS				
Main body/vacuum chamber	SS 316	By Molybdenum Kit/ Technical Certificate.		
Door	SS 316	By Molybdenum Kit/ Technical Certificate.		
Heating selves	SS 316	By Molybdenum Kit/ Technical Certificate.		
Trays	SS 316	By Molybdenum Kit/ Technical Certificate.		
NON CONTACT PARTS				
View glass on door and chamber	Borosil	By Molybdenum Kit/ Technical Certificate.		
Door gasket	Silicon(Food grade)	By Molybdenum Kit/ Technical Certificate.		
Base/legs	SS 304	By Molybdenum Kit/ Technical Certificate.		
Vacuum line	SS 304	By Molybdenum Kit/ Technical Certificate.		
H.W Headers	SS304	By Molybdenum Kit/ Technical Certificate.		
Condenser	SS304	By Molybdenum Kit/ Technical Certificate.		
Receiver	SS304	By Molybdenum Kit/ Technical Certificate.		



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Insulation panels	SS304	By Molybdenum Kit/ Technical Certificate.		
Door Hinge and bolts.	SS304	By Molybdenum Kit/ Technical Certificate.		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

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

Remark: -----

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

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

Safety Features Description	Location/Identification	Method of Verification	Observation	IdentifiedBy Sign/Date
Earthing	Equipment connected with earthing strip.	Physically		
Emergency	Emergency switch provided to stop machine.	Physically		
Edges	All the sharp edges must be rounded to avoid accident.	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

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

S.No.	SOP Title	Verified 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)



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5.11 ABBREVIATIONS:

Following Abbreviations are used in the installation qualification protocol of Vacuum Tray Dryer:

MOC: Material of construction

DP: Differential pressure

WIP: Wash in place

FLP: Flame proof

SS: Stainless steel



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

Following deficiency was verified 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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5.13 Annexure (S):

Annexure No. Details of Annexure:

Remarks (if any): -----

Done By & Date:

Verified By & Date:



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6.0 INSTALLATION 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. All amendments and discrepancies (If applicable) are documented, approved and attached to this protocol.

Signatures in the block below indicates that all items in this qualification report of Vacuum Tray Dryer 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 Vacuum Tray Dryer 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		